Excerpt from Minister of Conservation Status Report – Week beginning 19 February 2024

(note: briefing mentioned not completed, meeting not held)

HPAI (Avian Influenza)	• We are working with iwi on strategies for resilience/recovery of Titi/Oi populations, economic implications, and human health in preparation for arrival of HPAI. • Vaccine trials with three species have commenced (takahē, red-crowned kākāriki, and tuturuatu), with the final two (kakī and kākāpō) due to start in March. No adverse events have been observed in any birds. Baseline health sample results from laboratories are not yet available, however, no health issues were detected on veterinary examination. • A briefing is in preparation for your upcoming meeting with the Minister for Biosecurity, Hon Andrew Hoggard. This will be completed once a meeting date is confirmed.

Excerpt from Status Report – Week beginning 18 March 2024

HPAI (Avian Influenza) Not yet in New Zealand, has arrived in Antarctica	• HPAI was confirmed to be present in mainland Antarctica on 8 February 2024. This has not changed MPI's assessment of the risk of arrival of HPAI in New Zealand, currently assessed as low. • The second stage of vaccine trials with five endemic New Zealand species has now commenced. The species in the trial are takahē, red-crowned kākāriki (as a proxy for kākāriki karaka), tuturuatu, kakī and kākāpō. No adverse events have been observed in any birds.

Week beginning 30 September 2024 – Tama Potaka

Bird flu vaccination and tara iti

- You requested further information amount the use of highly pathogenic avian influenza (HPAI, bird flu) vaccination for protecting tara iti (fairy tern).

Bird flu / Highly Pathogenic Avian Influenza (HPAI) Vaccination

- Vaccination trial is in the final phase – monitoring response and efficacy of the vaccine – the final phase will be completed by July 2025. This trial will inform how and when to use the vaccine to be effective; preliminary data has been used to update vaccination criteria.
- The six-month health and blood assessments are underway or completed for all birds in the trial. None of the birds have shown adverse reactions to the vaccine and initial tests show antibodies have been produced in all five species.
- All threatened species are being assessed to determine their risk from HPAI and to develop Species Specific management plans.
- Management plans include determining if vaccination is a viable response tool for each species. All identified candidates will be captured in a wildlife vaccination plan for MPI to review.
- DOC vets are meeting with US and Australian wildlife vets to discuss the technical details of vaccination planning in early October.

Tara iti preparedness and response to HPAI

- Tara iti are considered vulnerable (to HPAI) due to their species type and low numbers, however their behaviour (dispersed breeding) reduces their risk of exposure.
- Mitigation and response options to protection tara iti from HPAI have been assessed by the Tara Iti Recovery Group with input from DOC vets and technical staff, that also considered the feasibility of vaccination.
- The Recovery Group has identified that business as usual species recovery activities are essential for protecting tara iti from HPAI. They have been working with technical staff to ensure staff and volunteer health and safety plans are in place so work can continue during HPAI outbreaks.
- Vaccination is not feasible mitigation tool to protect tara iti from HPAI due to technical and logistical constraints of capturing free living birds twice, four weeks apart, initiated close to initial species exposure (c. 2-4 weeks), to administer the initial vaccination and required booster.
- A fully resourced recovery plan for tara iti will be critical for insuring this species survival against all threats, including HPAI.

Contact: Hilary Aikman, Director Terrestrial Biodiversity: 9(2)(a)

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, takahē

- *NOTE: The AEC will not generally give an approval for longer than two years at one time. Please state if this manipulation is likely to extend longer than two years from the commencement date.*

Anticipated start date:	February 2024	Anticipated finish date:	June 2025

2e. What months of the year is the manipulation most likely to be undertaken? e.g., October – March
For the duration of the dates specified but breeding birds will not be handled during September to January.

3a. Summary of the proposed manipulation for a LAYPERSON

- *Provide an abstract describing the manipulation (maximum 400 words).*

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain is decimating many populations of wild birds overseas, is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia, October 2023.

We want to test the safety and efficacy of vaccination to protect critically endangered species.
The vaccine is a commercial product registered in New Zealand by Ministry for Primary Industries. It is considered very safe and highly effective. It contains inactivated (dead) virus so it cannot cause avian influenza. Vaccination reduces risk of illness or death and reduces shedding of virus, thus protecting the individual and its flock.

Takahē are a critically threatened species where it is possible to reliably administer a full course of vaccine (2 injections under the skin, one month apart) to individually identified birds. At the captive Burwood Takahē Centre, we are able to handle them repeatedly for veterinary examination and blood testing to detect any effects on health status, and measure the immune response by detection of antibodies over a 12 month period.

Captive takahē will be caught outside of the breeding season, commencing in February/March 2024. Each bird will receive a pre-vaccination health check by a veterinarian, and a blood test for health and antibody testing. Up to 2mL of blood will be collected from the leg or wing vein, as is standard for this species.

The vaccine is given under the skin. One month later the bird will receive a second vaccination and blood test. Further blood will be collected at 2-3, 6 and 12 months post vaccination to determine the level of antibody response and how long it lasts.

A cloacal and choanal (oral) swab will be collected on day 0 for PCR testing to demonstrate the birds were not incubating avian influenza at the time of vaccination.

Normal husbandry practices will be undertaken including observation of the bird's activity and food intake to monitor of any adverse reactions.

We propose to work with a total of 10 adult or juvenile takahē, divided into two cohorts. Cohort 1 will first receive the vaccination & blood tests, and a recheck at 1 month. If no safety issues are identified, then Cohort 2 will receive vaccinations & blood tests. This allows a careful start to the trial where the first 1 month is the most important to test vaccine safety. The following blood samples will determine level of immune response and duration of antibody presence and determine when further boosters would be required.

Additional approval given on 16/4/24 to collect a 10-14 week blood sample to target peak antibody levels, and to collect an opportunistic blood sample for further antibody testing, if birds are being handled for routine management purposes, with no more than twice per bird over the 12 months of the trial.

3b. Description of the proposed manipulation (methods)

- *Provide a more detailed explanation. Describe the equipment, the location, and any environmental factors: weather, time of the year. Why have you decided to undertake the manipulation in this way? What advice have you sought? Include the species, the number of individuals, the source of animals, and the disposal/fate of animals at the conclusion of the manipulation.*
- *Be specific about the timelines for the proposed investigation and the purpose of the research, testing or teaching.*
- *Include some consideration and planning for when things might not go right.*

Please note: this is one of five trials to assess avian influenza vaccination safety and efficacy in nationally critical threatened species (takahē, kākāpō, kakī, tūturuatu, kākāriki karaka). Manipulation details which are specific to this species (takahē) have been highlighted in yellow. All other details are consistent across the five trials. By highlighting the species specific details I hope to assist the AEC with the volume of workload associated with simultaneously assessing these trials.

This trial is designed to test the safety and efficacy of a vaccine in a critically threatened species.

Selection of the species for potential vaccination is based on the risk that they could undergo an extinction event when Highly Pathogenic Avian Influenza (HPAI) reaches New Zealand. Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and risk of extinction.

The current wild adult takahē population is approximately 290 individuals, and modelling suggests that the species would be functionally extinct in 15-20 years without the intensive intervention from DOC's captive rearing programme. The captive management programme, and intensively managed insurance population across 17 mainland and island sites, produces between 40-50 birds per year. These individuals are primarily used to support existing wild populations, or establish new ones.

Based on the global evidence during this HPAI epizootic, the species most at risk of infection are those which exhibit congregation behaviours e.g. feeding, breeding or roosting in groups, those which are exposed to at risk species e.g. where seabirds overlap with another threatened species, and birds held in captive facilities where biosecurity options are limited e.g. open pens and large aviaries.

Takahē are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. See DOC-7111177 Mitigation Options Guideline for HPAI.

Use of the vaccine is dependent on Ministry for Primary Industries approval, and currently requires the birds to be held in captivity or in a defined restricted area. Birds require two injections one month apart and must be individually identified with a permanent mark e.g. microchip or leg band. Takahe already have an individual leg band as part of the routine husbandry of the species.

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment (Animal Health Australia, 2021).

There is precedent for undertaking a vaccination program in takahē. Since 2005 there has been a vaccination program in place to protect takahē against death from a bacterial disease – erysipelas. This current vaccination program means that there are staff highly skilled in this procedure on takahē and that

vaccination is a standard management tool for this species. No adverse events in takahē have been recorded as a result of the erysipelas vaccination programme.

Additionally, vaccination of California Condor was approved in the United States following an outbreak in the wild population. This was the first avian influenza vaccination programme in a wild endangered species. Advice from the veterinary and technical advisors to the condor vaccination programme has been received and is incorporated into this trial design.

We wish to undertake a limited trial to determine the safety and efficacy of the avian influenza specific vaccine in takahē as a preparedness measure for the arrival of HPAI in New Zealand.

The vaccine is produced commercially by Zoetis for use in poultry: Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine - see Appendix 1. It has been in production since 2006 and is widely used in the poultry industry. Publications on AI vaccine use in poultry and avian species in zoos have indicated a very high level of safety across a wide range of species, and efficacy has been well established. (Kandeil et al 2018, Philippa et al 2006, Philippa 2007a, Philippa 2007b, Pitman 2006). The vaccine is inactivated, so there is no live virus present, and it cannot cause avian influenza.

Advice from Zoetis (USA) indicates that this vaccine should provide good protection against the current strain of HPAI with 91% amino acid homology with the circulating strain. A newer vaccine based on the circulating strain is in production but is will not be available until the end of 2024 at the earliest.

Vaccine will be obtained from PacificVet in Christchurch and transported in a chilly bin with ice-packs by overnight courier (as per their standard transportation procedures for vaccines) to ensure cold chain is maintained. Use in the field will be managed by extraction of sterile aliquots into sterile vials or syringes. This enables sustainable use of the 1000 dose vial and maintenance of sterility of product. This process was discussed with the Zoetis Senior Research Advisor responsible for poultry products and is considered safe and appropriate.

Sterile aliquots will be obtained by using a sterile needle and syringe to extract the aliquot from the closed vaccine vial. The vial will be shaken to homogenise the contents, then the rubber stopper will be swabbed with alcohol. The sterile needle will be attached to the sterile syringe and the needle inserted via the rubber stopper. The aliquot will be drawn up into the syringe, then the needle & syringe removed from the stopper and the cap replaced on the needle. The needle will be swapped for a new sterile needle or a sterile vaccine cap. Both the aliquots and the vaccine vial will be stored refrigerated in accordance with the packaging instructions. Stored vaccine will be shaken to homogenise and drawn up immediately before use, then warmed to room temperature just prior to injection.

DOC veterinarians Kate McInnes and Lydia Uddstrom will administer the vaccination.

All birds will receive a full veterinary physical examination at the start of the trial. Only birds in good body condition exhibiting signs of good health will be included. (Any birds which show signs off poor health will be further investigated as per normal veterinary practices).

The takahē recovery team have been involved in the design of the study, and selection of study animals. The Burwood Takahē Centre holds takahē in enclosures for breeding and feeding training. Use of these birds, as opposed to those on offshore islands or in the Murchison Mountains, will enable reliable capture and monitoring. Additionally, it meets the MPI requirements for the birds to be contained during the trial.

Individuals for vaccination will be selected by the takahē recovery team at the end of the 2023.24 breeding season, based on the programme's planning for any translocations or releases.

Each individually permanently marked (leg band) captive bird will receive two doses of vaccine by subcutaneous injection into the inguinal (groin) region with a 1 month interval (no less than 3 weeks apart and a maximum of 6 weeks apart). The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds <1.5kg will receive 0.20ml per dose. Birds >1.5kg will receive 0.5ml per dose (as per dosages used in Vergara-Alert et al 2011).

Individual birds within the two cohorts will be determined on the day by takahē Lead rangers based on available birds' suitability and any management requirements.

At the start of the trial, each bird will receive a cloacal and oral swab to determine presence/absence of virus at day 0.
The technique will follow the draft SOP Avian swab sampling DOC-6840491 which has undergone veterinary peer review & user testing and is awaiting AEC endorsement before Director sign-off. These types of swabs are used in standard health testing on avian species and would be undertaken by the veterinarian. The test would be considered a baseline health test to demonstrate the birds were not incubating avian influenza at the time of vaccination. The swabs will undergo PCR testing at BioPacifica to look for avian influenza virus.
This is important to be able to demonstrate that any antibody response is due to the vaccination rather than the bird being infected by a wild strain of avian influenza.

First trial - Cohort 1: Five individuals (or 4-6 dependent on the aviary groupings) will be vaccinated as per the described protocol above. Blood (up to 2ml) will be collected at 0, 1 and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test to measure antibody titre). Antibody testing will be undertaken at a commercial laboratory (BioPacifica, Christchurch).

Note: 1% of body weight is considered an acceptable amount of blood to collect from a healthy bird. Adult takahē weigh ~2kg, therefore up to 20 ml would be within the safe range. We propose only up to 2ml will be collected to maintain a high margin of safety.

Second trial - Cohort 2: Based on consideration of the results of the first trial, if safety has been demonstrated, a second cohort of 5 (4-6) individuals will receive the vaccination as per the described protocol above, and blood (up to 1.5mL) will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test). We will wait 1 month until we have established the vaccine is safe in cohort 1 before we start cohort 2.

Note: If antibody response at 2-3 months is noted to be muted (i.e. a low response) then the DOC vets (Kate McInnes and Lydia Uddstrom) will discuss the use of a third dose of vaccine. This was used in some species in European zoos where the initial antibody responses were considered insufficient. Consideration will be given to the level of response detected, the impacts of additional handling, and any other welfare factors noted during the preceding handling events. The benefits of testing a third dose of vaccine will be carefully considered, and this will only be undertaken if the welfare impacts are considered minimal. The justification for a third dose in this trial would be to confirm if this dose is warranted and would deliver protection for the takahē population in the event of an outbreak of HPAI in Aotearoa New Zealand.

Two additional blood samples will be collected from both cohorts at approximately 6 months and 12 months to measure duration of antibody response.

A maximum of 10 birds will be included in the trial. It is estimated that there will be 70-100 takahē on site at the Burwood Takahē Centre at the time of the trial.

These trials are modelled on the vaccination of California Condor in the USA. (FWS.gov 2023) however the 1 month interval is based on the European zoo data, and considered more appropriate to allow for recovery between handling events in birds which normally have minimal handling by humans.

Estimated timing/schedule of manipulations:

First vaccination and blood sample	Second vaccination and blood sample	2-3 month blood sample	6 month blood sample	12 month blood sample
First cohort of 5 birds (4-6)				
~ 1st March 2024	~ 1st April 2024	~1st May 2024	~30th August 2024	~15th March 2025
Second cohort of 5 birds (4-6, maximum 10 total))				
~ 1st April 2024	~1st May 2024	~1st June 2024	~30th August 2024	~15th March 2025

Second cohort of 5 birds (4-6 maximum 10 total) – same timeline but 1 month after first cohort have been vaccinated and shown no negative reaction. Blood collection at ~6 and ~12 months may be undertaken at the same time for both cohorts – these sample are about longevity of antibody presence, so the exact timing is less critical.

During a handling event, all involved staff will gather and have a pre-handling briefing by the veterinarian and the team leader to ensure all roles and responsibilities are clearly understood. Any issues can be raised at that time for clarification. The takahē team leader will be responsible for the safe capture and handling of the bird. The veterinarian will be responsible for the health examination, vaccination and blood collection.

All equipment will be prepared prior to capture to minimise handling time. Staff will know where to situate themselves and what actions are required so that an efficient process is maintained. Captive takahē receive annual vaccinations to protect them against erysipelas (a bacterial disease) so the staff at Burwood Takahē Centre are highly skilled in carrying out blood collection as this is a routine process for them.

The takahē selected for this trial will be housed in their normal enclosures (in pairs, family groups or small groups of juveniles (>3 months old)). They are either lured into a small catch pen using supplementary food or takahē team rangers will slowly and steadily walk across the enclosure corralling the birds into a small area where they can safely be caught by hand, as per normal procedures. Catching and handling of the birds will be carried out by takahē team rangers who have extensive experience in these procedures.

Takahē team rangers will be consulted to select appropriate birds based on their previous observations. It is possible to encounter birds with a "stressy" personality. Such a bird is not a good candidate for a trial which requires repeated handling events, and therefore it would be excluded from the trial. If any birds are observed to exhibit any significant distress during any of the procedures, the takahē team rangers and DOC vets will call a stop to the procedure and reassess the procedures being undertaken and the suitability of the bird(s) for inclusion in the trial. If necessary, changes will be made to reduce issues such as, but not limited to; reducing number of people present, slowing down the capture process, taking a break so birds and humans can calm down, rejecting individual birds or enclosures of birds from the trial,

changing handlers/vet to allow a rest break, abandoning the work for the day, or if serious issues are encountered, potentially stopping the trial and discussing a redesign or full abandonment. At all times bird welfare is paramount and will determine the actions of the takahē team and veterinarians.

Once caught the takahē will be weighed using a hanging scale (standard technique) and undergo a physical examination to determine its health status prior to any further manipulation. If the takahē is determined to be healthy blood collection and vaccination will proceed.

For blood collection and vaccination a trained takahē handler will restrain the bird on its side or back.

The blood collection site (usually the leg vein but may include the wing vein) will be swabbed with a sterile alcohol wipe immediately prior to collection. Blood will be collected using a 1ml or 3ml sterile syringe attached to a 25 – 22 gauge ¾ to 1 inch sterile hypodermic needle.

In the event that the temperature is cool, and on examination of the wing vein we determine that blood collection likely to be slow due to the presence of small contracted veins, the foot/leg will be warmed for 3-5 minutes using Kathmandu hand warmers wrapped in gauze, to boost circulation and enhance blood flow to enable effective blood collection.

After collection, the site of blood collection will be covered with a gauze swab and pressure applied to control any bleeding. In the very unlikely event of uncontrolled bleeding, pressure will be applied for a further 1-5 minutes. If still uncontrolled, alcohol will be rubbed onto the foot and leg to cool the limb to reduce blood flow. If required, a silver nitrate stick will be carefully used to stop the bleeding.

Blood will be transferred into a blood microtainer and spun in a centrifuge to separate the serum from the blood cells. Serum will be drawn off using a sterile pipette and transferred into an epindorf tube for storage in the freezer, prior to transfer to the commercial laboratory in batches for antibody testing.

1-2 drops of blood will be used to make blood smears which will be sent to a commercial veterinary pathology laboratory for a white cell count and differential. This provides a baseline health analysis which can detect infection or inflammation. Any abnormal results will be further investigated by the veterinarian in consultation with the takahē team staff.

Once bleeding has stopped, the bird will be vaccinated using a 1mL syringe attached to a 20 gauge ½ inch needle. The vaccination site will be swabbed with a sterile alcohol wipe immediately prior to vaccination. See Appendix 2 for details of the vaccination technique.

The bird will then be checked for any abnormalities and the veterinarian will determine if any further actions are required for health or welfare. It will be quietly released back and observed as it moves away. Regular observations during routine husbandry will continue for all birds, and any abnormalities will be reported to the veterinarian.

At subsequent handling events, the vaccination site will be examined and any discolouration, swelling, granuloma formation or unexpected abnormality will be noted and reported to the veterinarian. Photographs of each bird's injection sites will be taken to provide a clear record of the trial.

Location & timing:
The trials will be undertaken at the Burwood Takahē Centre outside of the breeding season (breeding takahē are not handled from September to January).

Safety:

Results from a meta-analysis of use of vaccine in European Zoos found very low adverse reaction rate at 0.04% local reactions and 0.015% general reactions reported (EFSA 2007). Based on this, we do not anticipate significant issues with the vaccine, however we will be prepared for immediate veterinary care if any reactions to occur.

The vaccine packaging label states: "Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique."

Anaphylaxis
A severe immediate immune hypersensitivity response could occur if the vaccine product stimulates such a response. This is considered unlikely due to the extensive use of this vaccine and other similar vaccine products in Europe, however it is possible and needs to be considered as a potential adverse event. The vaccination team will include a veterinarian who will have access to emergency drugs and supportive care for management of anaphylaxis (including corticosteroids, adrenaline, oxygen, fluids).

Injection site reactions:
The vaccine contains an adjuvant (oil) which is present so that it stimulates a stronger immune response with greater antibody production. This can sometimes be associated with a small pea-sized lump at the site of injection. This is normal and expected, although generally not all birds will develop a lump. This will be checked at the 1 month mark, and recorded with notes and a photograph. If an excessive sized reaction is detected in an individual (>1cm), then the vaccination will be paused until it is determined that the lump does not enlarge further, or cause any impacts on the bird(s) – this is likely to be a period of 2-4 weeks. The food intake, body weight etc will be reviewed and a full physical examination undertaken.

A localised bacterial infection could result if poor sterile technique is used. Only veterinarians or specifically trained DOC staff members will be administering the vaccine, and these operators will have training in appropriate sterile techniques. If a bird experiences an infection at the site, it will receive veterinary care and follow-up to ensure the issue is managed.

Mis-injection could occur if the bird is poorly restrained and moves during vaccination. This will be managed by only using well trained experienced takahē handlers to restrain the birds. For some individual birds, they are calmer with head cover which can aid in handling. This will be determined on an individual bird basis. If a mis-injection occurs, the veterinarian will determine the appropriate next steps. This may include, re-injection if the first injection merely failed to enter the bird, appropriate first aid measures if any injury was caused, and/or exclusion from the trial and follow-up care. As noted previously, "stressy" birds will not be included in the trial which will reduce the risk of injury or mis-injection.

Injury could occur during capture and handling. This is minimised by only using trained experienced staff, careful selection of trial birds, and a "stop for safety" approach which resets the work programme and ensures time out to reassess and replan the work and procedures if necessary.

In the event of a serious reaction or injury during the vaccination trial, the bird will be taken to Dunedin Wildlife Hospital for specialist care by s.9(2)(a) [redacted]. This has been done in the past for sick takahe. Birds can be transported to the Dunedin Wildlife Hospital within 4 hours from the Burwood Takahē Centre.

Results:

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, takahē

The results of this trial will determine if this vaccine is safe to use in this species, and the level of antibody response produced by a 2-dose vaccination. In some other species, notably penguins, the antibody levels following vaccination remain low and, in some species a third vaccination was used to ensure a stronger response (ESFA 2007). The duration of antibody presence also varied between species. Therefore, this trial will help to determine the appropriate vaccination regime for takahē in the event that more widespread vaccination is required during a highly pathogenic avian influenza outbreak in New Zealand.

3c. Attach Photos of equipment, the species, the location (or a map); to help set the context.

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
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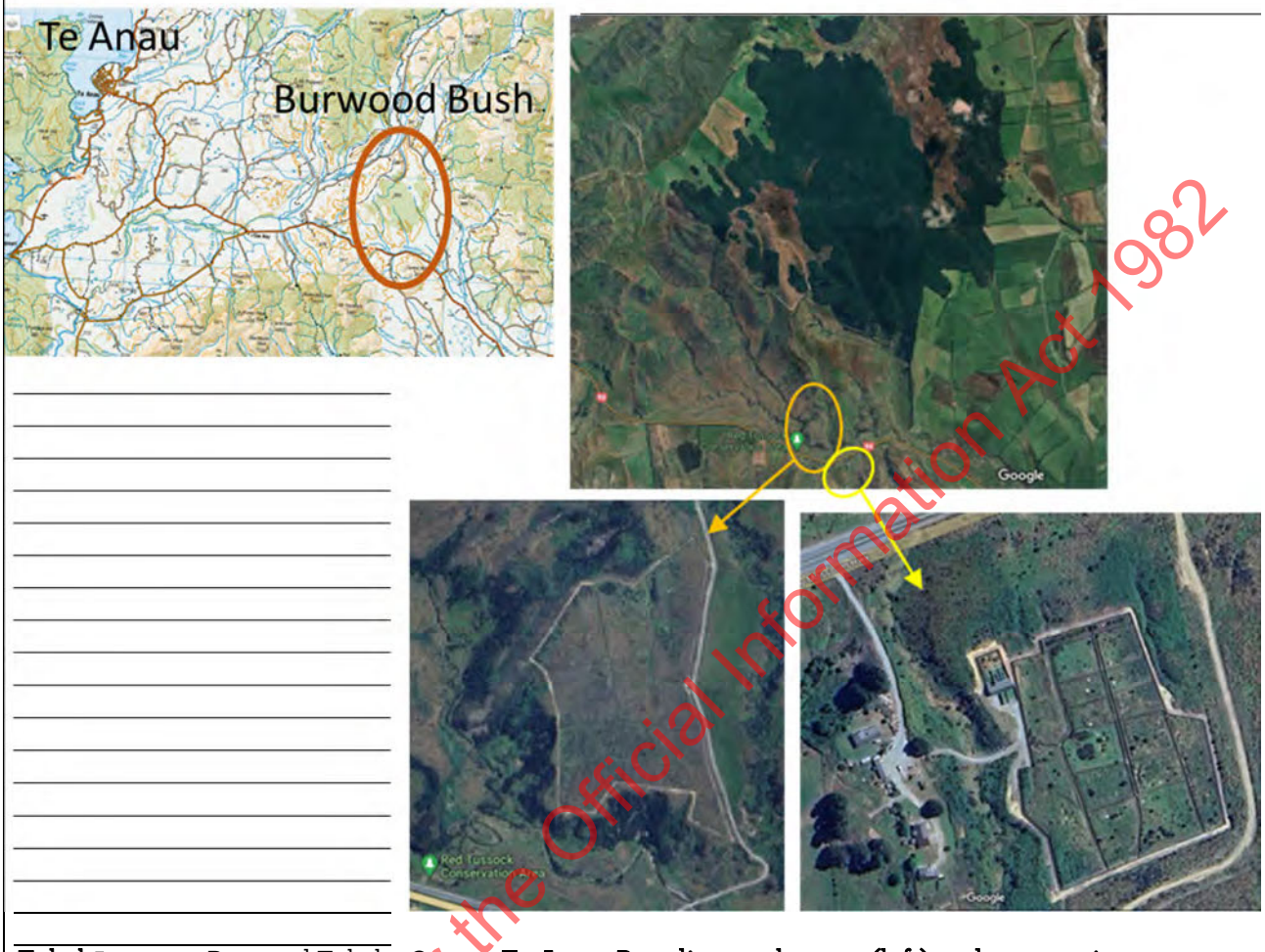

Takahē pens at Burwood Takahē Centre**, Te Anau. Breeding enclosures (left) and -quarantine pens (right)**

Takahē reciving an erysipelas vaccination at Burwood Takahē Centre

3d. References

- *List the references referred to in the application*

DOC-7111177 Mitigation Options Guideline for HPAI
https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7111177

EFSA 2007. Vaccination against avian influenza of H5 and H7 subtypes as a preventative measure carried out in Member States in birds kept in zoos under Community approved programmes. ESFA journal, 450. ESFA-Q-20006-156
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Philippa JWD 2007a, in XI. Vaccination of Non-domestic Avian Species, Transmissible Disease Handbook. European Zoo Vets 5th Edition link

Philippa J, Bass C, Beyer W, Bestebroer T, Fouchier R, Smith D, Schaftenaar W, Osterhaus, A. Vaccination against highly pathogenic avian influenza H5Na virus in zoos using an adjuvanted inactivated H5N2 vaccine. Vaccine, 2007b, 25: 3800-3808. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499841

Pitman 2006. M Pittman, European Commission 12th Annual meeting of national avian influenza laboratories Veterinary and Agrochemical Research Centre (VAR) Uccle, Brussels, 16-18 October 2006 LINK: link.

Vergara-alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499845

4. INVOLVEMENT OF OTHER ANIMAL ETHICS COMMITTEES:

4a. Is this Application; or a related or similar application; been or is being considered by another Animal Ethics Committee. Has this project been requested to be considered by any other AEC?

If so, please provide details.

No

4b. Does this manipulation interact with a manipulation approved by other Animal Ethics Committee? If so, detail your communications with those committee(s), and state any conditions imposed by (an)other AEC.

No

5. JUSTIFICATION FOR PROPOSED MANIPULATION:

5a. Detail any action undertaken to determine that the proposed work has not already been done.

Avian Influenza vaccine safety and efficacy has been undertaken on other avian species, however it has not been undertaken in New Zealand endemic species. Although we expect similar results, it is prudent to undertake this trial to provide more evidence of safety and efficacy in the species which we intend to vaccinate in the event of an HPAI outbreak.

5b. Have alternatives been considered to the proposed manipulation involving reduction, or replacement of live animals, or refinement of techniques?

We are looking at the species-specific response and have selected a minimum size divided into two cohorts, so other methods of reduction are not appropriate for this work.

The cohort approach allows us to cautiously approach the safety issue, and assess initial results before involving the full number of birds.

5c. To what extent has there been assessment of the suitability of using non-sentient or non-living alternatives in the project; or replacement of animals as subjects with suitable non-sentient or non-living alternatives?

N/A, see above

5d. How will the proposed work result in the extension of knowledge relevant to the health, welfare, or conservation of animals?

This work will specifically contribute to the future health of the species for conservation purposes by providing evidence of the safety and efficacy (or not) of this vaccine in this species, and inform the appropriate vaccine schedule for the species. This will determine if, and how, the vaccine is employed in the future in the face of an avian influenza outbreak in New Zealand.

5e. Is the manipulation required as part of an approved training programme?

No.

5f. How will the results of this work be made available to staff within and outside DOC? (*For example internal report, journal paper, best practice guide, workshops etc*).
Internal report, journal paper, conference presentations.

6. SELECTION OF SPECIES & NUMBER OF INDIVIDUALS FOR PROPOSED MANIPULATION

6a. What will be the source of the animals to be manipulated, and how many from each source will be manipulated?
Takahē at Burwood Takahē Centre. 10 birds in total from a range of adults and juveniles (>3 months old), dependent on time of year and breeding success.

6b. Will any of the animals involved be used more than once, and if so, how many times will each animal be used?
Only once (but each animal handled/manipulated multiple times – twice for vaccinating and four more times for blood sampling, although the 6 & 12 month handling for blood collection will be planned to coincide with routine handling for health management)

6c. What factors have been taken into account in the choice of the animal species?
Takahē are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction.

6d. Could the information being sought be obtained by work on some other species?
No. The trial specifically uses takahē since the safety and efficacy needs to be tested in the target species, and due to our unique avifauna, there are no reasonable surrogate species in the world.

6e. Will the question be answered with the size of the sample?
Yes.

6f. Is the number of animals proposed to be manipulated the minimum necessary to provide a scientifically interpretable result, consistent with the level of statistical precision required? What consideration has been given to the design of the study with regard to:

- **The level of precision necessary in the results?**

The purpose of the small trial is to establish if there is a species-specific sensitivity to the vaccine and its adjuvant. For this purpose, we require only a small number of birds to extrapolate a species sensitivity. Similarly, for determining vaccine response by antibody response levels, a sample size of 10 will provide sufficient individual variation to establish an overall species response level. Additionally if a bird is removed from the trial for any reason (e.g. other health issues, injury, behavioural), starting with 10 birds allows sufficient number to still be able to make a reasonable conclusion on the vaccine efficacy for future management purposes.

A larger sample size would ensure a more nuanced examination of the species' response to vaccination, however we are examining a general level of impact/effect, rather than subtle differences.
Thus, results which showed >1 bird having a safety issue, or the majority or average antibody response to be low, would be sufficient to inform the next steps for decision making regarding takahē vaccination.

- **The possible confounding effects of animal variation?**

We expect some individual variation since the immune response is affected by individual health status and biological variation. This sample size is sufficient to ensure we have a range of individual responses to examine.

- **The needs of statistical analysis?**

There is likely to be individual variation, which, for the antibody response, requires a reasonable sample size. We determined that 10 was the maximum which was feasible to include in the trial, and also sufficient to allow for individual variation to establish some baseline parameters of antibody response.

Ultimately, in an outbreak situation, the results of a sample size of 10 will be sufficient to make reasonably informed decisions about the use of a commercially produced killed vaccine which has a good history of safety and efficacy across a wide range of species.

7. WELFARE OF ANIMALS DURING PROPOSED MANIPULATION:

7a. What measures will be taken to ensure: the general health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of over-crowding, and prevention and control of disease?

Birds will be sourced from the s.9(2)(a) [redacted] where DOC staff already maintain appropriate husbandry practices and monitoring of all the birds. Each bird will be held within its normal enclosure so that there is minimum disturbance to their daily lives. Staff will continue to monitor birds throughout the trial, including food consumption and behaviour.

Each bird will receive a veterinary examination at the start of the trial. Equipment will be disinfected between individuals, or new equipment will be used. Once blood has been collected and vaccination undertaken the bird will be re-released in their home enclosure.

The vaccination trial will occur after the breeding season has finished, so will not interfere with any breeding behaviour. No female birds will be gravid at the time of manipulation, and any chicks will be over 3 months old before the trial begins (takahē chicks typically stay with their parents for 1-2 years).

7b. What movement and transportation measures will be followed for the animals to be manipulated to ensure their welfare and humane treatment?

Birds will be vaccinated on site, within their -enclosure, therefore there will be no transport should be required.

However, if a bird requires specialist veterinary care e.g. in the event of an injury or serious reaction, then it will be transferred to Dunedin Wildlife Hospital (DWH) by car, using the standard takahē transport crates, and in accordance with normal takahē transportation procedures. Briefly, birds will have non-slip flooring the crate, be transported via car to Dunedin. Transport will be managed to reduce noise and allow for temperature control. Radio will be off and driver/passenger will ensure minimal noise. Travel will be direct and the hospital will be alerted ahead of time to enable a fast hand-over a and rapid care.

Dr Lisa Argilla at DWH has treated multiple takahē during her time at Massey University Wildbase hospital and DWH and is familiar with their requirements for hospital care.

Supportive therapy would be provided prior to transport which may include pain relief and fluids, the DOC staff are trained and competent in administering medications on direction from the veterinarians.

7c. What measures are to be taken to minimise the pain or distress of any animal manipulated? *Stating there will not be any impact is not acceptable. The AEC is looking for the Applicant to (1) provide analysis about the potential for pain and/or distress to the animal(s), and (2) describe how they will manage that pain or distress. Identify how you would ascertain pain or distress animal's behaviour, environmental conditions likely to lead to pain or distress.*

Birds will be captured and handled by experienced DOC takahē staff using their routine techniques. Only experienced staff will handle the birds. Initial physical examination, vaccination and blood collection will be undertaken by a veterinarian.

Any bird detected to have abnormalities will be examined and rejected from the trial, and receive normal veterinary investigation/intervention.

Subsequent examination and blood collection may be undertaken by DOC staff trained in blood collection from takahē, provided the initial results (0,1 & 2-3 months vaccination and check) are normal across the cohorts.

The subcutaneous injection is not considered painful, and the vaccine dose will be warmed to room temperature prior to injection. Blood collection is associated with a minorly painful pin-prick when the needle is inserted. This will be minimised by careful planning and handling.

If birds are observed to have any pain response to the vaccination, the staff will report it to the veterinarian who will investigate. In the event that there is an injection site reaction (painful inflammation) then an anti-inflammatory such as Metacam may be prescribed veterinarian, as well as antibiotics if infection is also present. These can be administered by staff by hiding the drug inside some food treats.

As noted earlier, if any serious adverse reactions occur, veterinary care by the attending veterinarian will be undertaken, and transfer to Dunedin Wildlife Hospital undertaken if required for more intensive specialist care.

8. CONTINGENCY PLAN:

8a. What arrangements have been made for the abandonment of any manipulation and/or the euthanasia of animals where pain or distress cannot be held within reasonable levels?

If pain or distress is apparent, during handling or following the procedure, the veterinarian will investigate. If the veterinarian deems the level to be unreasonable, then the manipulation will be abandoned and all efforts made to ameliorate the event e.g. anti-inflammatory, pain relief medication, antibiotics.

In the unlikely event that the pain is not temporary and cannot be managed, transfer to Dunedin Wildlife Hospital will allow for intensive veterinary intervention and care. This includes the ability to undertake orthopaedic intervention e.g. in the event of a broken bone, or intensive surgery e.g. in the event of a severe localised vaccine reaction.

Supportive therapy would be provided prior to transport which may include pain relief and fluids.

9. PEOPLE TO UNDERTAKE PROPOSED MANIPULATION:

9a. Who are the person(s) primarily involved in carrying out the proposed manipulation?

Drs Kate McInnes and Lydia Uddstrom are the primary persons.

9b. What is the experience and qualifications of the person primarily responsible (9a) for the undertaking and supervising the manipulation (including selection of animals, their care and disposal?)

Kate McInnes has been the DOC vet since 2000 and has worked across a range of avian species, and is currently the lead technical advisor for the DOC HPAI response.

Lydia Uddstrom is contracted full time to the DOC kakapo team, has undertaken postgraduate training as a zoo veterinarian and has experience with a wide range of New Zealand native species veterinary care.

Both Kate and Lydia have previously been involved in capture and handling of threatened species including takahē, undertaking vaccination and blood collection for a range of threatened species, and have trained multiple DOC staff to safely and effectively undertake these procedures.

9c. Who else is in the team undertaking the manipulation? State their role in the team, and their relevant experience with the procedure(s) proposed in the application? Include DOC and non-DOC staff in the team.

Name of Manipulation Team member	*Role in the manipulation*	*Experience and qualifications relevant to the manipulation*
Nichollette Brown	Team leader for catching, handling,	**Takahē Recovery Programme Supervisor**

	monitoring & follow-up blood collection of takahē.	Trains personnel in blood collection and vaccination in takahē. Sub-cut vaccinations completed over past 5 years = 154 Blood sampling completed over 6 years on programme = ~48
Phil Marsh	Team leader for catching, handling, monitoring & follow-up blood collection of takahē	**Project Lead – Takahē Sanctuary Sites** Trains personnel in blood collection and vaccination in takahē. Sub-cut vaccinations completed over past 5 years = 128 Blood sampling completed over 10 years on programme = ~80
Glen Greaves	Team leader for catching, handling, monitoring & follow-up blood collection of takahē	**Takahē Recovery Programme Senior Ranger** Sub-cut vaccinations completed over past 5 years = 16 (plus many others over his 17 years on the programme) Blood sampling completed over 17 years on programme = ~80
Jason van de Wetering	Team leader for catching, handling, monitoring & follow-up blood collection of takahē	**Project Lead – Takahē Future Sites** Sub-cut vaccinations completed over past 5 years = 78 Blood sampling completed over 7 years on programme = ~56
James Bohan	Team leader for catching, handling, monitoring & follow-up blood collection of takahē	**Takahē team Site Lead at** Burwood Takahē Centre Sub-cut vaccinations completed over past 5 years = 243 Blood sampling completed over 5 years on programme = ~40
Lisa van Beek	Team leader for catching, handling, monitoring. Carry out follow-up blood collection with supervision.	**Takahē Ranger** based at Burwood Takahē Centre since December 2019 Sub-cut vaccinations completed over past 5 years = 112 Blood sampling completed over 4 years on programme = ~10
Tommy McKerras	Assist during handling procedures, follow	Takahē and kakapo ranger since August 2020

	veterinary and team leader directions	
Erica Hansen	Assist during handling procedures, follow veterinary and team leader directions	Takahē ranger based at Burwood Takahē Centre for the last 2 years

9d. What training will be given to the people identified in 9c to help them undertake the manipulation proposed in the application?

Team leaders have undertaken prior training in blood collection and vaccination of takahē (for the bacterial disease erysipelas) and have trained takahē rangers over repeated seasons to undertake normal husbandry practices including capture and handling.

The capture and handling will be undertaken according to the direction of the team leaders.

The handling and vaccination procedures used in this trial are all normal management procedures that are carried out under a Veterinary Operating Instruction for Eryvac vaccination (for prevention of erysipelas). Vaccination for this trial will be undertaken by the veterinarians present. Blood collection may be done by suitably skilled rangers independently of veterinarians being present.

Vaccination will be undertaken by the DOC veterinarian.

10. COMPLIANCE WITH CONDITIONS of the APPROVAL:

- Please outline any opportunities for a member, or members, of the DOC Animal Ethics Committee to observe this work.

10a. Identify ways that the manipulation(s) can be monitored by the AEC.

AEC members could attend a vaccination session at Burwood Takahē Centre or receive a video or photographs of the manipulation being undertaken.

11. Are there any other aspects which ought to be brought to the attention of the DOC Animal Ethics Committee?

No

12. Does the research, testing or teaching involve a species which is covered by a Department of Conservation Species Recovery Plan and if so, has the Recovery Group been consulted and their endorsement for the work received? Please provide a summary of communication.

Yes. The Takahē Recovery team have been fully involved in the development of this trial and it has been specifically requested by the team that this work is carried out urgently.
Lydia Uddstrom and Kate McInnes met with the takahē team members (Nicholette Brown and Glen Greaves) to discuss the inclusion of takahē in the trial and the logistics of undertaking the work on 26th September. Their advice has been incorporated into the trial design.
This application has been shared with the takahē team on 2nd November for review prior to submission to the AEC.

13. What month of year is most useful to report back to the AEC (depending on the project schedule and the animal's biology)?

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, takahē

September

13. Manipulation Grading

Please work through the document *'Grading of Manipulations'* (Please refer to DOCDM-870472), and determine the grading you believe best applies to the manipulation proposed in this application. Please also provide a rationale for the grading.

Grade A: No impact or virtually no impact.
Grade B: Little impact. Manipulations of minor impact and short duration.
Grade C: Moderate impact. Includes manipulations of minor impact and long duration or moderate impact and short duration.
Grade D: High impact. Includes manipulations of moderate impact and long duration or high impact and short duration.
Grade E: Very high impact. Manipulations of high impact and long duration.

Grading determined by the Applicant: B

Your rationale for the grading:
Grade B includes "**Disease/injury/functional impairment:** Studies of vaccines using killed pathogens." The animals will be kept in their normal husbandry conditions for the duration of the study. There will be capture and handling for blood collection and vaccination, and two doses of a killed vaccine administered. Handling time & stress will be minimised by using only skilled staff and it will be undertaken at site.

Note: The grading determined by the Applicant is not the grading assigned by the AEC. The Applicant will be advised of the AEC's grading and any conditions in writing.

DECLARATION by the APPLICANT

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I declare that the information in this Application is correct; and
[☑] I agree to comply with the conditions imposed by DOC's AEC for the manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be aware of the contents of this AEC application; and
[☑] I declare the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff
[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application.
[☑] I agree to comply with the reporting requirements stipulated by the AEC on approval of this research project.

9(2)(a) [redacted]

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, takahē

Signed by the Applicant _____

Full Name: Catherine McInnes Date: 13/11/2023

DECLARATION by the ACCOUNTABLE MANAGER

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I agree to ensure my staff member complies with the conditions imposed by DOC's AEC for this manipulation; and

[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be made aware of the contents of this AEC application; and

[☑] I agree the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff

[☑] I agree to oversee this Application via MORs, PDPs and other means to ensure the manipulation remains within the scope of the Application and the Approval, and all reporting required by the AEC is delivered on time;

[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application, and to advise the AEC if the Applicant leaves the Department, or if the work should be transferred to another staff member for operational reasons' or if the manipulations is abandoned for any reason.

Signed by the Manager: 9(2)(a)

Full Name: John Lyall

Role: Fauna Advice Manager

Date: 15/11/2023

Application Number DOCDM	AEC443 APPLICATION DOC-7483666
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, takahē

Appendix 1: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.
• Use contents of each vial within 6 hours of opening

Appendix 2: General Instructions for subcutaneous injection of vaccine

- The vaccine is supplied in a 500mL bottle and is given to the bird using a needle and syringe.
- The vaccine is injected under the skin but NOT into the muscle below.
- The vaccine should be drawn up into the syringe and then allowed to warm to room temperature (this is more comfortable for the bird).

EQUIPMENT NEEDED

1. Vaccine container
2. 1 mL syringe
3. 25 gauge 5/8th inch needle
4. alcohol swab (mediswab or cotton wool and meths)
5. dry swab (gauze or cotton wool)
6. Sharps container for needle disposal
7. Bird
8. Bird handler
9. Veterinarian

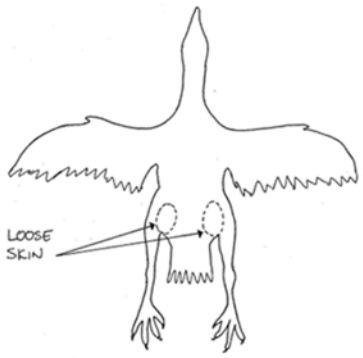
PREPARING THE VACCINATION

1. Store the vaccine in the fridge at 2-8 degrees C in the dark. Do not Freeze.
2. When ready to use, take the vaccine out of the fridge and shake well to mix.
3. Write the date on the vaccine bottle.
4. Break off the metal seal on the top of the rubber injection port.
5. Swab the injection port on the vaccine with alcohol to sterilise it with a mediswab or cotton ball soaked in methylated spirits.
6. Firmly attach the needle to the syringe – 25 gauge 5/8th inch needle to a 1mL syringe.
7. Insert the needle through the centre of the rubber stopper CAREFULLY.
8. Hold the vaccine upside down and slowly suck vaccine into the syringe until you have a little more than the prescribed dose of vaccine.
9. Flick the syringe to dislodge any air bubbles and squirt them slowly back into the vaccine bottle.
10. Keep squirting until all the bubbles are gone and you have the prescribed dose of vaccine left in the syringe.
11. Pull the needle out of the vaccine bottle and CAREFULLY recap the needle.
12. Leave the syringe and needle to warm to room temperature.
13. Repeat this procedure to draw up all the doses you need for your vaccination session.
14. Put the vaccine back in the fridge.
15. Once open, the vaccine can be used for 30 days. (Note that this expiry is based on Zoetis technical advice for limited use of the vaccine in this trial, and only applies when following the above instructions for maintaining sterility of the product and correct storage.)
16. If you are in doubt that the vaccine has been stored correctly (kept refrigerated), then discard it and get a new bottle.

GIVING THE INJECTION

1. Have the following equipment ready for use:
    - The correct dose of vaccine drawn up in syringe with needle attached and warmed to room temperature. (the cap should be on the needle to avoid accidental stabbing or contamination of the needle)
    - One alcohol swab (mediswab or cotton wool in meths)
    - One dry swab (gauze or cotton wool)
2. Have an assistant restrain the bird on its back or side with its legs restrained to provide access to the groin (where the bird's leg joins its belly).

Diagram of ventral (belly) of a bird showing the groin region for subcutaneous vaccination sites:



3. Spread the feathers in the groin area.
4. Wet down the feathers with the swab to clear a patch of skin and swab the skin.
5. Lift the loose skin 1-2cm off the body to make a "tent".

Diagram of the skin being lifted to make a "tent" for a subcutaneous injection

6. Take the cap off the needle and aim the needle about halfway down the side of the tent. Keep the needle parallel to the body wall. When the needle goes through the skin, it should still be above the muscle of the groin i.e. you are injecting into the space inside the tent, not into the muscle.
7. Suck back on the syringe to check for blood. This is to avoid injecting into a blood vessel.
8. Inject the vaccine with a steady firm pressure.
9. Withdraw the needle and place it into the Sharps container.
10. Use the dry swab to press over the injection site if there is any bleeding.
11. Release the bird.

12. Record:	Bird ID	Date	Dose	L or R side	Vaccinator	Holder	Vaccine Batch	Expiry Date	Notes

13. Transfer this data to the vaccination record spreadsheet
14. Note any other specifics about the injection process not described above. E.g. if there was bleeding at the injection site.

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāpō

Revised September 2023

DEPARTMENT OF CONSERVATION
APPLICATION TO MANIPULATE LIVE ANIMALS
Code of Ethical Conduct for the Care and Manipulation of Live Animals

1. APPLICANT'S DETAILS:

Name: Kate McInnes

Date: 24 October 2023

Role: DOC Veterinarian

Unit: BH&V Group, Wellington

APPLICANT'S ADDRESS:

Phone no: 9(2)(a) [redacted]

Email: kmcinnes@doc.govt.nz

2. ACCOUNTABLE MANAGER'S DETAILS:

Name: John Lyall

ACCOUNTABLE MANAGER'S ADDRESS:

As above or: DOC, Hokitika

Phone no: 9(2)(a) [redacted]
Email: jlyall@doc.govt.nz

2a. AEC444

2b. **MANIPULATION TITLE: Avian Influenza vaccination safety and efficacy trial kākāpō**

2d. **Duration of the manipulation**

- *Over what timeframe are you seeking the approval?*
- *You must not commence the manipulation until you have received the approval, signed by you, your accountable manager, and the AEC Chair.*

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāpō

- *NOTE: The AEC will not generally give an approval for longer than two years at one time. Please state if this manipulation is likely to extend longer than two years from the commencement date.*

Anticipated start date:	February 2024	Anticipated finish date:	June 2025

2e. What months of the year is the manipulation most likely to be undertaken? e.g., October – March
For the duration of the dates specified

3a. Summary of the proposed manipulation for a LAYPERSON

- *Provide an abstract describing the manipulation (maximum 400 words).*

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain is decimating many populations of wild birds overseas, is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia, October 2023.

We want to test the safety and efficacy of vaccination to protect critically endangered species.
The vaccine is a commercial product registered in New Zealand by Ministry for Primary Industries. It is considered very safe and highly effective. It contains inactivated (dead) virus so it cannot cause avian influenza. Vaccination reduces risk of illness or death and reduces shedding of virus, thus protecting the individual and its flock.

Kākāpō are a critically threatened species where it is possible to reliably administer a full course of vaccine (2 injections under the skin, one month apart) to individually identified birds. We are able to handle them repeatedly for a veterinary examination and blood testing to detect any effects on health status, and measure the immune response by detection of antibodies over a 12 month period.

Free-living kākāpō will be tracked using telemetry and captured on the predator free off-shore island of Whenua Hou. Each bird will receive a pre-vaccination health check by a veterinarian, and a blood test for health and antibody testing. Up to 1.5mL of blood will be collected from the leg or wing vein, as is standard for this species.

The vaccine is given under the skin. One month later the bird will receive a second vaccination and blood test. Further blood will be collected at 2-3, 6 and 12 months post vaccination to determine the level of antibody response and how long it lasts.

A cloacal and choanal (oral) swab will be collected on day 0 for PCR testing to demonstrate the birds were not incubating avian influenza at the time of vaccination.

Smart transmitters that report individual birds' daily activity levels will be used to remotely monitor for any adverse reactions.

We propose to work with a total of 10 adult or juvenile kākāpō, divided into two cohorts. Cohort 1 will first receive the vaccination & blood tests, and a recheck at 1 month. If no safety issues are identified, then Cohort 2 will receive vaccinations & blood tests. This allows a careful start to the trial where the first 1 month the most important to test vaccine safety. The following blood sample months will determine level and duration of antibody presence and determine when further boosters would be required.

Additional approval given on 16/4/24 to collect a 10-14 week blood sample to target peak antibody levels, and to collect an opportunistic blood sample for further antibody testing, if birds are being handled for routine management purposes, with no more than twice per bird over the 12 months of the trial.

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
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3b. Description of the proposed manipulation (methods)

- *Provide a more detailed explanation. Describe the equipment, the location, and any environmental factors: weather, time of the year. Why have you decided to undertake the manipulation in this way? What advice have you sought? Include the species, the number of individuals, the source of animals, and the disposal/fate of animals at the conclusion of the manipulation.*
- *Be specific about the timelines for the proposed investigation and the purpose of the research, testing or teaching.*
- *Include some consideration and planning for when things might not go right.*

Please note: this is one of five trials to assess avian influenza vaccination safety and efficacy in nationally critical threatened species (takahē, kākāpō, kakī, tūturuatu, kākāriki karaka). Manipulation details which are specific to this species (kākāpō) have been highlighted in yellow. All other details are consistent across the five trials. By highlighting the species specific details I hope to assist the AEC with the volume of workload associated with simultaneously assessing these trials.

This trial is designed to test the efficacy and safety of a vaccine in a critically threatened species.

Selection of the species for potential vaccination is based on the risk that they could undergo an extinction event when highly pathogenic avian influenza (HPAI) reaches New Zealand. Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and risk of extinction.

The current kākāpō population is 247. Kākāpō are very slow breeding with chicks only produced in years with rimu fruit masting. This last happened in 2022 and they will not breed again until at least 2026. This leaves the species exceptionally vulnerable to disease outbreaks as individuals who die are not quickly replaced. Kākāpō are also very slow to start breeding – females do not breed until 5 years of age and males generally are in their teens before they successfully breed. Kākāpō do not do well in a confined space (captivity) therefore all management must be done at their wild sites.

Based on the global evidence from overseas during this epizootic, the species most at risk of infection are those which exhibit congregation behaviours e.g. feeding, breeding or roosting in groups, those which are exposed to at risk species e.g. where seabirds overlap with another threatened species, and birds held in captive facilities where biosecurity options are limited e.g. open pens and large aviaries.

Kākāpō are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. See DOC-7111177 Mitigation Options Guideline for HPAI.

There are only 247 kākāpō in existence and they have very low reproductive rates only breeding every 2-4 years. Whenua Hou has been the primary breeding island for many years and also contains large breeding petrel and shearwater populations. There has previously been evidence of disease transfer from petrels and shearwaters to kākāpō.

Use of the vaccine is dependent on Ministry for Primary Industries approval, and currently requires the birds to be held in captivity or in a defined restricted area. Birds require two injections one month apart and must be individually identified with a permanent mark e.g. microchip or leg band. All kakapo have a microchip for individual identification as part of routine husbandry.

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment (Animal Health Australia, 2021).

There is precedent for undertaking a vaccination program in kākāpō. Since 2004 there has been a vaccination program in place to protect kākāpō against death from a bacterial disease – erysipelas. This current vaccination program means that there are staff highly skilled in this procedure on kākāpō and that vaccination is a standard management tool for this species. No adverse events in kākāpō have been recorded as a result of the erysipelas vaccination programme.

Additionally, vaccination of California Condor was approved in the United States following an outbreak in the wild population. This was the first avian influenza vaccination programme in a wild endangered species. Advice from the veterinary and technical advisors to the condor vaccination programme has been received and is incorporated into this trial design.

We wish to undertake a limited trial to determine the safety and efficacy of the avian influenza specific vaccine in kākāpō as a preparedness measure for the arrival of HPAI in New Zealand.

The vaccine is produced commercially by Zoetis for use in poultry: Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine - see Appendix 1. It has been in production since 2006 and is widely used in the poultry industry. Publications on AI vaccine use in poultry and avian species in zoos have indicated a very high level of safety across a wide range of species, and efficacy has been well established. (Kandeil et al 2018, Philippa et al 2006, Philippa 2007a, Philippa 2007b, Pitman 2006). The vaccine in inactivated, so there is no live virus present, and it cannot cause avian influenza.

Advice from Zoetis (USA) indicates that this vaccine should provide good protection against the current strain of HPAI with 91% amino acid homology with the circulating strain. A newer vaccine based on the circulating strain is in production but is will not be available until the end of 2024 at the earliest.

Vaccine will be obtained from PacificVet in Christchurch and transported in a chilly bin with ice-packs by overnight courier (as per their standard transportation procedures for vaccines) to ensure cold chain is maintained. Use in the field will be managed by extraction of sterile aliquots into sterile vials or syringes. This enables sustainable use of the 1000 dose vial and maintenance of sterility of product. This process was discussed with the Zoetis Senior Research Advisor responsible for poultry products and is considered safe and appropriate.

Sterile aliquots will be obtained by using a sterile needle and syringe to extract the aliquot from the closed vaccine vial. The vial will be shaken to homogenise the contents, then the rubber stopper will be swabbed with alcohol. The sterile needle will be attached to the sterile syringe and the needle inserted via the rubber stopper. The aliquot will be drawn up into the syringe, then the needle & syringe removed from the stopper and the cap replaced on the needle. The needle will be swapped for a new sterile needle or a sterile vaccine cap. Both the aliquots and the vaccine vial will be stored refrigerated in accordance with the packaging instructions. Vaccine doses will be drawn up immediately before use and allowed to warm to body temperature just prior to injection.

DOC veterinarians Kate McInnes and Lydia Uddstrom will administer the vaccination.

All birds will receive a full veterinary physical examination at the start of the trial. Only birds in good body condition exhibiting signs of good health will be included. (Any birds which show signs off poor health will be further investigated as per normal veterinary practices).

The kākāpō recovery team have been involved in the design of the study, and selection of study animals. Whenua Hou is the easiest location to access, track and capture the kākāpō required for this trial.

Individuals for vaccination will be selected by the kākāpō recovery team, based on the knowledge of individual home ranges and ability to be captured as well as the programme's planning for any translocations.

Each individually permanently marked (microchipped) bird will receive two doses of vaccine by subcutaneous injection into the inguinal (groin) region with a 1 month interval (no less than 3 weeks apart and a maximum of 6 weeks apart). The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds <1.5kg will receive 0.20ml per dose. Birds >1.5kg will receive 0.5ml per dose (as per dosages used in Vergara-Alert et al 2011).

At the start of the trial, each bird will receive a cloacal and oral swab to determine presence/absence of virus at day 0.
The technique will follow the draft SOP Avian swab sampling DOC-6840491 which has undergone veterinary peer review & user testing and is awaiting AEC endorsement before Director sign-off. These types of swabs are used in standard health testing on avian species and would be undertaken by the veterinarian. The test would be considered a baseline health test to demonstrate the birds were not incubating avian influenza at the time of vaccination. The swabs will undergo PCR testing at BioPacifica to look for avian influenza virus.
This is important to be able to demonstrate that any antibody response is due to the vaccination rather than the bird being infected by a wild strain of avian influenza.

First trial - Cohort 1: Five individuals will be vaccinated as per the described protocol above. Blood (up to 1.5ml) will be collected at 0, 1 and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test to measure antibody titre). Antibody testing will be undertaken at a commercial laboratory (BioPacifica, Christchurch).

Note: 1% of body weight is considered an acceptable amount of blood to collect from a healthy bird. Adult kākāpō weigh 1.5-2kg, therefore 15-20ml would be within the safe range. We propose only up to 1.5ml will be collected to maintain a high margin of safety.)

Second trial - Cohort 2: Based on consideration of the results of the first trial, if safety has been demonstrated, a second cohort of 5 individuals will receive the vaccination as per the described protocol above, and blood (up to 1.5mL) will be collected at 0, 1 and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test). We will wait 1 month until we have established the vaccine is safe in cohort 1 before we start cohort 2.

Amendment April 2024: where birds have received a blood sample at 8 weeks, they will receive an additional blood sample at 10-14 weeks. Otherwise birds will not be tested at 8 weeks and will be tested at 10-14 weeks instead.

Two additional blood samples will be collected from both cohorts at approximately 6 and 12 months to measure duration of antibody response.

Note: If antibody response at 2-3 months is noted to be muted (i.e. a low response) then the DOC vets (Kate McInnes and Lydia Uddstrom) will discuss the use of a third dose of vaccine. This was used in some species in European zoos where the initial responses were considered insufficient. Consideration will be

given to the level of response detected, the impacts of additional handling, and any other welfare factors noted during the preceding handling events. The benefits of testing a third dose of vaccine will be carefully considered, and this will only be undertaken if the welfare impacts are considered minimal. The justification for a third dose in this trial would be to confirm if this dose is warranted and would deliver protection for the kākāpō population in the event of an outbreak of HPAI in Aotearoa New Zealand.

A maximum of 10 birds will be included in the trial. There will be 70-80 kākapō on Whenua Hou at the time of the trial.

These trials are modelled on the vaccination of California Condor in the USA. (FWS.gov 2023) however the 1 month interval is based on the European zoo data, and considered more appropriate to allow for recovery between handling events in birds which normally have minimal handling by humans.

Estimated timing/schedule of manipulations:

First vaccination and blood sample	Second vaccination and blood sample	2-3 month blood sample	6 month blood sample	12 month blood sample
First cohort of 5 birds				
~ 1st March 2024	~ 1st April 2024	~1st May 2024	~30th August 2024	~15th March 2025
Second cohort of 5 birds (maximum 10 total)				
~ 1st April 2024	~1st May 2024	~1st June 2024	~30th August 2024	~15th March 2025

Second cohort of 5 birds – same timeline but 1 month after first cohort have been vaccinated and shown no negative reaction. Blood collection at ~6 and ~12 months may be undertaken at the same time for both cohorts – these samples are about longevity of antibody presence, so the exact timing is less critical.

During a handling event, all involved staff will gather and have a pre-handling briefing by the veterinarian and the team leader to ensure all roles and responsibilities are clearly understood. Any issues can be raised at that time for clarification. The kākāpō team leader will be responsible for the safe capture and handling of the bird. The veterinarian will be responsible for the health examination, vaccination and blood collection.

All equipment will be prepared prior to capture to minimise handling time. Staff will know where to situate themselves and what actions are required so that an efficient process is maintained. Kākāpō chicks and juveniles receive vaccinations to protect them against erysipelas (a bacterial disease). The kākāpō rangers involved in this trial will be team members with previous experience in vaccination and blood collection in kākāpō.

Kākāpō team rangers will be consulted to select appropriate birds based on their previous observations. It is possible to encounter birds with a "stressy" personality. Such a bird is not a good candidate for a trial which requires repeated handling events, and therefore it would be excluded from the trial. If any birds are observed to exhibit any significant distress during any of the procedures, the kākāpō team rangers and DOC vets will call a stop to the procedure and reassess the procedures being undertaken and the suitability of the bird(s) for inclusion in the trial. If necessary, changes will be made to reduce issues such as, but not limited to; reducing number of people present, slowing down the capture process, taking a break so birds and humans can calm down, rejecting individual birds from the trial, changing handlers/vet to allow a rest break, abandoning the work for the day, or if serious issues are encountered, potentially

stopping the trial and discussing a redesign or full abandonment. At all times bird welfare is paramount and will determine the actions of the kākāpō team and veterinarians.

Catching a kākāpō involves walking to their home range then using an aerial and receiver to track the VHF channel produced by an individual's transmitter. This allows the rangers to determine where the bird is located. Kākāpō may be anywhere from an underground roost to perching in the canopy. Once a bird is sighted the rangers assess the access to the bird and catch them by hand. Often once caught the bird is placed in a 'catch bag' (a soft cotton bag with a draw string which provides a safe restraint for temporary holding and transport of kākāpō) to allow them to be carefully and safely carried a short distance to a suitable location for examination.

Once caught the kākāpō will be weighed in the bag using a hanging scale (standard technique) and then will be carefully removed to undergo a physical examination to determine its health status prior to any further manipulation. If the kākāpō is determined to be healthy, blood collection and vaccination will proceed.

For blood collection and vaccination, a trained kākāpō handler will restrain the bird on its side or back.

The blood collection site (leg or wing vein) will be swabbed with a sterile alcohol wipe immediately prior to collection. Blood will be collected using a 1ml or 3ml sterile syringe attached to a 25 – 26 gauge ¾ - ½ inch sterile hypodermic needle.

In the event that the temperature is cool and blood collection likely to be slow due to the presence of small contracted veins, the feet will be warmed for 3-5 minutes using Kathmandu hand warmers wrapped in gauze to boost circulation and enhance blood flow to enable effective blood collection.

After collection, the site of blood collection will be covered with a gauze swab and pressure applied to control any bleeding. In the very unlikely event of uncontrolled bleeding, pressure will be applied for a further 1-5 minutes. If still uncontrolled, alcohol will be rubbed onto the foot and leg to cool the limb to reduce blood flow If required, a silver nitrate stick will be carefully used to stop the bleeding.

Blood will be transferred into a blood microtainer and spun in a centrifuge to separate the serum from the blood cells. Serum will be drawn off using a sterile pipette and transferred into an epindorf tube for storage in the freezer, prior to transfer to the commercial laboratory in batches for antibody testing.

1-2 drops of blood will be used to make blood smears which will be sent to a commercial veterinary pathology laboratory for a white cell count and differential. This provides a baseline health analysis which can detect infection or inflammation. Any abnormal results will be further investigated by the veterinarian in consultation with the kākāpō staff.

Once bleeding has stopped, the bird will be vaccinated using a 1mL syringe attached to a 20 gauge ½ inch needle. The vaccination site will be swabbed with a sterile alcohol wipe immediately prior to vaccination. See Appendix 2 for details of the vaccination technique.

The bird will then be checked for any abnormalities and the veterinarian will determine if any further actions are required for health or welfare. It will be quietly released and observed as it moves away.

The bird will be monitored via the remote monitoring system on Whenua Hou which allows tracking of birds and records their daily activity levels. This is used to monitor health and behaviour and is capable of alerting staff to changes which indicate reduced activity and possible health concerns. If any bird's data

indicates a significant reduction in activity following vaccination, the bird will be recaptured for a physical examination, and appropriate steps taken by the DOC veterinarian if ill health is detected.

At subsequent handling events, the vaccination site will be examined and any discolouration, swelling, granuloma formation or unexpected abnormality will be noted and reported to the veterinarian. Photographs will be taken to provide a clear record of the trial.

Location & timing:
The trials will be undertaken on Whenua Hou between Feb 2024 and June 2025. Whenua Hou/Codfish Island is 1396 ha and 3km off the north-west coast of Rakiura/Stewart Island. Vegetation is mostly coastal and podocarp forest, similar to that on Rakiura/Stewart Island. It is one of the islands used in the Kākāpō Recovery Programme. Whenua Hou was chosen because it holds a large portion of the kākāpō population and has well-established logistics.

Safety:

Results from a meta-analysis of use of vaccine in European Zoos found very low adverse reaction rate at 0.04% local reactions and 0.015% general reactions reported. EFSA 2007. Based on this, we do not anticipate significant issues with the vaccine, however we will be prepared for immediate veterinary care if any reactions to occur.

The vaccine packaging label states: “Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.”

Anaphylaxis:
A severe immediate immune hypersensitivity response could occur if the vaccine product stimulates such a response. This is considered unlikely due to the extensive use of this vaccine and other similar vaccine products in Europe, however it is possible and needs to be considered as a potential adverse event. The vaccination team will include a veterinarian who will have access to emergency drugs and supportive care for management of anaphylaxis (including corticosteroids, adrenaline, oxygen, fluids).

Injection site reactions:
The vaccine contains an adjuvant (oil) which is present so that it stimulates a stronger immune response with greater antibody production. This can sometimes be associated with a small pea-sized lump at the site of injection. This is normal and expected, although generally not all birds will develop a lump. This will be checked at the 1 month mark, and records kept of any reactions detected. If an excessive size reaction is detected in an individual, then the vaccination will be paused until it is determined that the lump does not enlarge further, or cause any impacts on the birds – this is likely to be a period of 2-4 weeks. Body weight, activity levels etc will be reviewed and a full physical examination undertaken.

A localised bacterial infection could result if poor sterile technique is used. Only veterinarians or specifically trained DOC staff members will be administering the vaccine, and these operators all have training in appropriate sterile techniques. If a bird experiences an infection at the site, it will receive veterinary care and follow-up to ensure the issue is managed.

Mis-injection could occur if the bird is poorly restrained and moved during vaccination. This will be managed by only using well trained, experienced bird handlers to restrain the birds. For some individual birds, they are calmer with head cover which can aid in handling. This will be determined on an individual bird basis. If a mis-injection occurs, the veterinarian will determine the appropriate next steps. This may

include, re-injection if the first injection merely failed to enter the bird, appropriate first aid measures if any injury was caused, and/or exclusion from the trial and follow-up care. As noted previously, "stressy" birds will not be included in the trial which will reduce the risk of injury or mis-injection.

In the event of a serious reaction or injury during the vaccination trail, the bird will be taken to Dunedin Wildlife Hospital for specialist care by Dr Lisa Argilla. This is standard procedure for kākāpō requiring a high level of veterinary care.

Results:
The results of this trial will determine if this vaccine is safe to use in this species, and the level of antibody response produced by a 2 dose vaccination. In some other species, notably penguins, the antibody levels following vaccination remain low and, in some species, a third vaccination was used to ensure a stronger response (ESFA 2007). The duration of antibody presence also varied between species. Therefore, this trial will help to determine the appropriate vaccination regime for kākāpō in the event that more widespread vaccination is required during a highly pathogenic avian influenza outbreak in New Zealand.

3c. Attach Photos of equipment, the species, the location (or a map); to help set the context.

Kākāpō positioned for eysipelas vaccination

3d. References

- *List the references referred to in the application*

DOC-7111177 Mitigation Options Guideline for HPAI.

DOC-7111177 Mitigation Options Guideline for HPAI
https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7111177

EFSA 2007. Vaccination against avian influenza of H5 and H7 subtypes as a preventative measure carried out in Member States in birds kept in zoos under Community approved programmes. ESFA journal, 450. ESFA-Q-20006-156
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Health Australia (2021). Response strategy: Avian influenza (version 5.0). Australian Veterinary Emergency Plan (AUSVETPLAN), edition 5, Canberra, ACT. Response_Avian-influenza.pdf (animalhealthaustralia.com.au) Animal

FWS.gov 2023 Southwest California Condor Flock HPAI Information Updates - 2023 | U.S. Fish & Wildlife Service (fws.gov)

Kandeil A, Sabir SM, Abdelaal A, Mattar EH, El-Taeel AN, Sabir MJ, Khalil AA, Webby R, Kayali G, Ali MA. Efficacy of commercial vaccines against newly emerging avian influenza H5N8 in Egypt. Nature Scientific Reports, 2018. 8:9697 | DOI:10.1038/s41598-018-28057-x https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499854

Philippa JDW, Munster VJ, van Bolhuis H, Bestebroer TM, Schaftenaar W, Beyer WEP, Fouchier RAM, Kuiken T, Osterhaus, ADME. Highly pathogenic avian influenza (H7N7): Vaccination of zoo birds and transmission to non-poultry species. Vaccine, 2005, 23:5743-5750. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499837

Philippa JWD 2007a, in XI. Vaccination of Non-domestic Avian Species, Transmissible Disease Handbook. European Zoo Vets 5th Edition link

Philippa J, Bass C, Beyer W, Bestebroer T, Fouchier R, Smith D, Schaftenaar W, Osterhaus, A. Vaccination against highly pathogenic avian influenza H5Na virus in zoos using an adjuvanted inactivated H5N2 vaccine. Vaccine, 2007b, 25: 3800-3808. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499841

Pitman 2006. M Pittman, European Commission 12th Annual meeting of national avian influenza laboratories Veterinary and Agrochemical Research Centre (VAR) Uccle, Brussels, 16-18 October 2006 LINK: link.

Vergara-alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499845

4. INVOLVEMENT OF OTHER ANIMAL ETHICS COMMITTEES:

4a. Is this Application; or a related or similar application; been or is being considered by another Animal Ethics Committee. Has this project been requested to be considered by any other AEC?

If so, please provide details.

No

4b. Does this manipulation interact with a manipulation approved by other Animal Ethics Committee? If so, detail your communications with those committee(s), and state any conditions imposed by (an)other AEC.

No

5. JUSTIFICATION FOR PROPOSED MANIPULATION:

5a. Detail any action undertaken to determine that the proposed work has not already been done.

Avian influenza vaccine efficacy and safety has been undertaken on other avian species, however it has not been undertaken in New Zealand endemic species. Although we expect similar results, it is prudent to undertake this trial to provide more evidence of safety and efficacy in the species which we intend to vaccinate in the event of a HPAI outbreak.

5b. Have alternatives been considered to the proposed manipulation involving reduction, or replacement of live animals, or refinement of techniques?

We are looking at the species-specific response and have selected a minimum size divided into two cohorts, so other methods of reduction are not appropriate for this work.

The cohort approach allows us to cautiously approach the safety issue and assess initial results before involving the full number of birds.

Typically, kākāpō are handled once every 18 months for a transmitter change. If this timing falls within the trial period, every effort will be made to coincide the required transmitter change with the trial handling to reduce the number of times an individual is handled.

5c. To what extent has there been assessment of the suitability of using non-sentient or non-living alternatives in the project; or replacement of animals as subjects with suitable non-sentient or non-living alternatives?

N/A, see above

5d. How will the proposed work result in the extension of knowledge relevant to the health, welfare, or conservation of animals?

This work will specifically contribute to the future health of the species for conservation purposes by providing evidence of the safety and efficacy (or not) of this vaccine in this species, and inform the appropriate vaccine schedule for the species. This will determine if the vaccine is employed in the future in the face of an avian influenza outbreak in New Zealand.

5e. Is the manipulation required as part of an approved training programme?

No.

5f. How will the results of this work be made available to staff within and outside DOC? (*For example internal report, journal paper, best practice guide, workshops etc*).
Internal report, journal paper, conference presentations.

6. SELECTION OF SPECIES & NUMBER OF INDIVIDUALS FOR PROPOSED MANIPULATION

6a. What will be the source of the animals to be manipulated, and how many from each source will be manipulated?
Kākāpō free-living on Whenua Hou. 10 birds in total from a range of adults and juveniles.

6b. Will any of the animals involved be used more than once, and if so, how many times will each animal be used?
Only once (but each animal handled/manipulated multiple times – twice for vaccinating and four more times for blood sampling).

6c. What factors have been taken into account in the choice of the animal species?

Kākāpō are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction.

6d. Could the information being sought be obtained by work on some other species?
No. The trial specifically uses kākāpō since the safety and efficacy needs to be tested in the target species, and due to our unique avifauna, there are no reasonable surrogate species in the world.

6e. Will the question be answered with the size of the sample?
Yes.

6f. Is the number of animals proposed to be manipulated the minimum necessary to provide a scientifically interpretable result, consistent with the level of statistical precision required? What consideration has been given to the design of the study with regard to:

- **The level of precision necessary in the results?**

The purpose of the small trial is to establish if there is a species-specific sensitivity to the vaccine and its adjuvant. For this purpose, we require only a small number of birds to extrapolate a species sensitivity. Similarly, for determining vaccine response, a sample size of 10 will provide sufficient individual variation to establish an overall species response level.

A larger sample size would ensure a more nuanced examination of the species' response to vaccination; however we are examining a general level of impact/effect, rather than subtle differences. Thus, results which showed >1 bird having a safety issue, or the majority or average antibody response to be low, would be sufficient to inform the next steps for decision making regarding kākāpō vaccination.

- **The possible confounding effects of animal variation?**

We expect some individual variation since the immune response is affected by individual health status and biological variation. This sample size is sufficient to ensure we have a range of individual responses to examine.

- **The needs of statistical analysis?**

There is likely to be individual variation, which, for the antibody response, requires a reasonable sample size. We determined that 10 was the maximum which was feasible to include in the trial, and also sufficient to allow for individual variation to establish some baseline parameters of antibody response.

Ultimately, in an outbreak situation, the results of a sample size of 10 will be sufficient to make reasonably informed decisions about the use of a commercially produced killed vaccine which has a good history of safety and efficacy across a wide range of species.

7. WELFARE OF ANIMALS DURING PROPOSED MANIPULATION:

7a. What measures will be taken to ensure: the general health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of over-crowding, and prevention and control of disease?

Kākāpō will be caught and handled by experienced rangers as per usual kākāpō protocols on Whenua hou/Codfish Island.

Each bird will receive a veterinary examination at the start of the trial. Equipment will be disinfected between individuals, or new equipment will be used. Once blood has been collected and vaccination undertaken the bird will be re-released where they were found.

Ongoing monitoring will be undertaken using remote monitoring tools to minimise disturbance of the bird.

There will not be any kākāpō breeding for the coming seasons (2023/24/25), so this trial will not interfere with any breeding behaviour.

7b. What movement and transportation measures will be followed for the animals to be manipulated to ensure their welfare and humane treatment?

Birds will be vaccinated on site, where they are captured, therefore there will be no transport required.

However, if a bird requires specialist veterinary care e.g. in the event of an injury or serious reaction, then it will be transferred to Dunedin Wildlife Hospital (DWH), using the standard kākāpō transport crates, and in accordance with normal kākāpō transportation procedures. Briefly, birds will have non-slip flooring the crate, be transported via helicopter to Invercargill, then car to Dunedin. Transport will be managed to reduce noise and allow for temperature control. Radio will be off and driver/passenger will ensure minimal noise. Travel will be direct and the hospital will be alerted ahead of time to enable a fast hand-over a and rapid care.

Dr Lisa Argilla at DWH has treated multiple kākāpō during her time at Massey University Wildbase hospital and DWH and is familiar with their requirements for hospital care.

Supportive therapy would be provided prior to transport which may include pain relief and fluids. The kakapo veterinary advisor would travel with the bird if ongoing supportive care was required during transport.

7c. What measures are to be taken to minimise the pain or distress of any animal manipulated? *Stating there will not be any impact is not acceptable. The AEC is looking for the Applicant to (1) provide analysis about the potential for pain and/or distress to the animal(s), and (2) describe how they will manage that pain or distress. Identify how you would ascertain pain or distress animal's behaviour, environmental conditions likely to lead to pain or distress.*

Birds will be captured and handled by experienced DOC kākāpō staff using their routine techniques. Only experienced staff will handle the birds. Initial physical examination, vaccination and blood collection will be undertaken by a veterinarian.

Any bird detected to have abnormalities will be examined and rejected from the trial, and receive normal veterinary investigation/intervention.

Subsequent examination and blood collection may be undertaken by DOC staff trained in blood collection from kākāpō, provided the initial results (0,1 and 2-3 months vaccination and check) are normal across the cohorts.

The subcutaneous injection is not considered painful, and the vaccine dose will be warmed to room temperature prior to injection. Blood collection is associated with a minorly painful pin-prick when the needle is inserted. This will be minimised by careful planning and handling.

If birds are observed to have any pain response to the vaccination, the staff will report it to the veterinarian who will investigate. In the event that there is an injection site reaction (painful inflammation) then an anti-

inflammatory such as Metacam may be prescribed by the attending veterinarian, as well as antibiotics if infection is also present.

As noted earlier, if any serious adverse reactions occur, veterinary care by the attending veterinarian will be undertaken, and transfer to Dunedin Wildlife Hospital undertaken if required for more intensive specialist care.

8. CONTINGENCY PLAN:

8a. What arrangements have been made for the abandonment of any manipulation and/or the euthanasia of animals where pain or distress cannot be held within reasonable levels?

If pain or distress is apparent, during handling or following the procedure, the veterinarian will investigate. If the veterinarian deems the level to be unreasonable, then the manipulation will be abandoned and all efforts made to ameliorate the event e.g. anti-inflammatory, pain relief medication, antibiotics.

In the unlikely event that the pain is not temporary and cannot be managed, transfer to Dunedin Wildlife Hospital will allow for intensive veterinary intervention and care. This includes the ability to undertake orthopaedic intervention e.g. in the event of a broken bone, or intensive surgery e.g. in the event of a severe localised vaccine reaction.

Supportive therapy would be provided during any transport which may include pain relief and fluids.

9. PEOPLE TO UNDERTAKE PROPOSED MANIPULATION:

9a. Who are the person(s) primarily involved in carrying out the proposed manipulation?
Kate McInnes and Lydia Uddstrom are the primary persons.

9b. What is the experience and qualifications of the person primarily responsible (9a) for the undertaking and supervising the manipulation (including selection of animals, their care and disposal?)
Kate McInnes has been the DOC vet since 2000 and has worked across a range of avian species, and is currently the lead technical advisor for the DOC HPAI response.
Lydia Uddstrom is contracted full time to the DOC kākāpō team and has undertaken postgraduate training as a zoo veterinarian.

Both Kate and Lydia have previously been involved in capture and handling of threatened species including kākāpō, undertaking vaccination and blood collection for a range of threatened species, and have trained multiple DOC staff to safely and effectively undertake these procedures.

9c. Who else is in the team undertaking the manipulation? State their role in the team, and their relevant experience with the procedure(s) proposed in the application? Include DOC and non-DOC staff in the team.

Name of Manipulation Team member	*Role in the manipulation*	*Experience and qualifications relevant to the manipulation*

Experienced kākāpō vaccinator - Deidre Vercoe - Andrew Digby - Daryl Eason - Jake Osborne - Bryony Hitchcock - Petrus Hedman - Brodie Philps - Sarah Little - Daniella Whitaker - Theo Thompson - Tommy McKerras	Team leader for tracking, catching, handling & monitoring	These are team members who have extensive kākāpō tracking, capture and handling experience. They have also undergone additional training to carry out vaccinations (as per the Veterinary Operating Instructions for Eryvac vaccination in Kākāpō).
Experienced kākāpō blood sampler - Deidre Vercoe - Andrew Digby - Daryl Eason - Jake Osborne - Bryony Hitchcock - Petrus Hedman - Brodie Philps - Sarah Little - Theo Thompson	Team leader for tracking, catching, handling, monitoring & follow-up blood collection in kākāpō.	These are team members who have extensive kākāpō tracking, capture and handling experience. They have also undergone additional training to carry out blood sampling in kākāpō.
Kākāpō field rangers - Everyone listed in the sections above, also: - Maddy Whittiker - Sarah Manktelow - Scott Latimer - Tim Raemaekers - Jenny Ricketts	Team member for tracking, catching, handling, and monitoring kākāpō	These are team members who have extensive kākāpō tracking, capture and handling experience.
Takahē field rangers - Nicholette Brown - Glen Greaves - Phil Marsh - Jason van de Wetering - James Bohan - Erica Hansen	Team member for tracking, catching, handling, and monitoring kākāpō	These are members of the takahē team who have also spent extensive time tracking, capturing and handling kākāpō

9d. What training will be given to the people identified in 9c to help them undertake the manipulation proposed in the application?

Team leaders have undertaken prior training in blood collection and vaccination of kākāpō (for the bacterial disease erysipelas). Team leaders have trained kākāpō rangers over repeated seasons to undertake normal practices including capture and handling.

The capture and handling will be undertaken according to the direction of the team leaders.

The handling and vaccination procedures used in this trial are all normal management procedures that are carried out under a Veterinary Operating Instruction for Eryvac vaccination (for prevention of erysipelas).

Vaccination for this trial will be undertaken by the veterinarians present. Blood collection may be done by suitably skilled rangers independently of veterinarians being present.

Vaccination will be undertaken by the DOC veterinarian.

10. COMPLIANCE WITH CONDITIONS of the APPROVAL:

- Please outline any opportunities for a member, or members, of the DOC Animal Ethics Committee to observe this work.

10a. Identify ways that the manipulation(s) can be monitored by the AEC.

Due to the "permit only" requirements which limit visitation to Whenua Hou, it is suggested that AEC members could attend a vaccination session at Burwood Takahe Centre to see the procedure in takahē and then receive a video or photographs of the manipulation being undertaken in kākāpō.

11. Are there any other aspects which ought to be brought to the attention of the DOC Animal Ethics Committee?

No

12. Does the research, testing or teaching involve a species which is covered by a Department of Conservation Species Recovery Plan and if so, has the Recovery Group been consulted and their endorsement for the work received? Please provide a summary of communication.

Yes. Kākāpō management is guided by a Kākāpō Recovery Plan (Draft 2021-2026). Objective 14.1 Is to analyse and develop detection and mitigation measures for emerging health issues and understand the subsequent risk to the population. The Kākāpō Recovery Group support the objectives of this trial.

This trial has been developed with the consensus of the Kākāpō Recovery Team, which has a close working relationship with Kaitiaki Rōpū o nga Murihiku Rūnanga o Ngāi Tahu who are also supportive of this work.

All involved have requested that this work is undertaken urgently to increase our understanding of the ability of the HPAI vaccine to protect kākāpō should HPAI arrive in New Zealand.

13. What month of year is most useful to report back to the AEC (depending on the project schedule and the animal's biology)?

September

13. Manipulation Grading

Please work through the document '*Grading of Manipulations*' (Please refer to DOCDM-870472), and determine the grading you believe best applies to the manipulation proposed in this application. Please also provide a rationale for the grading.

Grade A: No impact or virtually no impact.
Grade B: Little impact. Manipulations of minor impact and short duration.
Grade C: Moderate impact. Includes manipulations of minor impact and long duration or moderate impact and short duration.
Grade D: High impact. Includes manipulations of moderate impact and long duration or high impact and short duration.
Grade E: Very high impact. Manipulations of high impact and long duration.

Grading determined by the Applicant: B

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāpō

Your rationale for the grading:
Grade B includes "**Disease/injury/functional impairment:** Studies of vaccines using killed pathogens." The animals will be kept in their normal husbandry conditions for the duration of the study. There will be capture and handling for blood collection and vaccination, and two doses of a killed vaccine administered. Handling time & stress will be minimised by using only skilled staff and it will be undertaken at site.

Note: The grading determined by the Applicant is not the grading assigned by the AEC. The Applicant will be advised of the AEC's grading and any conditions in writing.

DECLARATION by the APPLICANT

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I declare that the information in this Application is correct; and
[☑] I agree to comply with the conditions imposed by DOC's AEC for the manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be aware of the contents of this AEC application; and
[☑] I declare the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff
[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application.
[☑] I agree to comply with the reporting requirements stipulated by the AEC on approval of this research project.

Signed by the Applicant 9(2)(a) [redacted]

Full Name: Catherine McInnes Date: 13/11/2023

DECLARATION by the ACCOUNTABLE MANAGER

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I agree to ensure my staff member complies with the conditions imposed by DOC's AEC for this manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be made aware of the contents of this AEC application; and

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāpō

[☑] I agree the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff

[☑] I agree to oversee this Application via MORs, PDPs and other means to ensure the manipulation remains within the scope of the Application and the Approval, and all reporting required by the AEC is delivered on time;

[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application, and to advise the AEC if the Applicant leaves the Department, or if the work should be transferred to another staff member for operational reasons' or if the manipulations is abandoned for any reason.

Signed by the Manager: 9(2)(a) [redacted]

Full Name: John Lyall

Role: Fauna Advice Manager

Date: 15/11/2023

Application Number DOCDM	AEC444 APPLICATION DOC-7483665
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāpō

Appendix 1: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.

• Use contents of each vial within 6 hours of opening

Appendix 2: General Instructions for subcutaneous injection of vaccine

- The vaccine is supplied in a 500mL bottle and is given to the bird using a needle and syringe.
- The vaccine is injected under the skin but NOT into the muscle below.
- The vaccine should be drawn up into the syringe and then allowed to warm to room temperature (this is more comfortable for the bird).

EQUIPMENT NEEDED

1. Vaccine container
2. 1 mL syringe
3. 25 gauge 5/8th inch needle
4. alcohol swab (mediswab or cotton wool and meths)
5. dry swab (gauze or cotton wool)
6. Sharps container for needle disposal
7. Bird
8. Bird handler
9. Veterinarian

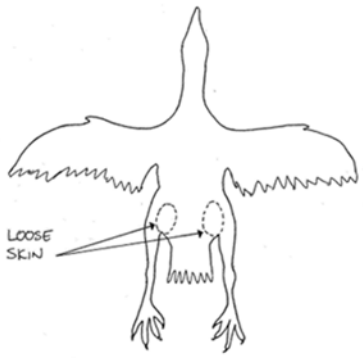
PREPARING THE VACCINATION

1. Store the vaccine in the fridge at 2-8 degrees C in the dark. Do not Freeze.
2. When ready to use, take the vaccine out of the fridge and shake well to mix.
3. Write the date on the vaccine bottle.
4. Break off the metal seal on the top of the rubber injection port.
5. Swab the injection port on the vaccine with alcohol to sterilise it with a mediswab or cotton ball soaked in methylated spirits.
6. Firmly attach the needle to the syringe – 25 gauge 5/8th inch needle to a 1mL syringe.
7. Insert the needle through the centre of the rubber stopper CAREFULLY.
8. Hold the vaccine upside down and slowly suck vaccine into the syringe until you have a little more than the prescribed dose of vaccine.
9. Flick the syringe to dislodge any air bubbles and squirt them slowly back into the vaccine bottle.
10. Keep squirting until all the bubbles are gone and you have the prescribed dose of vaccine left in the syringe.
11. Pull the needle out of the vaccine bottle and CAREFULLY recap the needle.
12. Leave the syringe and needle to warm to room temperature.
13. Repeat this procedure to draw up all the doses you need for your vaccination session.
14. Put the vaccine back in the fridge.
15. Once open, the vaccine can be used for 30 days. (Note that this expiry is based on Zoetis technical advice for limited use of the vaccine in this trial, and only applies when following the above instructions for maintaining sterility of the product and correct storage.)
16. If you are in doubt that the vaccine has been stored correctly (kept refrigerated), then discard it and get a new bottle.

GIVING THE INJECTION

1. Have the following equipment ready for use:
   - The correct dose of vaccine drawn up in syringe with needle attached and warmed to room temperature. (the cap should be on the needle to avoid accidental stabbing or contamination of the needle)
   - One alcohol swab (mediswab or cotton wool in meths)
   - One dry swab (gauze or cotton wool)
2. Have an assistant restrain the bird on its back or side with its legs restrained to provide access to the groin (where the bird's leg joins its belly).

Diagram of ventral (belly) of a bird showing the groin region for subcutaneous vaccination sites:



3. Spread the feathers in the groin area.
4. Wet down the feathers with the swab to clear a patch of skin and swab the skin.
5. Lift the loose skin 1-2cm off the body to make a "tent".

Diagram of the skin being lifted to make a "tent" for a subcutaneous injection

6. Take the cap off the needle and aim the needle about halfway down the side of the tent. Keep the needle parallel to the body wall. When the needle goes through the skin, it should still be above the muscle of the groin i.e. you are injecting into the space inside the tent, not into the muscle.
7. Suck back on the syringe to check for blood. This is to avoid injecting into a blood vessel.
8. Inject the vaccine with a steady firm pressure.
9. Withdraw the needle and place it into the Sharps container.
10. Use the dry swab to press over the injection site if there is any bleeding.
11. Release the bird.

12. Record:	Bird ID	Date	Dose	L or R side	Vaccinator	Holder	Vaccine Batch	Expiry Date	Notes

13. Transfer this data to the vaccination record spreadsheet
14. Note any other specifics about the injection process not described above. E.g. if there was bleeding at the injection site.

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kakī

Revised September 2023

DEPARTMENT OF CONSERVATION
APPLICATION TO MANIPULATE LIVE ANIMALS
Code of Ethical Conduct for the Care and Manipulation of Live Animals

1. APPLICANT'S DETAILS:

Name: Kate McInnes

Date: 24 October 2023

Role: DOC Veterinarian

Unit: BH&V Group, Wellington

APPLICANT'S ADDRESS:

Phone no: 9(2)(a) [redacted]

Email: kmcinnes@doc.govt.nz

2. ACCOUNTABLE MANAGER'S DETAILS:

Name: John Lyall

ACCOUNTABLE MANAGER'S ADDRESS:

As above or: DOC, Hokitika

Phone no: 9(2)(a) [redacted]
Email: jlyall@doc.govt.nz

2a. AEC443

2b. **MANIPULATION TITLE: Avian Influenza vaccination safety and efficacy trial in kāki**

2d. **Duration of the manipulation**

- *Over what timeframe are you seeking the approval?*
- *You must not commence the manipulation until you have received the approval, signed by you, your accountable manager, and the AEC Chair.*

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kakī

- *NOTE: The AEC will not generally give an approval for longer than two years at one time. Please state if this manipulation is likely to extend longer than two years from the commencement date.*

Anticipated start date:	February 2024	Anticipated finish date:	June 2025

2e. What months of the year is the manipulation most likely to be undertaken? e.g., October – March

For the duration of the dates specified but breeding birds will not be handled during September to January

3a. Summary of the proposed manipulation for a LAYPERSON

- *Provide an abstract describing the manipulation (maximum 400 words).*

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain is decimating many populations of wild birds overseas, is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia, October 2023.

We want to test the safety and efficacy of vaccination to protect critically endangered species.
The vaccine is a commercial product registered in New Zealand by Ministry for Primary Industries. It is considered very safe and highly effective. It contains inactivated (dead) virus so it cannot cause avian influenza. Vaccination reduces risk of illness or death and reduces shedding of virus, thus protecting the individual and its flock.

Kāki are a critically threatened species which is reliant on a captive breeding programme where it is possible to reliably administer a full course of vaccine (2 injections under the skin, one month apart) to individually identified birds, and where we are able to handle them again for a veterinary examination and blood testing to detect any effects on health status, and measure the immune response by detection of antibodies over a 12 month period.

Captive kakī will be captured in the aviary and receive a pre-vaccination health check by a veterinarian, and a blood test for health and antibody testing. Up to 1 mL of blood will be collected from the wing vein, as is standard for this species.

The vaccine is given under the skin. One month later the bird will receive a second vaccination and blood test. Further blood will be collected at 2-3, 6 and 12 months post vaccination to determine the level of antibody response and how long it lasts.

A cloacal and choanal (oral) swab will be collected on day 0 for PCR testing to demonstrate the birds were not incubating avian influenza at the time of vaccination.

Normal husbandry practices will be undertaken including observation of the bird's activity and food intake to monitor of any adverse reactions.

We propose to work with a total of 10 adult or juvenile kāki, divided into two cohorts. Cohort 1 will first receive the vaccination & blood tests, and a recheck at 1 month. If no safety issues are identified, then Cohort 2 will receive vaccinations & blood tests. This allows a careful start to the trial where the first month is the most important to test vaccine safety. The following blood samples at 6 – 12 months will determine level and duration of antibody presence and determine when further boosters would be required.

Additional approval given on 16/4/24 to collect a 10-14 week blood sample to target peak antibody levels, and to collect an opportunistic blood sample for further antibody testing, if birds are being handled for routine management purposes, with no more than twice per bird over the 12 months of the trial.

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
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3b. Description of the proposed manipulation (methods)

- *Provide a more detailed explanation. Describe the equipment, the location, and any environmental factors: weather, time of the year. Why have you decided to undertake the manipulation in this way? What advice have you sought? Include the species, the number of individuals, the source of animals, and the disposal/fate of animals at the conclusion of the manipulation.*
- *Be specific about the timelines for the proposed investigation and the purpose of the research, testing or teaching.*
- *Include some consideration and planning for when things might not go right.*

Please note: this is one of five trials to assess avian influenza vaccination safety and efficacy in nationally critical threatened species (takahē, kākāpō, kakī, tūturuatu, kākāriki karaka). Manipulation details which are specific to this species (kakī) have been highlighted in yellow. All other details are consistent across the five trials. By highlighting the species specific details I hope to assist the AEC with the volume of workload associated with simultaneously assessing these trials.

This trial is designed to test the efficacy and safety of a vaccine in a nationally critical threatened species.

Selection of the species for potential vaccination is based on the risk that they could undergo an extinction event when highly pathogenic avian influenza (HPAI) reaches New Zealand. Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and risk of extinction.

The current wild adult kakī population is approximately 150 individuals, and modelling suggests that the species would be functionally extinct in 6-8 years without the intensive intervention from DOC's captive rearing programme. The captive management programme produces between 100-200 birds per year for release back into the wild population.

Based on the evidence from overseas during this epizootic, the species most at risk of infection are those which exhibit congregation behaviours e.g. feeding, breeding or roosting in groups, those which are exposed to at risk species e.g. where seabirds overlap with another threatened species, and birds held in captive facilities where biosecurity options are limited e.g. open pens and large aviaries.

Kāki are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. See DOC-7111177 Mitigation Options Guideline for HPAI.

Use of the vaccine is dependent on Ministry for Primary Industries approval, and currently requires the birds to be held in captivity. Birds require two injections one month apart and must be individually identified with a permanent mark e.g. microchip or leg band. Birds are currently individual marked with leg bands as part of routine husbandry.

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment (Animal Health Australia, 2021).

Additionally, vaccination of California Condor was approved in the United States following an outbreak in the wild population. This was the first avian influenza vaccination programme in a wild endangered species. Advice from the veterinary and technical advisors to the condor vaccination programme has been received and is incorporated into this trial design.

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
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We wish to undertake a limited trial to determine the safety and efficacy of the avian influenza specific vaccine in kakī as a preparedness measure for the arrival of HPAI in New Zealand.

The vaccine is produced commercially by Zoetis for use in poultry: Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine - see Appendix 1. It has been in production since 2006 and is widely used in the poultry industry. Publications on AI vaccine use in poultry and avian species in zoos have indicated a very high level of safety across a wide range of species, and efficacy has been well established. (Kandeil et al 2018, Philippa et al 2006, Philippa 2007a, Philippa 2007b, Pitman 2006, Vergara-Alert 2011). The vaccine is inactivated, so there is no live virus present and it cannot cause avian influenza.

Advice from Zoetis (USA) indicates that this vaccine should provide good protection against the current strain of HPAI with 91% amino acid homology with the circulating strain. A newer vaccine based on the circulating strain is in production but is will not be available until the end of 2024 at the earliest.

Vaccine will be obtained from PacificVet in Christchurch and transported in a chilly bin with ice-packs by overnight courier (as per their standard transportation procedures for vaccines) to ensure cold chain is maintained. Use in the field will be managed by extraction of sterile aliquots into sterile vials or syringes. This enables sustainable use of the 1000 dose vial and maintenance of sterility of product. This process was discussed with the Zoetis Senior Research Advisor responsible for poultry products and is considered safe and appropriate.

Sterile aliquots will be obtained by using a sterile needle and syringe to extract the aliquot from the closed vaccine vial. The vial will be shaken to homogenise the contents, then the rubber stopper will be swabbed with alcohol. The sterile needle will be attached to the sterile syringe and the needle inserted via the rubber stopper. The aliquot will be drawn up into the syringe, then the needle& syringe removed from the stopper and the cap replace on the needle. The needle will be swapped for a new sterile needle or a sterile vaccine cap. Both the aliquots and the vaccine vial will be stored refrigerated in accordance with the packaging instructions. Vaccine doses will be drawn up immediately before use and allowed to warm to room temperature just prior to injection.

DOC veterinarians Kate McInnes and Lydia Uddstrom will administer the vaccination.

All birds will receive a full veterinary physical examination at the start of the trial. Only birds in good body condition exhibiting signs of good health will be included. (Any birds which show signs of poor health will be further investigated as per normal veterinary practices).

The kāki recovery team have been involved in the design of the study, and selection of study animals. The Twizel kaki breeding centre was chosen for being one of only 2 facilities holding kakī, presence of experienced staff, and the ability to access a total of 10 birds.

Individuals for vaccination will be selected by the kāki recovery team, based on the programme's planning for any translocations.

Each individually permanently marked (leg band) bird will receive two doses of vaccine by subcutaneous injection into the inguinal (groin) region with a 1 month interval (no less than 3 weeks apart and a maximum of 6 weeks apart). The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds will receive 0.2ml per dose (as per dosages used in Vergara-Alert et al 2011).

Individual birds within the two cohorts will be determined on the day by Kakī Project Lead Liz Brown based on available birds' suitability and any management requirements. Cohorts will aim to hold 5 birds in each, however depending on the birds' group numbers, this may be 4, 5 or 6 birds in each cohort, up to a maximum total of 10 birds altogether. This allows for some flexibility based on outcomes of the current breeding season.

At the start of the trial, each bird will receive a cloacal and oral swab to determine presence/absence of virus at day 0.
The technique will follow the draft SOP Avian swab sampling DOC-6840491 which has undergone veterinary peer review & user testing and is awaiting AEC endorsement before Director sign-off. These types of swabs are used in standard health testing on avian species and would be undertaken by the veterinarian. The test would be considered a baseline health test to demonstrate the birds were not incubating avian influenza at the time of vaccination. The swabs will undergo PCR testing at BioPacifica to look for avian influenza virus.
This is important to be able to demonstrate that any antibody response is due to the vaccination rather than the bird being infected by a wild strain of avian influenza.

First trial - Cohort 1: Five (4-6) individuals will be vaccinated as per the described protocol above. Blood (up to 1ml) will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test to measure antibody titre). Antibody testing will be undertaken at a commercial laboratory (BioPacifica, Christchurch).

Note: 1% of body weight is considered an acceptable amount of blood to collect from a healthy bird. Adult weigh ~220g, therefore up to 2.2 ml would be within the safe range for an adult. We propose to only collect up to 1ml to maintain a high margin of safety. For juveniles or subadults birds, the maximum collection would be up to 1% of body weight of the bird at the time of sampling.

Second trial - Cohort 2: Based on consideration of the results of the first trial, if safety has been demonstrated, a second cohort of 5 individuals (4-6) will receive the vaccination as per the described protocol above, and blood will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test). We will wait 1 month until we have established the vaccine is safe in cohort 1 before we start cohort 2.

Note: If antibody response at 2-3 months is noted to be muted (i.e. a low response) then the DOC vets (Kate McInnes and Lydia Uddstrom) will discuss the use of a third dose of vaccine. This was used in some species in European zoos where the initial antibody responses were considered insufficient. Consideration will be given to the level of response detected, the impacts of additional handling, and any other welfare factors noted during the preceding handling events. The benefits of testing a third dose of vaccine will be carefully considered, and this will only be undertaken if the welfare impacts are considered minimal. The justification for a third dose in this trial would be to confirm if this dose is warranted and would deliver protection for the kakī population in the event of an outbreak of HPAI in Aotearoa New Zealand.

Two additional blood samples will be collected from both cohorts at approximately 6 months and 12 months to measure duration of antibody response.

A maximum of 10 birds will be included in the trial. It is estimated that there will be 80-120 kakī on site at the DOC facility at the time of the trial.

These trials are modelled on the vaccination of California Condor in the USA. (FWS.gov 2023) however the 1 month interval is based on the European zoo data, and considered more appropriate to allow for recovery between handling events in birds which normally have minimal handling by humans.

Estimated timing/schedule of manipulations:

First vaccination and blood sample	Second vaccination and blood sample	2-3 month blood sample	~6 month blood sample	~12 month blood sample
First cohort of 5 birds (4-6)				
~ 1st February 2024	~ 1st March 2024	~1st April 2024	~ 14th August 2024	~ 14th February 2025
Second cohort of 5 birds (4-6, maximum 10 total)				
~ 1st March 2024	~1st April 2024	~1st May 2024	~14th August 2024	~ 14th February 2025

Second cohort of 5 birds (4-6, with maximum total of 10) – same timeline but 1 month after first cohort have been vaccinated and shown no negative reaction. Blood collection at ~6 and ~12 months may be undertaken at the same time for both cohorts – these sample are about longevity of antibody presence, so the exact timing is less critical.

During a handling event, all involved staff will gather and have a pre-handling briefing by the veterinarian and the team leader to ensure all roles and responsibilities are clearly understood. Any issues can be raised at that time for clarification. The kāki team leader will be responsible for the safe capture and handling of the bird. The veterinarian will be responsible for the health examination, vaccination, and blood collection.

All equipment will be prepared prior to capture to minimise handling time. Staff will know where to situate themselves and what actions are required so that an efficient process is maintained. The kāki rangers involved in this trial will be team members with previous experience in blood collection in kāki.

Kakī are caught according to the following procedures as detailed in the kaki husbandry manual:

4.4.2 Adults, juveniles and sub-adults

Birds in aviaries should not be caught in wet weather or in high winds unless unavoidable. . Handling wet birds can damage their plumage, and strong wind increases the risk of injury. Various methods have been trialled for catching birds in the aviaries, including drop nets, tunnel nets and hand nets. Hand nets are mainly used in holding aviaries, as this is the quickest method. Ensure that the net is kept dry, and fabric does drag on the ground or through the pond. This method is most effective with three or more people, in the larger breeding compartments more people will be needed. In small aviaries it is possible for one or two people to catch birds. Birds should not be caught when they are in the water and should not be caught in flight. The safest method for capture is to gently hover the net over the bird and slowly lower the net to ensure you do not damage the bird. The bird can then be gently untangled from the net by placing your hands over it. Most birds will fly when approached and you will need to wait for them to land, before gently placing the net over them. Inexperienced catchers should watch experienced staff first, and not be pressured to catch birds until they feel confident. Adults can be more difficult to catch, and occasionally it may be necessary to catch them while flying. This should be done as a last resort and only if catching is essential to their wellbeing, and the catching attempt has already exceeded 25 minutes. Catching while in flight should only be attempted when the bird is slowing down to land, or just taking off, and the movement should be followed with the net to prevent damaging the bird. Birds should never be caught when flying at full speed.

Figure 1. Catching kakī with large whitebait nets, the bird in the foreground is being held through the net before it can be extracted. Photo: Ursula Paul

Birds are held by cradling them in both hands, with thumbs on top holding the wings and little fingers hooked behind the birds' legs to keep the bird secure. The hold should be light, without undue pressure on the bird.

Once caught the bird is placed in a 'catch bag' (a soft cotton bag with a draw string which provides a safe restraint for temporary holding) to be weighed in the bag using a hanging scale (standard technique) and

then carefully removed and undergo a physical examination to determine its health status prior to any further manipulation. If the kāki is determined to be healthy, blood collection and vaccination will proceed.

For blood collection and vaccination a trained kakī handler will restrain the bird on its side or back.

The blood collection site (wing vein) will be swabbed with a sterile alcohol wipe immediately prior to collection. Blood will be collected from the wing vein either using a 1ml sterile syringe attached to a 25 or 26 gauge ¾ inch sterile hypodermic needle or via the pin-prick method where the vein is pricked using a sterile 25 or 26 gauge hypodermic needle, and then the bleb of blood is collected in capillary tubes (also known as haematocrit tubes). The method will be dependent on the skills and confidence of the collector. Both methods are valid for blood collection from a small bird.

In the event that the temperature is cool, and on examination of the wing vein we determine that blood collection likely to be slow due to the presence of small contracted veins, the wing will be warmed for 3-5 minutes using Kathmandu hand warmers wrapped in gauze, to boost circulation and enhance blood flow to enable effective blood collection.

After collection, the site of blood collection will be covered with a gauze swab and pressure applied to control any bleeding. In the very unlikely event of uncontrolled bleeding, pressure will be applied for a further 1-5 minutes. If still uncontrolled, an icepack wrapped in gauze swabs will be held on the wing area to cool the limb and reduce blood flow. If required, a silver nitrate stick will be carefully used to stop the bleeding.

Blood will be transferred into a blood microtainer and spun in a centrifuge to separate the serum from the blood cells. Serum will be drawn off using a sterile pipette and transferred into an epindorf tube for storage in the freezer, prior to transfer to the commercial laboratory in batches for antibody testing.

1-2 drops of blood will be used to make blood smears which will be sent to a commercial veterinary pathology laboratory for a white cell count and differential. This provides a baseline health analysis which can detect infection or inflammation. Any abnormal results will be further investigated by the veterinarian in consultation with the kakī staff.

Once bleeding has stopped, the bird will be vaccinated using a 1mL syringe attached to a 20 gauge ½ inch needle. The vaccination site will be swabbed with a sterile alcohol wipe immediately prior to vaccination. See Appendix 2 for details of the vaccination technique.

The bird will then be checked for any abnormalities and the veterinarian will determine if any further actions are required for health or welfare. Once the procedures are complete the bird will be quietly released and observed as it moves away. Regular observations during routine husbandry will continue for all birds, and any abnormalities will be reported to the veterinarian. The birds are visited and monitored at least twice daily by DOC staff when they are being fed the artificial diet.

At subsequent handling events, the vaccination site will be examined and any discolouration, swelling, granuloma formation or unexpected abnormality will be noted and reported to the veterinarian. Photographs of each bird's injection sites will be taken to provide a clear record of the trial.

Location & timing:
The trials will be undertaken at the DOC Twizel kakī breeding facility between Feb 2024 and June 2025 (breeding kakī will not be handled).

Safety:

Results from a meta-analysis of use of vaccine in European Zoos found very low adverse reaction rate at 0.04% local reactions and 0.015% general reactions reported. EFSA 2007. Based on this, we do not anticipate significant issues with the vaccine, however we will be prepared for immediate veterinary care if any reactions to occur.

The vaccine packaging label states: "Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique."

Anaphylaxis:
A severe immediate immune hypersensitivity response could occur if the vaccine product stimulates such a response. This is considered unlikely due to the extensive use of this vaccine and other similar vaccine products in Europe, however it is possible and needs to be considered as a potential adverse event. The vaccination team will include a veterinarian who will have access to emergency drugs and supportive care for management of anaphylaxis (including corticosteroids, adrenaline, oxygen, fluids).

Injection site reactions:
The vaccine contains an adjuvant (oil) which is present so that it stimulates a stronger immune response with greater antibody production. This can sometimes be associated with a small pea-sized lump at the site of injection. This is normal and expected, although generally not all birds will develop a lump. This will be checked at the 1 month mark, and records kept of any reactions detected. If an excessive size reaction is detected in an individual (>1cm), then the vaccination will be paused until it is determined that the lump does not enlarge further, or cause any impacts on the bird(s) – this is likely to be a period of 2-4 weeks. Body weight, activity levels etc will be reviewed and a full physical examination undertaken.

A localised bacterial infection could result if poor sterile technique is used. Only veterinarians or specifically trained DOC staff members will be administering the vaccine, and these operators all have training in appropriate sterile techniques. If a bird experiences an infection at the site, it will receive veterinary care and follow-up to ensure the issue is managed.

Mis-injection could occur if the bird is poorly restrained and moved during vaccination. This will be managed by only using well trained, experienced kakī handlers to restrain the birds. For some individual birds, they are calmer with head cover which can aid in handling. This will be determined on an individual bird basis. If a mis-injection occurs, the veterinarian will determine the appropriate next steps. This may include, re-injection if the first injection merely failed to enter the bird, appropriate first aid measures if any injury was caused, and/or exclusion from the trial and follow-up care. As noted previously, "stressy" birds will not be included in the trial which will reduce the risk of injury or mis-injection.

Injury could occur during capture and handling. This is minimised by only using trained experienced staff, careful selection of trial birds, and a "stop for safety" approach which resets the work programme and ensures time out to reassess and replan the work and procedures if necessary.

In the event of a serious reaction or injury during the vaccination trail, the bird will be taken to Dunedin Wildlife Hospital for specialist care by Dr Lisa Argilla. This is standard procedure for kāki requiring a high level of veterinary care. Birds can be transported to the Dunedin Wildlife Hospital within 4 hours from the DOC Twizel site.

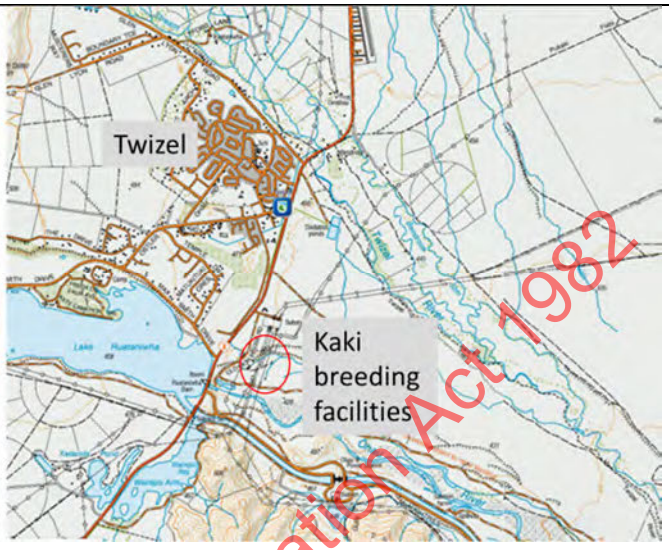
Results:

The results of this trial will determine if this vaccine is safe to use in this species, and the level of antibody response produced by a 2 dose vaccination. In some other species, notably penguins, the antibody levels following vaccination remain low and, in some species, a third vaccination was used to ensure a stronger response (ESFA 2007). The duration of antibody presence also varied between species. Therefore, this trial will help to determine the appropriate vaccination regime for kāki in the event that more widespread vaccination is required during a highly pathogenic avian influenza outbreak in New Zealand.

3c. Attach Photos of equipment, the species, the location (or a map); to help set the context.

Kakī release 2018

Kakī in aviary, Twizel



DOC Twizel aviaries

3d. References

- *List the references referred to in the application*

DOC-7111177 Mitigation Options Guideline for HPAI https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7111177

EFSA 2007. Vaccination against avian influenza of H5 and H7 subtypes as a preventative measure carried out in Member States in birds kept in zoos under Community approved programmes. ESFA journal, 450, ESFA-Q-20006-156 https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499835

Health Australia (2021). Response strategy: Avian influenza (version 5.0). Australian Veterinary Emergency Plan (AUSVETPLAN), edition 5, Canberra, ACT. Response_Avian-influenza.pdf (animalhealthaustralia.com.au) Animal

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Kandeil A, Sabir SM, Abdelaal A, Mattar EH, El-Taeel AN, Sabir MJ, Khalil AA, Webby R, Kayali G, Ali MA. Efficacy of commercial vaccines against newly emerging avian influenza H5N8 in Egypt. Nature Scientific Reports, 2018. 8:9697 | DOI:10.1038/s41598-018-28057-x https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499854

Kakī husbandry manual (in draft). Internal DOC document https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7495734

Philippa JDW, Munster VJ, van Bolhuis H, Bestebroer TM, Schaftenaar W, Beyer WEP, Fouchier RAM, Kuiken T, Osterhaus, ADME. Highly pathogenic avian influenza (H7N7): Vaccination of zoo birds and transmission to non-poultry species. Vaccine, 2005, 23:5743-5750. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499837

Philippa JWD 2007a, in XI. Vaccination of Non-domestic Avian Species, Transmissible Disease Handbook. European Zoo Vets 5th Edition link

Philippa J, Bass C, Beyer W, Bestebroer T, Fouchier R, Smith D, Schaftenaar W, Osterhaus, A. Vaccination against highly pathogenic avian influenza H5Na virus in zoos using an adjuvanted inactivated H5N2 vaccine. Vaccine, 2007b, 25: 3800-3808. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499841

Pitman 2006. M Pittman, European Commission 12th Annual meeting of national avian influenza laboratories Veterinary and Agrochemical Research Centre (VAR) Uccle, Brussels, 16-18 October 2006 LINK: link.

Vergara-alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499845

4. INVOLVEMENT OF OTHER ANIMAL ETHICS COMMITTEES:

4a. Is this Application; or a related or similar application; been or is being considered by another Animal Ethics Committee. Has this project been requested to be considered by any other AEC?

If so, please provide details.

No

4b. Does this manipulation interact with a manipulation approved by other Animal Ethics Committee? If so, detail your communications with those committee(s), and state any conditions imposed by (an)other AEC.

No

5. JUSTIFICATION FOR PROPOSED MANIPULATION:

5a. Detail any action undertaken to determine that the proposed work has not already been done.

Avian Influenza vaccine efficacy and safety has been undertaken on other avian species, however it has not been undertaken in New Zealand endemic species. Although we expect similar results, it is prudent to

undertake this trial to provide more evidence of safety and efficacy in the species which we intend to vaccinate in the event of a HPAI outbreak.

5b. Have alternatives been considered to the proposed manipulation involving reduction, or replacement of live animals, or refinement of techniques?

We are looking at the species-specific response and have selected a minimum size divided into two cohorts, so other methods of reduction are not appropriate for this work.

The cohort approach allows us to cautiously approach the safety issue, and assess initial results before involving the full number of birds.

All captive kakī undergo twice yearly health screens, including testing and treatment for internal parasites and a physical check requiring capture. The first vaccination will be timed to coincide with the post-breeding season health screen, and the 6 month blood test will coincide with a pre-breeding season health screen. This reduces the number of times the birds are handled specifically for this trial from six to four.

5c. To what extent has there been assessment of the suitability of using non-sentient or non-living alternatives in the project; or replacement of animals as subjects with suitable non-sentient or non-living alternatives?

N/A, see above

5d. How will the proposed work result in the extension of knowledge relevant to the health, welfare, or conservation of animals?

This work will specifically contribute to the future health of the species for conservation purposes by providing evidence of the safety and efficacy (or not) of this vaccine in this species, and inform the appropriate vaccine schedule for the species. This will determine if the vaccine is employed in the future in the face of an avian influenza outbreak in New Zealand.

5e. Is the manipulation required as part of an approved training programme?

No.

5f. How will the results of this work be made available to staff within and outside DOC? (*For example internal report, journal paper, best practice guide, workshops etc*).
Internal report, journal paper, conference presentations, shared with other captive institutions that hold kakī.

6. SELECTION OF SPECIES & NUMBER OF INDIVIDUALS FOR PROPOSED MANIPULATION

6a. What will be the source of the animals to be manipulated, and how many from each source will be manipulated?
Kakī at the DOC Twizel breeding centre. 10 birds in total from a range of adults, sub-adults and juveniles. It is estimated that there will be 80-120 kakī on site at the DOC facility at the start of the time of the trial.

6b. Will any of the animals involved be used more than once, and if so, how many times will each animal be used?

Only once (but each animal handled/manipulated multiple times – twice for vaccinating and four more times for blood sampling, although the 6 & 12 month handling for blood collection will be planned to coincide with routine handling for health management)

6c. What factors have been taken into account in the choice of the animal species?
Kakī are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction.

6d. Could the information being sought be obtained by work on some other species?
No. The trial specifically uses kakī since the safety and efficacy needs to be tested in the target species, and there are no captive populations available of a reasonable surrogate species, such as pied stilt, nor would it be good welfare to obtain wild pied stilt to hold in captivity due to the stress this would induce, and finally, there are no appropriate facilities available to hold wild pied stilt for this trial.

6e. Will the question be answered with the size of the sample?
Yes.

6f. Is the number of animals proposed to be manipulated the <u>minimum</u> necessary to provide a scientifically interpretable result, consistent with the level of statistical precision required? What consideration has been given to the design of the study with regard to:

- **The level of precision necessary in the results?**

The purpose of the small trial is to establish if there is a species-specific sensitivity to the vaccine and its adjuvant. For this purpose, we require only a small number of birds to extrapolate a species sensitivity. Similarly, for determining vaccine response by antibody response levels, a sample size of 10 will provide sufficient individual variation to establish an overall species response level. Additionally, if a bird is removed from the trial for any reason (e.g. other health issues, injury, behavioural), starting with 10 birds allows sufficient number to still be able to make a reasonable conclusion on the vaccine efficacy for future management purposes.

A larger sample size would ensure a more nuanced examination of the species' response to vaccination; however, we are examining a general level of impact/effect, rather than subtle differences. Thus, if results which showed >1 bird having a safety issue, or the majority or average antibody response to be low, that would be sufficient to inform the next steps for decision making regarding kakī vaccination.

- **The possible confounding effects of animal variation?**

We expect some individual variation since the immune response is affected by individual health status and biological variation. This sample size is sufficient to ensure we have a range of individual responses to examine.

- **The needs of statistical analysis?**

There is likely to be individual variation, which, for the antibody response, requires a reasonable sample size. We determined that 10 was the maximum which was feasible to include in the trial, and also sufficient to allow for individual variation to establish some baseline parameters of antibody response.

Ultimately, in an outbreak situation, the results of a sample size of 10 will be sufficient to make reasonably informed decisions about the use of a commercially produced killed vaccine which has a good history of safety and efficacy across a wide range of species.

7. WELFARE OF ANIMALS DURING PROPOSED MANIPULATION:

7a. What measures will be taken to ensure: the general health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of over-crowding, and prevention and control of disease?

Kakī will be caught and handled by experienced rangers as per usual kakī protocols at DOC Twizel breeding centre where DOC staff already maintain appropriate husbandry practices and monitoring of all the birds. Each bird will be held within its normal enclosure so that there is minimum disturbance to their daily lives. Staff will continue to monitor birds throughout the trial, including food consumption and behaviour.

Each bird will receive a veterinary examination at the start of the trial. Equipment will be disinfected between individuals, or new equipment will be used. Once blood has been collected and vaccination undertaken the bird will be re-released in their home aviary.

The vaccination trial will occur after the breeding season has finished, so will not interfere with any breeding behaviour. No female birds will be gravid at the time of manipulation, and any breeding birds will have raised and fledged their chicks before the trial begins.

All captive kakī undergo twice yearly health screens, including testing and treatment for internal parasites and a physical check requiring capture. The first vaccination will be timed to coincide with the post-breeding season health screen, and the 6 month blood test will coincide with a pre-breeding season health screen. This reduces the number of times the birds are handled specifically for this trial from six to four.

7b. What movement and transportation measures will be followed for the animals to be manipulated to ensure their welfare and humane treatment?

Birds will be vaccinated on site, in their aviary where they are captured, therefore there will be no transport required.

However, if a bird requires specialist veterinary care e.g. in the event of an injury or serious reaction, then it will be transferred to Dunedin Wildlife Hospital (DWH), using the standard kakī transport crates, and in accordance with normal kakī transportation procedures. Briefly, birds will have non-slip flooring the crate, be transported via car to Dunedin. Transport will be managed to reduce noise and allow for temperature control. Radio will be off and driver/passenger will ensure minimal noise. Travel will be direct, and the hospital will be alerted ahead of time to enable a fast hand-over and rapid care.

More than 20 kakī have been treated by the Dunedin Wildlife Hospital in the past 3 years, and they are familiar with their requirements for hospital care.

Supportive therapy would be provided prior to transport which may include pain relief and fluids, the DOC staff are trained and competent in administering medications on direction from the veterinarians.

7c. What measures are to be taken to minimise the pain or distress of any animal manipulated? *Stating there will not be any impact is not acceptable. The AEC is looking for the Applicant to (1) provide analysis about the potential for pain and/or distress to the animal(s), and (2) describe how they will manage that pain or distress. Identify how you would ascertain pain or distress animal's behaviour, environmental conditions likely to lead to pain or distress.*

Birds will be captured and handled by experienced DOC kakī staff using their routine techniques. Only experienced staff will handle the birds. Initial physical examination, vaccination and blood collection will be undertaken by a veterinarian.

Any bird detected to have abnormalities will be examined and rejected from the trial, and receive normal veterinary investigation/intervention.

Subsequent examination and blood collection may be undertaken by DOC staff trained in blood collection from kakī, provided the initial results (0,1, and 2-3 month check) are normal across the cohorts.

The subcutaneous injection is not considered painful, and the vaccine dose will be warmed to room temperature prior to injection. Blood collection is associated with a minorly painful pin-prick when the needle is inserted. This will be minimised by careful planning and handling.

If birds are observed to have any pain response to the vaccination, the staff will report it to the veterinarian who will investigate. Ifthere is an injection site reaction (painful inflammation) then an anti-inflammatory such as Metacam may be prescribed by the attending veterinarian, as well as antibiotics if infection is also present.

As noted earlier, if any serious adverse reactions occur, veterinary care by the attending veterinarian will be undertaken, and transfer to Dunedin Wildlife Hospital undertaken if required for more intensive specialist care.

8. CONTINGENCY PLAN:

8a. What arrangements have been made for the abandonment of any manipulation and/or the euthanasia of animals where pain or distress cannot be held within reasonable levels?

If pain or distress is apparent, during handling or following the procedure, the veterinarian will investigate. If the veterinarian deems the level to be unreasonable, then the manipulation will be abandoned and all efforts made to ameliorate the event e.g. anti-inflammatory, pain relief medication, antibiotics.

In the unlikely event that the pain is not temporary and cannot be managed, transfer to Dunedin Wildlife Hospital will allow for intensive veterinary intervention and care. This includes the ability to undertake orthopaedic intervention e.g. in the event of a broken bone, or intensive surgery e.g. in the event of a severe localised vaccine reaction.

Supportive therapy would be provided during any transport which may include pain relief and fluids.

9. PEOPLE TO UNDERTAKE PROPOSED MANIPULATION:

9a. Who are the person(s) primarily involved in carrying out the proposed manipulation?
Kate McInnes and Lydia Uddstrom are the primary persons.

9b. What is the experience and qualifications of the person primarily responsible (9a) for the undertaking and supervising the manipulation (including selection of animals, their care and disposal?)
Kate McInnes has been the DOC vet since 2000 and has worked across a range of avian species , and is currently the lead technical advisor for the DOC HPAI response.

Lydia Uddstrom is contracted full time to the DOC kākāpō team, has undertaken postgraduate training as a zoo veterinarian and has experience with a wide range of New Zealand native species veterinary care.

Both Kate and Lydia have previously been involved in capture and handling of threatened species undertaking vaccination and blood collection for a range of threatened species, and have trained multiple DOC staff to safely and effectively undertake these procedures.

9c. Who else is in the team undertaking the manipulation? State their role in the team, and their relevant experience with the procedure(s) proposed in the application? Include DOC and non-DOC staff in the team.

Name of Manipulation Team member	*Role in the manipulation*	*Experience and qualifications relevant to the manipulation*
Liz Brown	Lead person for catching, handling, monitoring & follow-up blood collection of kakī.	Kakī Recovery Programme - project lead for the captive kakī programme. Liz has 15 years experience managing kakī in captivity, and has routinely been collecting blood samples from all kakī raised in captivity for the past 8 years.
Taleigha Tuer	Catching, handling, monitoring & follow-up blood collection of kakī	Kakī Recovery Programme – captive kakī ranger. Taleigha has 5 years of experience working with kakī in captivity, including routine blood sampling.
Serena O'Brien	Catching, handling, monitoring & follow-up blood collection of kakī	Kakī Recovery Programme – captive kakī ranger. Serena has 2 year of experience working with kakī in captivity, including routine blood sampling.
Scott Bourke	catching and handling for the first vaccination session	currently employed on a seasonal contract working with the captive kakī team. Scott has also assisted with catching kakī for several releases, as a student volunteer
Claudia Mischler	May be called on to assist with helping catch and handle during vaccination sessions or follow up sampling	kakī operations team specialising in wild population management. Claudia has 6 years of experience catching and handling kakī in captivity.
Cody Thyne	May be called on to assist with helping catch and handle during vaccination sessions or follow up sampling.	Biodiversity supervisor (and previously kakī operations team). Cody has 10 years of experience catching and handling kakī in captivity

9d. What training will be given to the people identified in 9c to help them undertake the manipulation proposed in the application?

Team leader and kakī rangers are trained in blood collection of kakī as per the DOC Avian Blood Collection SOP training requirements, and to undertake normal practices including capture & handling.

The capture and handling will be undertaken according to the direction of the team leader.

Vaccination will be undertaken by the DOC veterinarian.

10. COMPLIANCE WITH CONDITIONS of the APPROVAL:

- Please outline any opportunities for a member, or members, of the DOC Animal Ethics Committee to observe this work.

10a. Identify ways that the manipulation(s) can be monitored by the AEC:

AEC members could attend a vaccination session at Twizel to see the procedure in kakī and/or receive a video or photographs of the manipulation being undertaken.

11. Are there any other aspects which ought to be brought to the attention of the DOC Animal Ethics Committee?

No

12. Does the research, testing or teaching involve a species which is covered by a Department of Conservation Species Recovery Plan and if so, has the Recovery Group been consulted and their endorsement for the work received? Please provide a summary of communication.

Yes. Kakī management is guided by a Kaki advisory group. The Advisory group have been consulted and are supportive of this trial. Liz Brown Pers comm.

This application has been shared with the kakī team on 10th November for review prior to submission to the AEC.

13. What month of year is most useful to report back to the AEC (depending on the project schedule and the animal's biology)?

September

13. Manipulation Grading

Please work through the document '*Grading of Manipulations*' (Please refer to DOCDM-870472), and determine the grading you believe best applies to the manipulation proposed in this application. Please also provide a rationale for the grading.

Grade A: No impact or virtually no impact.
Grade B: Little impact. Manipulations of minor impact and short duration.
Grade C: Moderate impact. Includes manipulations of minor impact and long duration or moderate impact and short duration.
Grade D: High impact. Includes manipulations of moderate impact and long duration or high impact and short duration.
Grade E: Very high impact. Manipulations of high impact and long duration.

Grading determined by the Applicant: B

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kakī

Your rationale for the grading:
Grade B includes "**Disease/injury/functional impairment:** Studies of vaccines using killed pathogens." The animals will be kept in their normal husbandry conditions for the duration of the study. There will be capture and handling for blood collection and vaccination, and two doses of a killed vaccine administered. Handling time & stress will be minimised by using only skilled staff and it will be undertaken at site.

Note: The grading determined by the Applicant is not the grading assigned by the AEC. The Applicant will be advised of the AEC's grading and any conditions in writing.

DECLARATION by the APPLICANT

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I declare that the information in this Application is correct; and
[☑] I agree to comply with the conditions imposed by DOC's AEC for the manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be aware of the contents of this AEC application; and
[☑] I declare the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff
[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application.
[☑] I agree to comply with the reporting requirements stipulated by the AEC on approval of this research project.

Signed by the Applicant 9(2)(a) [redacted]

Full Name: Catherine McInnes Date: 13/11/2023

DECLARATION by the ACCOUNTABLE MANAGER

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I agree to ensure my staff member complies with the conditions imposed by DOC's AEC for this manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be made aware of the contents of this AEC application; and

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kakī

[☑] I agree the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff

[☑] I agree to oversee this Application via MORs, PDPs and other means to ensure the manipulation remains within the scope of the Application and the Approval, and all reporting required by the AEC is delivered on time;

[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application, and to advise the AEC if the Applicant leaves the Department, or if the work should be transferred to another staff member for operational reasons' or if the manipulations is abandoned for any reason.

Signed by the Manager: 9(2)(a) [redacted]

Full Name: John Lyall

Role: Fauna Advice Manager

Date: 14/11/2023

Application Number DOCDM	AEC445 APPLICATION DOC-7483662
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kakī

Appendix 1: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.
• Use contents of each vial within 6 hours of opening

Appendix 2: General Instructions for subcutaneous injection of vaccine

- The vaccine is supplied in a 500mL bottle and is given to the bird using a needle and syringe.
- The vaccine is injected under the skin but NOT into the muscle below.
- The vaccine should be drawn up into the syringe and then allowed to warm to room temperature (this is more comfortable for the bird).

EQUIPMENT NEEDED

1. Vaccine container
2. 1 mL syringe
3. 25 gauge 5/8th inch needle
4. alcohol swab (mediswab or cotton wool and meths)
5. dry swab (gauze or cotton wool)
6. Sharps container for needle disposal
7. Bird
8. Bird handler
9. Veterinarian

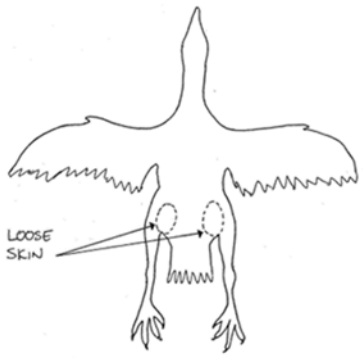
PREPARING THE VACCINATION

1. Store the vaccine in the fridge at 2-8 degrees C in the dark. Do not Freeze.
2. When ready to use, take the vaccine out of the fridge and shake well to mix.
3. Write the date on the vaccine bottle.
4. Break off the metal seal on the top of the rubber injection port.
5. Swab the injection port on the vaccine with alcohol to sterilise it with a mediswab or cotton ball soaked in methylated spirits.
6. Firmly attach the needle to the syringe – 25 gauge 5/8th inch needle to a 1mL syringe.
7. Insert the needle through the centre of the rubber stopper CAREFULLY.
8. Hold the vaccine upside down and slowly suck vaccine into the syringe until you have a little more than the prescribed dose of vaccine.
9. Flick the syringe to dislodge any air bubbles and squirt them slowly back into the vaccine bottle.
10. Keep squirting until all the bubbles are gone and you have the prescribed dose of vaccine left in the syringe.
11. Pull the needle out of the vaccine bottle and CAREFULLY recap the needle.
12. Leave the syringe and needle to warm to room temperature.
13. Repeat this procedure to draw up all the doses you need for your vaccination session.
14. Put the vaccine back in the fridge.
15. Once open, the vaccine can be used for 30 days. (Note that this expiry is based on Zoetis technical advice for limited use of the vaccine in this trial, and only applies when following the above instructions for maintaining sterility of the product and correct storage.)
16. If you are in doubt that the vaccine has been stored correctly (kept refrigerated), then discard it and get a new bottle.

GIVING THE INJECTION

1. Have the following equipment ready for use:
    - The correct dose of vaccine drawn up in syringe with needle attached and warmed to room temperature. (the cap should be on the needle to avoid accidental stabbing or contamination of the needle)
    - One alcohol swab (mediswab or cotton wool in meths)
    - One dry swab (gauze or cotton wool)
2. Have an assistant restrain the bird on its back or side with its legs restrained to provide access to the groin (where the bird's leg joins its belly).

Diagram of ventral (belly) of a bird showing the groin region for subcutaneous vaccination sites:



3. Spread the feathers in the groin area.
4. Wet down the feathers with the swab to clear a patch of skin and swab the skin.
5. Lift the loose skin 1-2cm off the body to make a "tent".

Diagram of the skin being lifted to make a "tent" for a subcutaneous injection

6. Take the cap off the needle and aim the needle about halfway down the side of the tent. Keep the needle parallel to the body wall. When the needle goes through the skin, it should still be above the muscle of the groin i.e. you are injecting into the space inside the tent, not into the muscle.
7. Suck back on the syringe to check for blood. This is to avoid injecting into a blood vessel.
8. Inject the vaccine with a steady firm pressure.
9. Withdraw the needle and place it into the Sharps container.
10. Use the dry swab to press over the injection site if there is any bleeding.
11. Release the bird.

12. Record:	Bird ID	Date	Dose	L or R side	Vaccinator	Holder	Vaccine Batch	Expiry Date	Notes

13. Transfer this data to the vaccination record spreadsheet
14. Note any other specifics about the injection process not described above. E.g. if there was bleeding at the injection site.

Application Number DOCDM	AEC446 APPLICATION DOC-7483658
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, tūturuatu

Revised September 2023

DEPARTMENT OF CONSERVATION
APPLICATION TO MANIPULATE LIVE ANIMALS
Code of Ethical Conduct for the Care and Manipulation of Live Animals

1. APPLICANT'S DETAILS:

Name: Kate McInnes

Date: 15 November 2023

Role: DOC Veterinarian

Unit: BH&V Group, Wellington

APPLICANT'S ADDRESS:

Phone no: 9(2)(a) [redacted]

Email: kmcinnes@doc.govt.nz

2. ACCOUNTABLE MANAGER'S DETAILS:

Name: John Lyall

ACCOUNTABLE MANAGER'S ADDRESS:

As above or: DOC, Hokitika

Phone no: 9(2)(a) [redacted]
Email: jlyall@doc.govt.nz

2a. AEC446

2b. **MANIPULATION TITLE: Avian Influenza vaccination safety and efficacy trial tūturuatu**

2d. **Duration of the manipulation**

- *Over what timeframe are you seeking the approval?*
- *You must not commence the manipulation until you have received the approval, signed by you, your accountable manager, and the AEC Chair.*

Application Number DOCDM	AEC446 APPLICATION DOC-7483658
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- *NOTE: The AEC will not generally give an approval for longer than two years at one time. Please state if this manipulation is likely to extend longer than two years from the commencement date.*

Anticipated start date:	February 2024	Anticipated finish date:	June 2025

2e. What months of the year is the manipulation most likely to be undertaken? e.g., October – March

For the duration of the dates specified but breeding birds will not be handled during September to January

3a. Summary of the proposed manipulation for a LAYPERSON

- *Provide an abstract describing the manipulation (maximum 400 words).*

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain is decimating many populations of wild birds overseas, is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia, October 2023.

We want to test the safety and efficacy of vaccination to protect critically endangered species.
The vaccine is a commercial product registered in New Zealand by Ministry for Primary Industries. It is considered very safe and highly effective. It contains inactivated (dead) virus so it cannot cause avian influenza. Vaccination reduces risk of illness or death and reduces shedding of virus, thus protecting the individual and its flock.

Tūturuatu are a critically threatened species which is reliant on a captive breeding programme where it is possible to reliably administer a full course of vaccine (2 injections under the skin, one month apart) to individually identified birds, and where we are able to handle them again for a veterinary examination and blood testing to detect any effects on health status, and measure the immune response by detection of antibodies over a 12 month period.

Captive tūturuatu will be captured in the aviary and receive a pre-vaccination health check by a veterinarian, and a blood test for health and antibody testing. Up to 0.4 mL of blood will be collected from the wing vein, as is standard for this species.

The vaccine is given under the skin. One month later the bird will receive a second vaccination and blood test. Further blood will be collected at 2-3, 6 and 12 months post vaccination to determine the level of antibody response and how long it lasts.

A cloacal and choanal (oral) swab will be collected on day 0 for PCR testing to demonstrate the birds were not incubating avian influenza at the time of vaccination.

Normal husbandry practices will be undertaken including observation of the bird's activity and food intake to monitor of any adverse reactions.

We propose to work with a total of 10 adult or juvenile tūturuatu, divided into two cohorts. Cohort 1 will first receive the vaccination & blood tests, and a recheck at 1 month. If no safety issues are identified, then Cohort 2 will receive vaccinations & blood tests. This allows a careful start to the trial where the month is the most important to test vaccine safety. The following blood samples (at 2-3, 6 & 12 months) will determine level and duration of antibody presence and determine when further boosters would be required.

Additional approval given on 16/4/24 to collect a 10-14 week blood sample to target peak antibody levels, and to collect an opportunistic blood sample for further antibody testing, if birds are being handled for routine management purposes, with no more than twice per bird over the 12 months of the trial.

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3b. Description of the proposed manipulation (methods)

- *Provide a more detailed explanation. Describe the equipment, the location, and any environmental factors: weather, time of the year. Why have you decided to undertake the manipulation in this way? What advice have you sought? Include the species, the number of individuals, the source of animals, and the disposal/fate of animals at the conclusion of the manipulation.*
- *Be specific about the timelines for the proposed investigation and the purpose of the research, testing or teaching.*
- *Include some consideration and planning for when things might not go right.*

Please note: this is one of five trials to assess avian influenza vaccination safety and efficacy in nationally critical threatened species (takahē, kākāpō, kakī, tūturuatu, kākāriki karaka). Manipulation details which are specific to this species (tūturuatu) have been highlighted in yellow. All other details are consistent across the five trials. By highlighting the species specific details I hope to assist the AEC with the volume of workload associated with simultaneously assessing these trials.

This trial is designed to test the efficacy and safety of a vaccine in a critically threatened species.

Selection of the species for potential vaccination is based on the risk that they could undergo an extinction event when highly pathogenic avian influenza (HPAI) reaches New Zealand. Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and risk of extinction.

The current wild adult tūturuatu population is approximately 130-150 adult birds on Rangatira, Chatham Islands. The captive management programme produces up to ~50 birds per year for release into mainland sites to establish/maintain additional populations.

Based on the evidence from overseas during this epizootic, the species most at risk of infection are those which exhibit congregation behaviours e.g. feeding, breeding or roosting in groups, those which are exposed to at risk species e.g. where seabirds overlap with another threatened species, and birds held in captive facilities where biosecurity options are limited e.g. open pens and large aviaries.

Tūturuatu are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. See DOC-7111177 Mitigation Options Guideline for HPAI.

Use of the vaccine is dependent on Ministry for Primary Industries approval, and currently requires the birds to be held in captivity. Birds require two injections one month apart and must be individually identified with a permanent mark e.g. microchip or leg band. Birds in this trial will already have these marks as part of routine husbandry/management procedures.

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment (Animal Health Australia, 2021).

Additionally, vaccination of California Condor was approved in the United States following an outbreak in the wild population. This was the first avian influenza vaccination programme in a wild endangered species. Advice from the veterinary and technical advisors to the condor vaccination programme has been received and is incorporated into this trial design.

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We wish to undertake a limited trial to determine the safety and efficacy of the avian influenza specific vaccine in tūturuatu as a preparedness measure for the arrival of HPAI in New Zealand.

The vaccine is produced commercially by Zoetis for use in poultry: Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine - see Appendix 1. It has been in production since 2006 and is widely used in the poultry industry. Publications on AI vaccine use in poultry and avian species in zoos have indicated a very high level of safety across a wide range of species, and efficacy has been well established. (Kandeil et al 2018, Philippa et al 2006, Philippa 2007a, Philippa 2007b, Pitman 2006, Vergara-Alert 2011). The vaccine is inactivated, so there is no live virus present and it cannot cause avian influenza.

Advice from Zoetis (USA) indicates that this vaccine should provide good protection against the current strain of HPAI with 91% amino acid homology with the circulating strain. A newer vaccine based on the circulating strain is in production but is will not be available until the end of 2024 at the earliest.

Vaccine will be obtained from PacificVet in Christchurch and transported in a chilly bin with ice-packs by overnight courier (as per their standard transportation procedures for vaccines) to ensure cold chain is maintained. Use in the field will be managed by extraction of sterile aliquots into sterile vials or syringes. This enables sustainable use of the 1000 dose vial and maintenance of sterility of product. This process was discussed with the Zoetis Senior Research Advisor responsible for poultry products and is considered safe and appropriate.

Sterile aliquots will be obtained by using a sterile needle and syringe to extract the aliquot from the closed vaccine vial. The vial will be shaken to homogenise the contents, then the rubber stopper will be swabbed with alcohol. The sterile needle will be attached to the sterile syringe and the needle inserted via the rubber stopper. The aliquot will be drawn up into the syringe, then the needle& syringe removed from the stopper and the cap replace on the needle. The needle will be swapped for a new sterile needle or a sterile vaccine cap.. Both the aliquots and the vaccine vial will be stored refrigerated in accordance with the packaging instructions. Vaccine doses will be drawn up immediately before use and allowed to warm to room temperature just prior to injection.

DOC veterinarians Kate McInnes or Lydia Uddstrom will administer the vaccination.

All birds will receive a full veterinary physical examination at the start of the trial. Only birds in good body condition exhibiting signs of good health will be included. (Any birds which show signs off poor health will be further investigated as per normal veterinary practices).

The tūturuatu recovery team have been involved in the design of the study, and selection of study animals. The Christchurch tūturuatu breeding centre (Isaacs Conservation & Wildlife Trust) was chosen for being one of only 3 facilities holding tūturuatu, the presence of experienced staff, and the ability to access a total of 10 birds at one site.

Individuals for vaccination will be selected by the tūturuatu recovery team, based on the programme's planning for any translocations.

Each individually permanently marked (leg band) bird will receive two doses of vaccine by subcutaneous injection into the inguinal (groin) region with a 1 month interval (no less than 3 weeks apart and a maximum of 6 weeks apart). The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds will receive 0.2ml per dose (as per dosages used in Vergara-Alert et al 2011).

Individual birds within the two cohorts will be determined on the day by tūturuatu staff based on available birds' suitability and any management requirements.

At the start of the trial, each bird will receive a cloacal and oral swab to determine presence/absence of virus at day 0.
The technique will follow the draft SOP Avian swab sampling DOC-6840491 which has undergone veterinary peer review & user testing and is awaiting AEC endorsement before Director sign-off. These types of swabs are used in standard health testing on avian species and would be undertaken by the veterinarian. The test would be considered a baseline health test to demonstrate the birds were not incubating avian influenza at the time of vaccination. The swabs will undergo PCR testing at BioPacifica to look for avian influenza virus.
This is important to be able to demonstrate that any antibody response is due to the vaccination rather than the bird being infected by a wild strain of avian influenza

First trial - Cohort 1: Four individuals will be vaccinated as per the described protocol above. Blood (up to 0.4ml) will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test to measure antibody titre). Antibody testing will be undertaken at a commercial laboratory (BioPacifica, Christchurch).

Note: 1% of body weight is considered an acceptable amount of blood to collect from a healthy bird. Adult weigh ~60g, therefore up to 0.6 ml would be within the safe range for an adult. We propose to only collect up to 0.4ml to maintain a high margin of safety.

Second trial - Cohort 2: Based on consideration of the results of the first trial, if safety has been demonstrated, a second cohort of six individuals will receive the vaccination as per the described protocol above, and blood will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test). We will wait 1 month until we have established the vaccine is safe in cohort 1 before we start cohort 2.

Note: If antibody response at 2-3 months is noted to be muted (i.e. a low response) then the DOC vets (Kate McInnes and Lydia Uddstrom) will discuss the use of a third dose of vaccine. This was used in some species in European zoos where the initial antibody responses were considered insufficient. Consideration will be given to the level of response detected, the impacts of additional handling, and any other welfare factors noted during the preceding handling events. The benefits of testing a third dose of vaccine will be carefully considered, and this will only be undertaken if the welfare impacts are considered minimal. The justification for a third dose in this trial would be to confirm if this dose is warranted and would deliver protection for the tūturuatu population in the event of an outbreak of HPAI in Aotearoa New Zealand.

Two additional blood samples will be collected from both cohorts at approximately 6 months and 12 months to measure duration of antibody response.

A maximum of 10 birds will be included in the trial. It is estimated that there will be ~12 breeding tūturuatu on site at the DOC facility at the time of the trial.

These trials are modelled on the vaccination of California Condor in the USA. (FWS.gov 2023) however the 1 month interval is based on the European zoo data, and considered more appropriate to allow for recovery between handling events in birds which normally have minimal handling by humans.

Estimated timing/schedule of manipulations:

First vaccination and blood sample	Second vaccination and blood sample	2-3 month blood sample	~6 month blood sample	~12 month blood sample
First cohort of 4 birds				
~ 1st February 2024	~ 1st March 2024	~1st April 2024	~ 1st August 2024	~ 1st February 2025
Second cohort of 6 birds (maximum 10 total)				
~ 1st March 2024	~1st April 2024	~1st May 2024	~1st August 2024	~ 1st February 2025

Second cohort of 6 birds – same timeline but 1 month after first cohort have been vaccinated and shown no negative reaction. Blood collection at ~6 and ~12 months may be undertaken at the same time for both cohorts – these sample are about longevity of antibody presence, so the exact timing is less critical.

During a handling event, all involved staff will gather and have a pre-handling briefing by the veterinarian and the team leader to ensure all roles and responsibilities are clearly understood. Any issues can be raised at that time for clarification. The tūturuatu team leader will be responsible for the safe capture and handling of the bird. The veterinarian will be responsible for the health examination, vaccination and blood collection.

All equipment will be prepared prior to capture to minimise handling time. Staff will know where to situate themselves and what actions are required so that an efficient process is maintained. The tūturuatu staff involved in this trial will be team members with previous experience in blood collection in tūturuatu.

Tūturuatu are caught according to the following procedures as detailed in the tūturuatu husbandry manual:

4.1.1 Noose mat

Shore plover are usually captured using a noose mat (Fig. 2). Noose mats consist of fishing line loops ('nooses'), attached to a strip of plastic mesh approximately 900 x 100 mm in size. When birds walk across the mat, their feet are caught in the nooses.

Noose mats work well with shore plover, as they prefer to walk rather than fly when displaced. They can be easily herded across a noose mat if they do not recognise what it is.

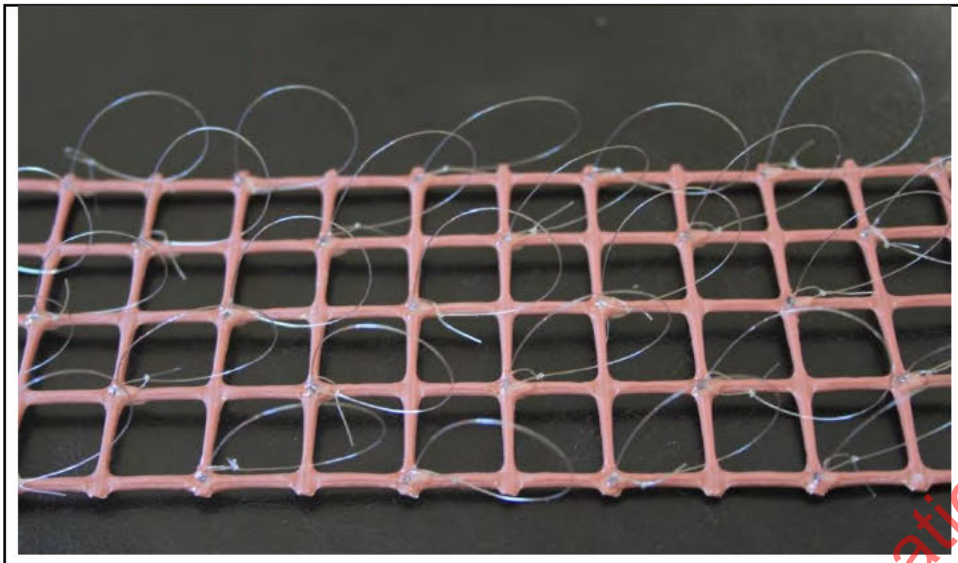

Figure 1. Noose mat used to capture shore plover

Tips for safe and successful noose mat use:

- When setting up the noose mat it is critical that the nooses are all standing upright and in the same direction, i.e. the noose sits parallel with the length of the mat, and there are no gaps between adjacent nooses that birds could walk through. Nooses will need to be replaced from time to time if they crinkle or twist in the wrong direction (refer to appendix 14.7 Making or fixing a noose mat).
- Place the noose mat across a logical pathway, or create one by placing obstacles either end of the mat so the birds are funnelled towards and across it.
- The noose mat must be pegged or weighed down so that when a bird is caught the mat does not lift or flip over and birds cannot fly away with it attached. This is easily done by tying the end tie cords securely to a heavy stone.
- Ensure the noose mat lies completely flat on the substrate. If possible, disguise it by sprinkling shingle over it so the plastic is less visible.
- Do not try to catch birds in windy conditions as movement of the nooses may alert birds and put them off walking across the noose mat. Otherwise place the noose mat in an area sheltered from the wind.
- It is often easier for just one person to do the 'herding' part of capture. Shore plover tend to get suspicious and nervous when there are two or more people involved.
- Never walk far away from a noose mat or leave it unattended. If a bird is snared, you need to be able to get to the mat very quickly to extract it (i.e. within 5-10 seconds).
- Once a bird is snared, walk quickly up to the noose mat to free it, but be careful not to stumble as the bird will be flapping around and there is the potential to stand or kneel on it.
- Be careful to only target birds that really need to be caught for a specific purpose. Unnecessary captures should be avoided whenever possible, because they will make birds wary and potentially jeopardise capture

attempts in future, when it may be particularly important to catch a bird (e.g. to replace a band). Aim to minimise the number of captures in any bird's lifetime (Dowding 1998).

Shore plover become more wary of a noose mat after being caught in one a few times, or witnessing other birds being captured. If it becomes difficult to catch particular individuals with a noose mat the following options can be tried:

- Place mealworms next to the noose mat as a lure or distraction.
- Play recordings of chick or juvenile alarms calls from the other side of the noose mat (these can be recorded when handling chicks in brooders). Most birds will be curious and come over to investigate. If using this method on a group of shore plover, ensure there are helpers standing by to release the birds if a number are captured at once.

Once caught the bird is placed in a 'catch bag' (a soft cotton bag with a draw string which provides a safe restraint for temporary holding) to be weighed in the bag using a hanging scale (standard technique) and then carefully removed undergo a physical examination to determine its health status prior to any further manipulation. If the tūturuatu is determined to be healthy blood collection and vaccination will proceed.

For blood collection and vaccination, a trained tūturuatu handler will restrain the bird on its side or back.

The blood collection site (brachial/wing vein) will be swabbed with a sterile alcohol wipe immediately prior to collection. Blood will be collected from the wing vein via the pin-prick method where the vein is pricked using a sterile 25 or 26 gauge hypodermic needle, and then the bleb of blood is collected in capillary tubes (also known as haematocrit tubes which can contain 75microlitres of blood).

In the event that the temperature is cool, and on examination of the wing vein we determine that blood collection likely to be slow due to the presence of small contracted veins, the wing will be warmed for 3-5 minutes using Kathmandu hand warmers wrapped in gauze, to boost circulation and enhance blood flow to enable effective blood collection.

After collection, the site of blood collection will be covered with a gauze swab and pressure applied to control any bleeding. In the very unlikely event of uncontrolled bleeding, pressure will be applied for a further 1-5 minutes. If still uncontrolled, an icepack wrapped in gauze swabs will be held on the wing area to cool the limb and reduce blood flow. If required, a silver nitrate stick will be carefully used to stop the bleeding.

Blood will be spun in a centrifuge to separate the serum from the blood cells. The tubes will be kept chilled and transferred ASAP to the commercial laboratory in batches for antibody testing.

1-2 drops of blood will be used to make blood smears which will be sent to a commercial veterinary pathology laboratory for a white cell count and differential. This provides a baseline health analysis which can detect infection or inflammation. Any abnormal results will be further investigated by the veterinarian in consultation with the tūturuatu staff.

Once bleeding has stopped, the bird will be vaccinated using a 1mL syringe attached to a 20 gauge ½ inch needle. The vaccination site will be swabbed with a sterile alcohol wipe immediately prior to vaccination. See Appendix 2 for details of the vaccination technique.

The bird will then be checked for any abnormalities and the veterinarian will determine if any further actions are required for health or welfare. Once the procedures are complete the bird will be quietly released and observed as it moves away. Regular observations during routine husbandry will continue for

all birds, and any abnormalities will be reported to the veterinarian. The birds are visited and monitored at least twice daily by staff when they are being fed the artificial diet.

At subsequent handling events, the vaccination site will be examined and any discolouration, swelling, granuloma formation or unexpected abnormality will be noted and reported to the veterinarian. Photographs of each bird's injection sites will be taken to provide a clear record of the trial.

Location & timing:
The trials will be undertaken at the Isaacs Conservation and Wildlife Trust tūturuatu breeding facility in Christchurch between Feb 2024 and June 2025 (breeding tūturuatu will not be handled which is from approximately September to January, dependent on the season and breeding success).

Safety:

Results from a meta-analysis of use of vaccine in European Zoos found very low adverse reaction rate at 0.04% local reactions and 0.015% general reactions reported. EFSA 2007. Based on this, we do not anticipate significant issues with the vaccine, however we will be prepared for immediate veterinary care if any reactions to occur.

The vaccine packaging label states: "Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique."

Anaphylaxis:
A severe immediate immune hypersensitivity response could occur if the vaccine product stimulates such a response. This is considered unlikely due to the extensive use of this vaccine and other similar vaccine products in Europe, however it is possible and needs to be considered as a potential adverse event. The vaccination team will include a veterinarian who will have access to emergency drugs and supportive care for management of anaphylaxis (including corticosteroids, adrenaline, oxygen, fluids).

Injection site reactions:
The vaccine contains an adjuvant (oil) which is present so that it stimulates a stronger immune response with greater antibody production. This can sometimes be associated with a small pea-sized lump at the site of injection. This is normal and expected, although generally not all birds will develop a lump. This will be checked at the 1 month mark, and records kept of any reactions detected. If an excessive size reaction is detected in an individual (>1cm), then the vaccination will be paused until it is determined that the lump does not enlarge further, or cause any impacts on the bird(s) – this is likely to be a period of 2-4 weeks. Body weight, activity levels etc will be reviewed and a full physical examination undertaken.

A localised bacterial infection could result if poor sterile technique is used. Only registered veterinarians will be administering the vaccine, and these operators all have training in appropriate sterile techniques. If a bird experiences an infection at the site, it will receive veterinary care and follow-up to ensure the issue is managed.

Mis-injection could occur if the bird is poorly restrained and moved during vaccination. This will be managed by only using well trained, experienced tūturuatu handlers to restrain the birds. For some individual birds, they are calmer with head cover which can aid in handling. This will be determined on an individual bird basis. If a mis-injection occurs, the veterinarian will determine the appropriate next steps. This may include, re-injection if the first injection merely failed to enter the bird, appropriate first aid

measures if any injury was caused, and/or exclusion from the trial and follow-up care. As noted previously, "stressy" birds will not be included in the trial which will reduce the risk of injury or mis-injection.

Injury could occur during capture and handling. This is minimised by only using trained experienced staff, careful selection of trial birds, and a "stop for safety" approach which resets the work programme and ensures time out to reassess and replan the work and procedures if necessary.

In the event of a serious reaction or injury during the vaccination trial, the bird will be taken to Wildbase Hospital Massey University for specialist care by Drs Megan Jolly and Brett Gartrell. This is standard procedure for tūturuatu requiring a high level of veterinary care. Birds have been transported this way via Air New Zealand on many occasions.

Results:
The results of this trial will determine if this vaccine is safe to use in this species, and the level of antibody response produced by a 2 dose vaccination. In some other species, notably penguins, the antibody levels following vaccination remain low and, in some species, a third vaccination was used to ensure a stronger response (ESFA 2007). The duration of antibody presence also varied between species. Therefore, this trial will help to determine the appropriate vaccination regime for tūturuatu in the event that more widespread vaccination is required during a highly pathogenic avian influenza outbreak in New Zealand.

3c. Attach Photos of equipment, the species, the location (or a map); to help set the context.

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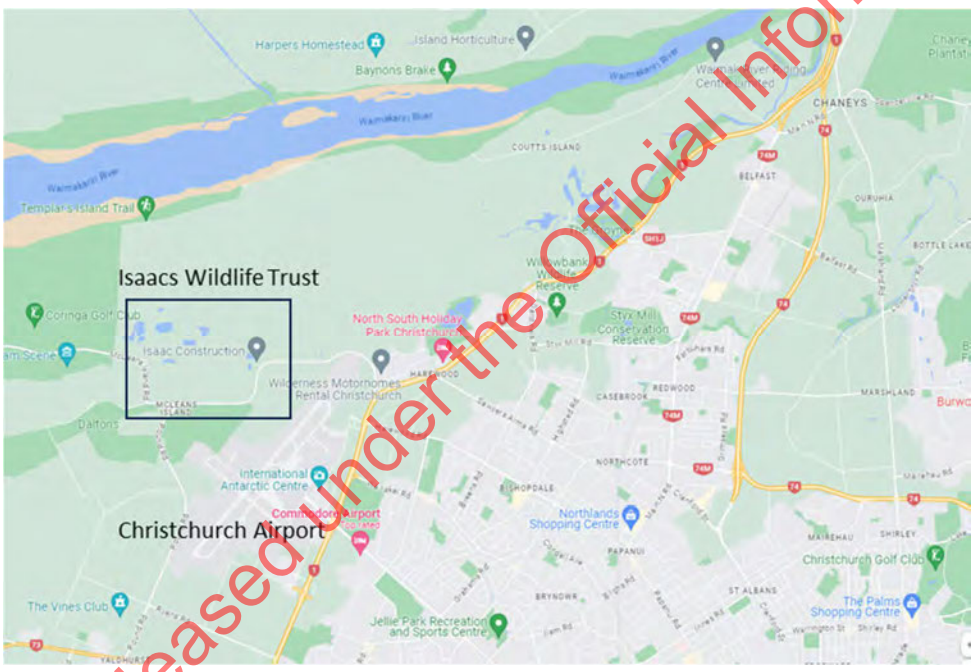
Key Words	avian influenza, vaccine, safety, efficacy, tūturuatu

Figure 2.Standard hold for shore plover

Figure 1. ICWT shore plover aviary block with service corridor.



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3d. References

- *List the references referred to in the application*

DOC-7111177 Mitigation Options Guideline for HPAI
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Tūturuatu/shoreplover husbandry manual. Internal DOC document

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Philippa JWD 2007a, in XI. Vaccination of Non-domestic Avian Species, Transmissible Disease Handbook. European Zoo Vets 5th Edition link

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Pitman 2006. M Pittman, European Commission 12th Annual meeting of national avian influenza laboratories Veterinary and Agrochemical Research Centre (VAR) Uccle, Brussels, 16-18 October 2006 LINK: link.

Vergara-alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706. https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7499845

4. INVOLVEMENT OF OTHER ANIMAL ETHICS COMMITTEES:

4a. Is this Application; or a related or similar application; been or is being considered by another Animal Ethics Committee. Has this project been requested to be considered by any other AEC?

If so, please provide details.

No

4b. Does this manipulation interact with a manipulation approved by other Animal Ethics Committee? If so, detail your communications with those committee(s), and state any conditions imposed by (an)other AEC.

No

5. JUSTIFICATION FOR PROPOSED MANIPULATION:

5a. Detail any action undertaken to determine that the proposed work has not already been done.

Avian Influenza vaccine efficacy and safety has been undertaken on other avian species, however it has not been undertaken in New Zealand endemic species. Although we expect similar results, it is prudent to undertake this trial to provide more evidence of safety and efficacy in the species which we intend to vaccinate in the event of a HPAI outbreak.

5b. Have alternatives been considered to the proposed manipulation involving reduction, or replacement of live animals, or refinement of techniques?

We are looking at the species-specific response and have selected a minimum size divided into two cohorts, so other methods of reduction are not appropriate for this work.

The cohort approach allows us to cautiously approach the safety issue, and assess initial results before involving the full number of birds.

5c. To what extent has there been assessment of the suitability of using non-sentient or non-living alternatives in the project; or replacement of animals as subjects with suitable non-sentient or non-living alternatives?

N/A, see above

5d. How will the proposed work result in the extension of knowledge relevant to the health, welfare, or conservation of animals?

This work will specifically contribute to the future health of the species for conservation purposes by providing evidence of the safety and efficacy (or not) of this vaccine in this species, and inform the appropriate vaccine schedule for the species.. This will determine if the vaccine is employed in the future in the face of an avian influenza outbreak in New Zealand.

5e. Is the manipulation required as part of an approved training programme?

No.

5f. How will the results of this work be made available to staff within and outside DOC? (*For example internal report, journal paper, best practice guide, workshops etc*).
Internal report, journal paper, conference presentations, shared with other captive institutions that hold tūturuatu.

6. SELECTION OF SPECIES & NUMBER OF INDIVIDUALS FOR PROPOSED MANIPULATION

6a. What will be the source of the animals to be manipulated, and how many from each source will be manipulated?
Tūturuatu at the Isaacs Conservation & Wildlife Trust Christchurch breeding centre. 10 birds in total. It is estimated that there will be 12 breeding tūturuatu on site at the facility at the start of the time of the trial.

6b. Will any of the animals involved be used more than once, and if so, how many times will each animal be used?
Only once (but each animal handled/manipulated multiple times – twice for vaccinating and four more times for blood sampling, although the 6 & 12 month handling for blood collection will be planned to coincide with routine handling for health management)

6c. What factors have been taken into account in the choice of the animal species?
Tūturuatu are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction.

6d. Could the information being sought be obtained by work on some other species?
No. The trial specifically uses tūturuatu since the safety and efficacy needs to be tested in the target species.

6e. Will the question be answered with the size of the sample?
Yes.

6f. Is the number of animals proposed to be manipulated the <u>minimum</u> necessary to provide a scientifically interpretable result, consistent with the level of statistical precision required? What consideration has been given to the design of the study with regard to:

- **The level of precision necessary in the results?**

The purpose of the small trial is to establish if there is a species-specific sensitivity to the vaccine and its adjuvant. For this purpose, we require only a small number of birds to extrapolate a species sensitivity. Similarly, for determining vaccine response by antibody response levels, a sample size of 10 will provide sufficient individual variation to establish an overall species response level. Additionally if a bird is removed from the trial for any reason (e.g. other health issues, injury, behavioural), starting with 10 birds allows sufficient number to still be able to make a reasonable conclusion on the vaccine efficacy for future management purposes.

A larger sample size would ensure a more nuanced examination of the species' response to vaccination; however we are examining a general level of impact/effect, rather than subtle differences. Thus, if results which showed >1 bird having a safety issue, or the majority or average antibody response to be low, that would be sufficient to inform the next steps for decision making regarding tūturuatu vaccination.

- **The possible confounding effects of animal variation?**

We expect some individual variation since the immune response is affected by individual health status and biological variation. This sample size is sufficient to ensure we have a range of individual responses to examine.

- **The needs of statistical analysis?**

There is likely to be individual variation, which, for the antibody response, requires a reasonable sample size. We determined that 10 was the maximum which was feasible to include in the trial, and also sufficient to allow for individual variation to establish some baseline parameters of antibody response.

Ultimately, in an outbreak situation, the results of a sample size of 10 will be sufficient to make reasonably informed decisions about the use of a commercially produced killed vaccine which has a good history of safety and efficacy across a wide range of species.

7. WELFARE OF ANIMALS DURING PROPOSED MANIPULATION:

7a. What measures will be taken to ensure: the general health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of over-crowding, and prevention and control of disease?

Tūturuatu will be caught and handled by experienced staff as per usual tūturuatu protocols at Isaacs Conservation & Wildlife Trust Christchurch breeding centre where DOC staff already maintain appropriate husbandry practices and monitoring of all the birds. Each bird will be held within its normal enclosure so that there is minimum disturbance to their daily lives. Staff will continue to monitor birds throughout the trial, including food consumption and behaviour

Each bird will receive a veterinary examination at the start of the trial. Equipment will be disinfected between individuals, or new equipment will be used. Once blood has been collected and vaccination undertaken the bird will be re-released in their home aviary.

The vaccination trial will occur after the breeding season has finished, so will not interfere with any breeding behaviour. No female birds will be gravid at the time of manipulation, and any breeding birds will have raised and fledged their chicks before the trial begins.

7b. What movement and transportation measures will be followed for the animals to be manipulated to ensure their welfare and humane treatment?

Birds will be vaccinated on site, in their aviary where they are captured, therefore there will be no transport required.

However, if a bird requires specialist veterinary care e.g. in the event of an injury or serious reaction, then the bird will be taken to Wildbase Hospital Massey University for specialist care by Drs Megan Jolly and Brett Gartrell. This is standard procedure for tūturuatu requiring a high level of veterinary care. Birds have been transported this way via Air New Zealand on many occasions.

Brids will be transported using the standard tūturuatu transport crates, and in accordance with normal tūturuatu transportation procedures. Briefly, birds will have non-slip flooring the crate, be transported via car to Christchurch Airport and flown direct to Palmerston North. Transport will be managed to reduce noise and allow for temperature control. Radio will be off and driver/passenger will ensure minimal noise. Travel will be direct and the hospital will be alerted ahead of time to enable a fast hand-over a and rapid care.

Supportive therapy would be provided prior to transport which may include pain relief and fluids, the staff are trained and competent in administering medications on direction from the veterinarians.

7c. What measures are to be taken to minimise the pain or distress of any animal manipulated? *Stating there will not be any impact is not acceptable. The AEC is looking for the Applicant to (1) provide analysis about the potential for pain and/or distress to the animal(s), and (2) describe how they will manage that pain or distress. Identify how you would ascertain pain or distress animal's behaviour, environmental conditions likely to lead to pain or distress.*

Birds will be captured and handled by experienced DOC tūturuatu staff using their routine techniques. Only experienced staff will handle the birds. Initial physical examination, vaccination and blood collection will be undertaken by a veterinarian.

Any bird detected to have abnormalities will be examined and rejected from the trial, and receive normal veterinary investigation/intervention.

Subsequent examination and blood collection may be undertaken by DOC staff trained in blood collection from tūturuatu, provided the initial results (0,1, and 2-3 month check) are normal across the cohorts.

The subcutaneous injection is not considered painful, and the vaccine dose will be warmed to room temperature prior to injection. Blood collection is associated with a minorly painful pin-prick when the needle is inserted. This will be minimised by careful planning and handling.

If birds are observed to have any pain response to the vaccination, the staff will report it to the veterinarian who will investigate. In the event that there is an injection site reaction (painful inflammation) then an anti-inflammatory such as Metacam may be prescribed by the attending veterinarian, as well as antibiotics if infection is also present.

As noted earlier, if any serious adverse reactions occur, veterinary care by the attending veterinarian will be undertaken, and transfer to Wildbase Hospital undertaken if required for more intensive specialist care.

8. CONTINGENCY PLAN:

8a. What arrangements have been made for the abandonment of any manipulation and/or the euthanasia of animals where pain or distress cannot be held within reasonable levels?

If pain or distress is apparent, during handling or following the procedure, the veterinarian will investigate. If the veterinarian deems the level to be unreasonable, then the manipulation will be abandoned and all efforts made to ameliorate the event e.g. anti-inflammatory, pain relief medication, antibiotics.

In the unlikely event that the pain is not temporary and cannot be managed, transfer to Dunedin Wildlife Hospital will allow for intensive veterinary intervention and care. This includes the ability to undertake orthopaedic intervention e.g. in the event of a broken bone, or intensive surgery e.g. in the event of a severe localised vaccine reaction.

Supportive therapy would be provided during any transport which may include pain relief and fluids.

9. PEOPLE TO UNDERTAKE PROPOSED MANIPULATION:

9a. Who are the person(s) primarily involved in carrying out the proposed manipulation?
Kate McInnes and Lydia Uddstrom are the primary persons.

9b. What is the experience and qualifications of the person primarily responsible (9a) for the undertaking and supervising the manipulation (including selection of animals, their care and disposal?)
Kate McInnes has been the DOC vet since 2000 and has worked across a range of avian species , and is currently the lead technical advisor for the DOC HPAI response.

Lydia Uddstrom is contracted full time to the DOC kākāpō team, has undertaken postgraduate training as a zoo veterinarian and has experience with a wide range of New Zealand native species veterinary care.

Both Kate and Lydia have previously been involved in capture and handling of threatened species undertaking vaccination and blood collection for a range of threatened species, and have trained multiple DOC staff to safely and effectively undertake these procedures.

9c. Who else is in the team undertaking the manipulation? State their role in the team, and their relevant experience with the procedure(s) proposed in the application? Include DOC and non-DOC staff in the team.

Name of Manipulation Team member	*Role in the manipulation*	*Experience and qualifications relevant to the manipulation*
Anne Richardson	Lead person for catching, handling & monitoring.	Anne has over 20 years experience managing tūturuatu in captivity, and has routinely been collecting blood samples from birds for >15 years.
Leigh Percasky	Catching, handling, monitoring & follow-up blood collection of tūturuatu	Leigh has 6 years of experience working with tūrutuatu in captivity, including routine blood sampling of birds.

9d. What training will be given to the people identified in 9c to help them undertake the manipulation proposed in the application?

Team leader and tūturuatu staff are trained in blood collection of tūturuatu as per the DOC Avian Blood Collection SOP training requirements, and to undertake normal practices including capture & handling.

The capture and handling will be undertaken according to the direction of the team leader.

Vaccination will be undertaken by the DOC veterinarian.

10. COMPLIANCE WITH CONDITIONS of the APPROVAL:

- Please outline any opportunities for a member, or members, of the DOC Animal Ethics Committee to observe this work.

10a. Identify ways that the manipulation(s) can be monitored by the AEC:

AEC members could attend a vaccination session at Christchurch to see the procedure in tūturuatu and/or receive a video or photographs of the manipulation being undertaken.

11. Are there any other aspects which ought to be brought to the attention of the DOC Animal Ethics Committee?

No

12. Does the research, testing or teaching involve a species which is covered by a Department of Conservation Species Recovery Plan and if so, has the Recovery Group been consulted and their endorsement for the work received? Please provide a summary of communication.

Yes. Tūturuatu management is guided by the tūturuatu Recovery group which has been consulted and are supportive of this trial.

This application has been shared with the tūturuatu team on 10th November for review prior to submission to the AEC, and the contents were discussed and agreed with the team on 15th November 2023.

13. What month of year is most useful to report back to the AEC (depending on the project schedule and the animal's biology)?

September

13. Manipulation Grading

Please work through the document '*Grading of Manipulations*' (Please refer to DOCDM-870472), and determine the grading you believe best applies to the manipulation proposed in this application. Please also provide a rationale for the grading.

Grade A: No impact or virtually no impact.
Grade B: Little impact. Manipulations of minor impact and short duration.
Grade C: Moderate impact. Includes manipulations of minor impact and long duration or moderate impact and short duration.
Grade D: High impact. Includes manipulations of moderate impact and long duration or high impact and short duration.
Grade E: Very high impact. Manipulations of high impact and long duration.

Grading determined by the Applicant: B

Application Number DOCDM	AEC446 APPLICATION DOC-7483658
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, tūturuatu

Your rationale for the grading:
Grade B includes "**Disease/injury/functional impairment:** Studies of vaccines using killed pathogens." The animals will be kept in their normal husbandry conditions for the duration of the study. There will be capture and handling for blood collection and vaccination, and two doses of a killed vaccine administered. Handling time & stress will be minimised by using only skilled staff and it will be undertaken at site.

Note: The grading determined by the Applicant is not the grading assigned by the AEC. The Applicant will be advised of the AEC's grading and any conditions in writing.

DECLARATION by the APPLICANT

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I declare that the information in this Application is correct; and
[☑] I agree to comply with the conditions imposed by DOC's AEC for the manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be aware of the contents of this AEC application; and
[☑] I declare the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff
[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application.
[☑] I agree to comply with the reporting requirements stipulated by the AEC on approval of this research project.

Signed by the Applicant 9(2)(a) _____

Full Name: Catherine McInnes Date: 13/11/2023

DECLARATION by the ACCOUNTABLE MANAGER

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I agree to ensure my staff member complies with the conditions imposed by DOC's AEC for this manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be made aware of the contents of this AEC application; and

Application Number DOCDM	AEC446 APPLICATION DOC-7483658
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, tūturuatu

[☑] I agree the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff

[☑] I agree to oversee this Application via MORs, PDPs and other means to ensure the manipulation remains within the scope of the Application and the Approval, and all reporting required by the AEC is delivered on time;

[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application, and to advise the AEC if the Applicant leaves the Department, or if the work should be transferred to another staff member for operational reasons' or if the manipulations is abandoned for any reason.

Signed by the Manager: 9(2)(a) [redacted]

Full Name: John Lyall

Role: Fauna Advice Manager

Date: 16/11 / 2023

Application Number DOCDM	AEC446 APPLICATION DOC-7483658
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, tūturuatu

Appendix 1: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.
• Use contents of each vial within 6 hours of opening

Appendix 2: General Instructions for subcutaneous injection of vaccine

- The vaccine is supplied in a 500mL bottle and is given to the bird using a needle and syringe.
- The vaccine is injected under the skin but NOT into the muscle below.
- The vaccine should be drawn up into the syringe and then allowed to warm to room temperature (this is more comfortable for the bird).

EQUIPMENT NEEDED

1. Vaccine container
2. 1 mL syringe
3. 25 gauge 5/8th inch needle
4. alcohol swab (mediswab or cotton wool and meths)
5. dry swab (gauze or cotton wool)
6. Sharps container for needle disposal
7. Bird
8. Bird handler
9. Veterinarian

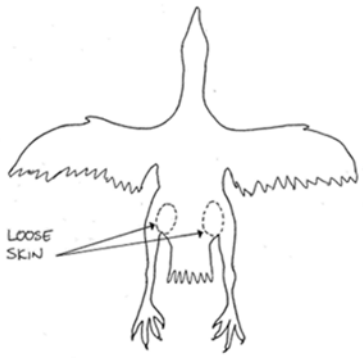
PREPARING THE VACCINATION

1. Store the vaccine in the fridge at 2-8 degrees C in the dark. Do not Freeze.
2. When ready to use, take the vaccine out of the fridge and shake well to mix.
3. Write the date on the vaccine bottle.
4. Break off the metal seal on the top of the rubber injection port.
5. Swab the injection port on the vaccine with alcohol to sterilise it with a mediswab or cotton ball soaked in methylated spirits.
6. Firmly attach the needle to the syringe – 25 gauge 5/8th inch needle to a 1mL syringe.
7. Insert the needle through the centre of the rubber stopper CAREFULLY.
8. Hold the vaccine upside down and slowly suck vaccine into the syringe until you have a little more than the prescribed dose of vaccine.
9. Flick the syringe to dislodge any air bubbles and squirt them slowly back into the vaccine bottle.
10. Keep squirting until all the bubbles are gone and you have the prescribed dose of vaccine left in the syringe.
11. Pull the needle out of the vaccine bottle and CAREFULLY recap the needle.
12. Leave the syringe and needle to warm to room temperature.
13. Repeat this procedure to draw up all the doses you need for your vaccination session.
14. Put the vaccine back in the fridge.
15. Once open, the vaccine can be used for 30 days. (Note that this expiry is based on Zoetis technical advice for limited use of the vaccine in this trial, and only applies when following the above instructions for maintaining sterility of the product and correct storage.)
16. If you are in doubt that the vaccine has been stored correctly (kept refrigerated), then discard it and get a new bottle.

GIVING THE INJECTION

1. Have the following equipment ready for use:
    - The correct dose of vaccine drawn up in syringe with needle attached and warmed to room temperature. (the cap should be on the needle to avoid accidental stabbing or contamination of the needle)
    - One alcohol swab (mediswab or cotton wool in meths)
    - One dry swab (gauze or cotton wool)
2. Have an assistant restrain the bird on its back or side with its legs restrained to provide access to the groin (where the bird's leg joins its belly).

Diagram of ventral (belly) of a bird showing the groin region for subcutaneous vaccination sites:



3. Spread the feathers in the groin area.
4. Wet down the feathers with the swab to clear a patch of skin and swab the skin.
5. Lift the loose skin 1-2cm off the body to make a "tent".

Diagram of the skin being lifted to make a "tent" for a subcutaneous injection

6. Take the cap off the needle and aim the needle about halfway down the side of the tent. Keep the needle parallel to the body wall. When the needle goes through the skin, it should still be above the muscle of the groin i.e. you are injecting into the space inside the tent, not into the muscle.
7. Suck back on the syringe to check for blood. This is to avoid injecting into a blood vessel.
8. Inject the vaccine with a steady firm pressure.
9. Withdraw the needle and place it into the Sharps container.
10. Use the dry swab to press over the injection site if there is any bleeding.
11. Release the bird.

12. Record:	Bird ID	Date	Dose	L or R side	Vaccinator	Holder	Vaccine Batch	Expiry Date	Notes

13. Transfer this data to the vaccination record spreadsheet
14. Note any other specifics about the injection process not described above. E.g. if there was bleeding at the injection site.

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāriki

Revised September 2023

DEPARTMENT OF CONSERVATION
APPLICATION TO MANIPULATE LIVE ANIMALS
Code of Ethical Conduct for the Care and Manipulation of Live Animals

1. APPLICANT'S DETAILS:

Name: Kate McInnes

Date: 17 November 2023

Role: DOC Veterinarian

Unit: BH&V Group, Wellington

APPLICANT'S ADDRESS:

Phone no: 9(2)(a) [redacted]

Email: kmcinnes@doc.govt.nz

2. ACCOUNTABLE MANAGER'S DETAILS:

Name: John Lyall

ACCOUNTABLE MANAGER'S ADDRESS:

As above or: DOC, Hokitika

Phone no: 9(2)(a) [redacted]
Email: jlyall@doc.govt.nz

2a. AEC443

2b. **MANIPULATION TITLE: Avian Influenza vaccination safety and efficacy trial kākāriki**

2d. **Duration of the manipulation**

- *Over what timeframe are you seeking the approval?*
- *You must not commence the manipulation until you have received the approval, signed by you, your accountable manager, and the AEC Chair.*

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāriki

- *NOTE: The AEC will not generally give an approval for longer than two years at one time. Please state if this manipulation is likely to extend longer than two years from the commencement date.*

Anticipated start date:	February 2024	Anticipated finish date:	June 2025

2e. What months of the year is the manipulation most likely to be undertaken? e.g., October – March
For the duration of the dates specified

3a. Summary of the proposed manipulation for a LAYPERSON

- *Provide an abstract describing the manipulation (maximum 400 words).*

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain is decimating many populations of wild birds overseas, is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia, October 2023.

We want to test the safety and efficacy of vaccination to protect critically endangered species.
The vaccine is a commercial product registered in New Zealand by Ministry for Primary Industries. It is considered very safe and highly effective. It contains inactivated (dead) virus so it cannot cause avian influenza. Vaccination reduces risk of illness or death and reduces shedding of virus, thus protecting the individual and its flock.

Kākāriki karaka are a critically threatened species which is reliant on a captive breeding programme where it is possible to reliably administer a full course of vaccine (2 injections under the skin, one month apart) to individually identified birds, and where we are able to handle them again for a veterinary examination and blood testing to detect any effects on health status, and measure the immune response by detection of antibodies over a 12 month period.

Captive Red-crowned kākāriki (as a surrogate species) will be captured in their aviary and receive a pre-vaccination health check by a veterinarian, and a blood test for health and antibody testing. Up to 0.4 mL of blood will be collected from the wing vein, as is standard for this species.

The vaccine is given under the skin. Once month later the bird will receive a second vaccination and blood test. Further blood will be collected at 2-3, 6 and 12 months post vaccination to determine the level of antibody response and how long it lasts.

A cloacal and choanal (oral) swab will be collected on day 0 for PCR testing to demonstrate the birds were not incubating avian influenza at the time of vaccination.

Normal husbandry practices will be undertaken including observation of the bird's activity and food intake to monitor of any adverse reactions.

We propose to work with a total of 10 adult or juvenile kākāriki, divided into two cohorts. Cohort 1 will first receive the vaccination & blood tests, and a recheck at 1 month. If no safety issues are identified, then Cohort 2 will receive vaccinations & blood tests. This allows a careful start to the trial where the month is the most important to test vaccine safety. The following blood samples (at 2-3, 6 and 12 months) will determine level and duration of antibody presence and determine when further boosters would be required.

Additional approval given on 16/4/24 to collect a 10-14 week blood sample to target peak antibody levels, and to collect an opportunistic blood sample for further antibody testing, if birds are being handled for routine management purposes, with no more than twice per bird over the 12 months of the trial.

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
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3b. Description of the proposed manipulation (methods)

- *Provide a more detailed explanation. Describe the equipment, the location, and any environmental factors: weather, time of the year. Why have you decided to undertake the manipulation in this way? What advice have you sought? Include the species, the number of individuals, the source of animals, and the disposal/fate of animals at the conclusion of the manipulation.*
- *Be specific about the timelines for the proposed investigation and the purpose of the research, testing or teaching.*
- *Include some consideration and planning for when things might not go right.*

Please note: this is one of five trials to assess avian influenza vaccination safety and efficacy in nationally critical threatened species (takahē, kākāpō, kakī, tūturuatu, kākāriki karaka). Manipulation details which are specific to this species (kākāriki) have been highlighted in yellow. All other details are consistent across the five trials. By highlighting the species specific details I hope to assist the AEC with the volume of workload associated with simultaneously assessing these trials.

This trial is designed to test the efficacy and safety of a vaccine in a critically threatened species, however for this species we plan to use a closely related surrogate.

Selection of the species for potential vaccination is based on the risk that they could undergo an extinction event when highly pathogenic avian influenza (HPAI) reaches New Zealand. Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and risk of extinction.

The wild adult kākāriki karaka numbers in the Hawdon, Andrews, and Poulter valleys are extremely low. The south branch of the Hurunui currently has the largest population on the mainland, being comprised almost entirely of birds that have been released from captivity. Even so, there are probably fewer than 100 mature parakeets on the mainland, and perhaps 200-300 on islands following translocations.

The surrogate species in this trial, red-crowned kakariki, are widely distributed throughout the New Zealand region, and very common on some islands, they are almost entirely absent from the two main islands. They are held in captivity for advocacy (display) and many institutions around New Zealand, and by private holders under permit form DOC. There are thriving populations on off-shore islands. Their conservation status in "endemic" and they are not considered threatened.

Based on the evidence from overseas during this epizootic, the species most at risk of infection are those which exhibit congregation behaviours e.g. feeding, breeding or roosting in groups, those which are exposed to at risk species e.g. where seabirds overlap with another threatened species, and birds held in captive facilities where biosecurity options are limited e.g. open pens and large aviaries.

Kākāriki karaka are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. See DOC-7111177 Mitigation Options Guideline for HPAI.

Use of the vaccine is dependent on Ministry for Primary Industries approval, and currently requires the birds to be held in captivity. Birds require two injections one month apart and must be individually identified with a permanent mark e.g. microchip or leg band. Kākāriki will already have a leg band as part of their normal husbandry.

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment (Animal Health Australia, 2021).

Additionally, vaccination of California Condor was approved in the United States following an outbreak in the wild population. This was the first avian influenza vaccination programme in a wild endangered species. Advice from the veterinary and technical advisors to the condor vaccination programme has been received and is incorporated into this trial design.

We wish to undertake a limited trial to determine the safety and efficacy of the avian influenza specific vaccine in kākāriki (using red crowned kakariki as a surrogate) as a preparedness measure for the arrival of HPAI in New Zealand.

The vaccine is produced commercially by Zoetis for use in poultry: Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine - see Appendix 1. It has been in production since 2006 and is widely used in the poultry industry. Publications on AI vaccine use in poultry and avian species in zoos have indicated a very high level of safety across a wide range of species, and efficacy has been well established. (Kandeil et al 2018, Philippa et al 2006, Philippa 2007a, Philippa 2007b, Pitman 2006, Vergara-Alert 2011). The vaccine is inactivated, so there is no live virus present and it cannot cause avian influenza.

Advice from Zoetis (USA) indicates that this vaccine should provide good protection against the current strain of HPAI with 91% amino acid homology with the circulating strain. A newer vaccine based on the circulating strain is in production but is will not be available until the end of 2024 at the earliest.

Vaccine will be obtained from PacificVet in Christchurch and transported in a chilly bin with ice-packs by overnight courier (as per their standard transportation procedures for vaccines) to ensure cold chain is maintained. Use in the field will be managed by extraction of sterile aliquots into sterile vials or syringes. This enables sustainable use of the 1000 dose vial and maintenance of sterility of product. This process was discussed with the Zoetis Senior Research Advisor responsible for poultry products and is considered safe and appropriate.

Sterile aliquots will be obtained by using a sterile needle and syringe to extract the aliquot from the closed vaccine vial. The vial will be shaken to homogenise the contents, then the rubber stopper will be swabbed with alcohol. The sterile needle will be attached to the sterile syringe and the needle inserted via the rubber stopper. The aliquot will be drawn up into the syringe, then the needle& syringe removed from the stopper and the cap replace on the needle. The needle will be swapped for a new sterile needle or a sterile vaccine cap.. Both the aliquots and the vaccine vial will be stored refrigerated in accordance with the packaging instructions. Vaccine doses will be drawn up immediately before use and allowed to warm to room temperature just prior to injection.

DOC veterinarians Kate McInnes and Lydia Uddstrom will administer the vaccination. DOC veterinarian Rachel Stayner who is contracted to assist with HPAI preparedness work may also participate in this trial.

All birds will receive a full veterinary physical examination at the start of the trial. Only birds in good body condition exhibiting signs of good health will be included. (Any birds which show signs off poor health will be further investigated as per normal veterinary practices).

The kākāriki karaka recovery team have been involved in discussions about this study, and are in agreement with the value of the vaccination to protect the breeding programme. The actual study design and selection of study animals has been determined by Kate McInnes, due to the accessibility of a suitable

surrogate species which can be held more widely in captive institutions and by private breeders. Red-crowned kakariki are approximately twice the size of kākāriki karaka (70-80g vs 30-50g) and are considered by aviculturalists to be a mor robust bird to tolerance of handling stress, making them a better candidate for this trial.

Natureland Wildlife Trust was selected because they are a Zoo Aquarium Association accredited professional wildlife conservation facility willing to participate to support the conservation outcomes, they have experienced staff, and they hold sufficient red-crowned kakariki for the completion of the trial.

Individual birds for vaccination will be selected by the staff at Natureland, based on the captive programme requirements.

Each individually permanently marked (leg band) bird will receive two doses of vaccine by subcutaneous injection into the inguinal (groin) region with a 1 month interval (no less than 3 weeks apart and a maximum of 6 weeks apart). The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds will receive 0.2ml per dose (as per dosages used in Vergara-Alert et al 2011).

Individual birds within the two cohorts will be determined on the day by kākāriki staff based on available birds' suitability and any management requirements.

Male and female kākāriki are held in separate aviaries. Currently there are 3 males and 6 females, however in the next 3 months, a few additional birds may be added to the collection. The cohort sizes below will be adjusted based on birds in the aviary at the commencement of the trial, up to a maximum of 10 birds in total.

At the start of the trial, each bird will receive a cloacal and oral swab to determine presence/absence of virus at day 0.
The technique will follow the draft SOP Avian swab sampling DOC-6840491 which has undergone veterinary peer review & user testing and is awaiting AEC endorsement before Director sign-off. These types of swabs are used in standard health testing on avian species and would be undertaken by the veterinarian. The test would be considered a baseline health test to demonstrate the birds were not incubating avian influenza at the time of vaccination. The swabs will undergo PCR testing at BioPacifica to look for avian influenza virus.
This is important to be able to demonstrate that any antibody response is due to the vaccination rather than the bird being infected by a wild strain of avian influenza.

First trial - Cohort 1: three to six individuals form the male group aviary will be vaccinated as per the described protocol above. Blood (up to 0.4ml) will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test to measure antibody titre). Antibody testing will be undertaken at a commercial laboratory (BioPacifica, Christchurch).

Note: 1% of body weight is considered an acceptable amount of blood to collect from a healthy bird. Adult red-crowned kākāriki weigh ~70-80g, therefore up to 0.7 ml would be within the safe range for an adult. We propose to only collect up to 0.4ml to maintain a high margin of safety.

Second trial - Cohort 2: Based on consideration of the results of the first trial, if safety has been demonstrated, a second cohort of four to seven individuals from the female group aviary (maximum of 10

in total) will receive the vaccination as per the described protocol above, and blood will be collected at 0, 1, and 2-3 months to measure health parameters (white cell count & differential) and antibody response (commercial serum ELISA test). We will wait 1 month until we have established the vaccine is safe in cohort 1 before we start cohort 2.

Note: If antibody response at 2-3 months is noted to be muted (i.e. a low response) then the DOC vets (Kate McInnes and Lydia Uddstrom) will discuss the use of a third dose of vaccine, and consult with Natureland if additional vaccination is recommended. This was used in some species in European zoos where the initial antibody responses were considered insufficient. Consideration will be given to the level of response detected, the impacts of additional handling, and any other welfare factors noted during the preceding handling events. The benefits of testing a third dose of vaccine will be carefully considered, and this will only be undertaken if the welfare impacts are considered minimal. The justification for a third dose in this trial would be to confirm if this dose is warranted and would likely be needed to deliver protection for the kākāriki karaka population in the event of an outbreak of HPAI in Aotearoa New Zealand.

Two additional blood samples will be collected from both cohorts at approximately 6 months and 12 months to measure duration of antibody response.

A maximum of 10 birds will be included in the trial. It is estimated that there will be a minimum of 9, but possibly more, display kākāriki on site at the DOC facility at the time of the trial. Thus it is possibly that only 9 birds will be enrolled in the trial but likely to be 10.

These trials are modelled on the vaccination of California Condor in the USA. (FWS.gov 2023) however the 1 month interval is based on the European zoo data, and considered more appropriate to allow for recovery between handling events in birds which normally have minimal handling by humans.

Estimated timing/schedule of manipulations:

First vaccination and blood sample	Second vaccination and blood sample	2-3 month blood sample	~6 month blood sample	~12 month blood sample
First cohort (3-6 birds)				
~ 1st February 2024	~1st March 2024	~1st April 2024	~ 1st August 2024	~ 1st February 2025
Second cohort (4-7 birds, to make up maximum of 10 birds)				
~ 1st March 2024	~1st April 2024	~1st May 2024	~1st August 2024	~ 1st February 2025

Second cohort of birds – similar timeline but commences 1 month after first cohort have been vaccinated and shown no negative reaction. Blood collection at 6 and 12 months may be undertaken at the same time for both cohorts – these sample are about longevity of antibody presence, so the exact timing is less critical.

During a handling event, all involved staff will gather and have a pre-handling briefing by the veterinarian and the team leader to ensure all roles and responsibilities are clearly understood. Any issues can be raised at that time for clarification. The Natureland kākāriki team leader will be responsible for the safe capture and handling of the bird. The veterinarian will be responsible for the health examination, vaccination and blood collection.

All equipment will be prepared prior to capture to minimise handling time. Staff will know where to situate themselves and what actions are required so that an efficient process is maintained. The Natureland kākāriki staff involved in this trial will be team members with previous experience in capture and handling of kākāriki.

Kākāriki are held in two flock aviaries, so they will be caught according to the following procedures:

Kākāriki will be captured using cage traps by experienced bird handlers. Briefly, the cage traps are installed permanently inside the aviary with the kakariki feeders inside so that birds are familiar with their presence . When capture is required, the birds are allowed to enter for feeding, and then the cage is triggered to close the mesh wall via a string control, capturing the bird inside. The birds is then quickly restrained and removed from the cage. By an experienced handler using the small side sliding door (see photographs below).

A second handler assists in the removal of the bird from the net directly into a catch bag (a soft cotton bag with a draw string which provides a safe restraint for temporary holding) to be weighed in the bag using a hanging scale (standard technique) and then carefully removed and undergo a physical examination to determine its health status prior to any further manipulation. If the kākāriki is determined to be healthy blood collection and vaccination will proceed.

This is the standard method of capture for kakariki used at Natureland Wildlife Trust.

For blood collection and vaccination, a trained kākāriki handler will restrain the bird on its back.

The blood collection site (wing vein) will be swabbed with a sterile alcohol wipe immediately prior to collection. Blood will be collected from the wing vein via the pin-prick method where the vein is pricked using a sterile 25 or 26 gauge hypodermic needle, and then the bleb of blood is collected in capillary tubes (also known as haematocrit tubes which can contain 75microlitres of blood).

In the event that the temperature is cool, and on examination of the wing vein we determine that blood collection likely to be slow due to the presence of small contracted veins, the wing will be warmed for 3-5 minutes using Kathmandu hand warmers wrapped in gauze, to boost circulation and enhance blood flow to enable effective blood collection.

After collection, the site of blood collection will be covered with a gauze swab and pressure applied to control any bleeding. In the very unlikely event of uncontrolled bleeding, pressure will be applied for a further 1-5 minutes. If still uncontrolled, an icepack wrapped in gauze swabs will be held on the wing area to cool the limb and reduce blood flow. If required, a silver nitrate stick will be carefully used to stop the bleeding.

Blood will be spun in a centrifuge to separate the serum from the blood cells. The tubes will be kept chilled and transferred ASAP to the commercial laboratory in batches for antibody testing.

1-2 drops of blood will be used to make blood smears which will be sent to a commercial veterinary pathology laboratory for a white cell count and differential. This provides a baseline health analysis which can detect infection or inflammation. Any abnormal results will be further investigated by the veterinarian in consultation with the kākāriki staff.

Once bleeding has stopped, the bird will be vaccinated using a 1mL syringe attached to a 20 gauge ½ inch needle. The vaccination site will be swabbed with a sterile alcohol wipe immediately prior to vaccination. See Appendix 2 for details of the vaccination technique.

The bird will then be checked for any abnormalities and the veterinarian will determine if any further actions are required for health or welfare. Once the procedures are complete the bird will be quietly released and observed as it moves away. Regular observations during routine husbandry will continue for

all birds, and any abnormalities will be reported to the veterinarian. The birds are visited and monitored at least twice daily by staff during routine husbandry.

At subsequent handling events, the vaccination site will be examined and any discolouration, swelling, granuloma formation or unexpected abnormality will be noted and reported to the veterinarian. Photographs of each bird's injection sites will be taken to provide a clear record of the trial.

Location & timing:
The trials will be undertaken using display birds only at the Natureland Wildlife Trust between February 2024 and June 2025

Safety:

Results from a meta-analysis of use of vaccine in European Zoos found very low adverse reaction rate at 0.04% local reactions and 0.015% general reactions reported. EFSA 2007. Based on this, we do not anticipate significant issues with the vaccine, however we will be prepared for immediate veterinary care if any reactions to occur.

The vaccine packaging label states: "Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique."

Anaphylaxis:
A severe immediate immune hypersensitivity response could occur if the vaccine product stimulates such a response. This is considered unlikely due to the extensive use of this vaccine and other similar vaccine products in Europe, however it is possible and needs to be considered as a potential adverse event. The vaccination team will include a veterinarian who will have access to emergency drugs and supportive care for management of anaphylaxis (including corticosteroids, adrenaline, oxygen, fluids).

Injection site reactions:
The vaccine contains an adjuvant (oil) which is present so that it stimulates a stronger immune response with greater antibody production. This can sometimes be associated with a small pea-sized lump at the site of injection. This is normal and expected, although generally not all birds will develop a lump. This will be checked at the 1 month mark, and records kept of any reactions detected. If an excessive size reaction is detected in an individual (>1cm), then the vaccination will be paused until it is determined that the lump does not enlarge further, or cause any impacts on the bird(s) – this is likely to be a period of 2-4 weeks. Body weight, activity levels etc will be reviewed and a full physical examination undertaken.

A localised bacterial infection could result if poor sterile technique is used. Only registered veterinarians will be administering the vaccine, and these operators all have training in appropriate sterile techniques. If a bird experiences an infection at the site, it will receive veterinary care and follow-up to ensure the issue is managed.

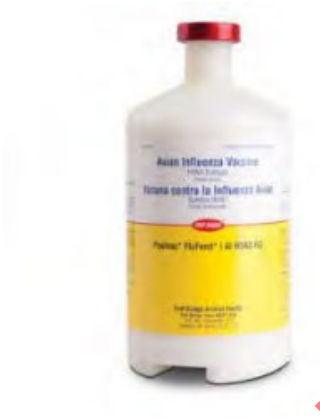
Mis-injection could occur if the bird is poorly restrained and moved during vaccination. This will be managed by only using well trained, experienced kākāriki handlers to restrain the birds. For some individual birds, they are calmer with head cover which can aid in handling. This will be determined on an individual bird basis. If a mis-injection occurs, the veterinarian will determine the appropriate next steps. This may include, re-injection if the first injection merely failed to enter the bird, appropriate first aid measures if any injury was caused, and/or exclusion from the trial and follow-up care. As noted previously, "stressy" birds will not be included in the trial which will reduce the risk of injury or mis-injection.

Injury could occur during capture and handling. This is minimised by only using trained experienced staff, careful selection of trial birds, and a "stop for safety" approach which resets the work programme and ensures time out to reassess and replan the work and procedures if necessary.

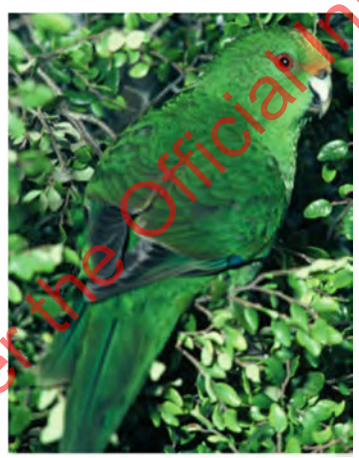
In the event of a serious reaction or injury during the vaccination trial, the bird will be taken to the local veterinary clinic of Rachel Stayner, the veterinarian who provides care for the Natureland animal collection.

Results:
The results of this trial will determine if this vaccine is safe to use in this species, and the level of antibody response produced by a 2 dose vaccination. In some other species, notably penguins, the antibody levels following vaccination remain low and, in some species, a third vaccination was used to ensure a stronger response (ESFA 2007). The duration of antibody presence also varied between species. Therefore, this trial will help to determine the appropriate vaccination regime for kākāriki in the event that more widespread vaccination is required during a highly pathogenic avian influenza outbreak in New Zealand.

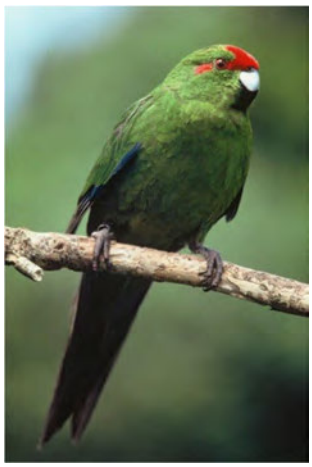
3c. Attach Photos of equipment, the species, the location (or a map); to help set the context.



Vaccine image

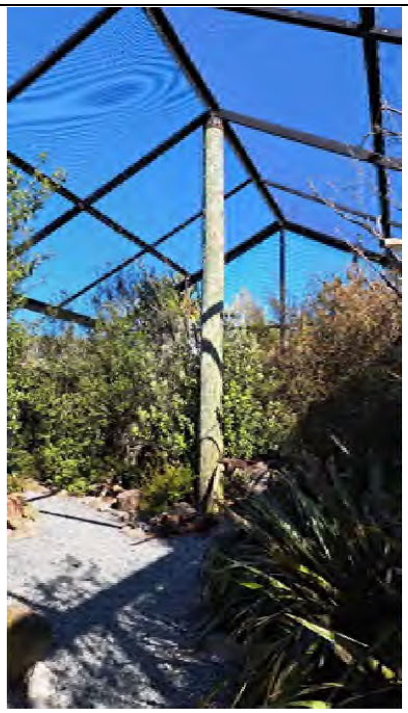


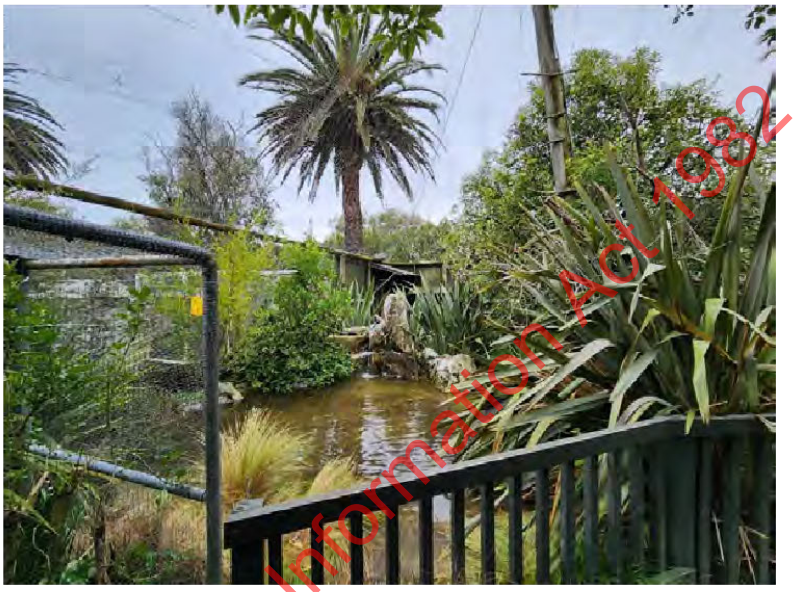
kākāriki karaka (orange-fronted)



red-crowned kākāriki

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāriki





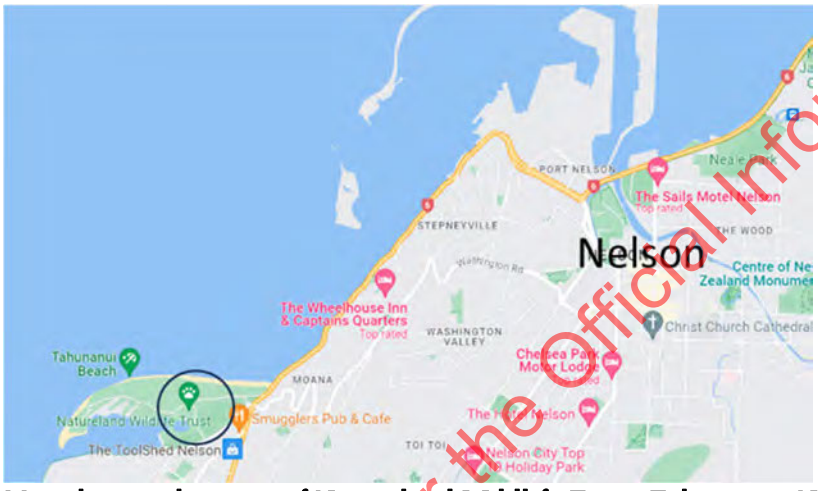
Aviary 1 – males **Aviary 2 - females**

Cage trap – The cage traps are located permanently within the kakariki aviary and birds are fed in the cages daily. The captured bird is accessed via the small sliding side door.

When capture is required, the side of the cage can be closed using the string control

Cage trap open, string control of sliding door.

Cage trap - door closing.



Map showing location of Natureland Wildlife Trust, Tahunanui, Nelson

Aerial view of Natureland Wildlife Trust, Tahunanui, Nelson

3d. References

- *List the references referred to in the application*

DOC-7111177 Mitigation Options Guideline for HPAI
https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-7111177

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4. INVOLVEMENT OF OTHER ANIMAL ETHICS COMMITTEES:

4a. Is this Application; or a related or similar application; been or is being considered by another Animal Ethics Committee. Has this project been requested to be considered by any other AEC?

If so, please provide details.

No

4b. Does this manipulation interact with a manipulation approved by other Animal Ethics Committee? If so, detail your communications with those committee(s), and state any conditions imposed by (an)other AEC.

No

5. JUSTIFICATION FOR PROPOSED MANIPULATION:

5a. Detail any action undertaken to determine that the proposed work has not already been done.

Avian Influenza vaccine efficacy and safety has been undertaken on other avian species, however it has not been undertaken in New Zealand endemic species. Although we expect similar results, it is prudent to undertake this trial to provide more evidence of safety and efficacy in the species which we intend to vaccinate in the event of a HPAI outbreak.

5b. Have alternatives been considered to the proposed manipulation involving reduction, or replacement of live animals, or refinement of techniques?

We are looking at the species-specific response and have selected a minimum size divided into two cohorts, so other methods of reduction are not appropriate for this work.

The cohort approach allows us to cautiously approach the safety issue, and assess initial results before involving the full number of birds.

5c. To what extent has there been assessment of the suitability of using non-sentient or non-living alternatives in the project; or replacement of animals as subjects with suitable non-sentient or non-living alternatives?

N/A, see above

5d. How will the proposed work result in the extension of knowledge relevant to the health, welfare, or conservation of animals?

This work will specifically contribute to the future health of the species for conservation purposes by providing evidence of the safety and efficacy (or not) of this vaccine in this species, and inform the appropriate vaccine schedule for the species. This will determine if the vaccine is employed in the future in the face of an avian influenza outbreak in New Zealand.

5e. Is the manipulation required as part of an approved training programme?

No.

5f. How will the results of this work be made available to staff within and outside DOC? (*For example internal report, journal paper, best practice guide, workshops etc*).

Internal report, journal paper, conference presentations, shared with other captive institutions that hold kākāriki.

6. SELECTION OF SPECIES & NUMBER OF INDIVIDUALS FOR PROPOSED MANIPULATION

6a. What will be the source of the animals to be manipulated, and how many from each source will be manipulated?

Natureland Wildlife Trust was selected for the trial because it is a readily accessible facility willing to participate in the trial to support the work, with experienced staff, and the ability to provide access a total of 10 red-crowned kākāriki at one site.

6b. Will any of the animals involved be used more than once, and if so, how many times will each animal be used?

Only once (but each animal handled/manipulated multiple times – twice for vaccinating and three more times for blood sampling)

6c. What factors have been taken into account in the choice of the animal species?

Kākāriki karaka are one of 5 species identified by the DOC HPAI Technical Advisory Group as at risk where administration of a full vaccination programme is feasible in sufficient number of individuals to provide protection against species extinction. We have selected a suitable surrogate species, red-crowned kakariki, which are approximately twice the size of kākāriki karaka (70-80g vs 30-50g) and are considered by aviculturalists to be a more robust bird to high tolerance of handling stress, making them a better candidate for this trial.

6d. Could the information being sought be obtained by work on some other species?

No. This trial is using the more common surrogate species instead of the nationally critical kakariki karaka.

6e. Will the question be answered with the size of the sample?

Yes.

6f. Is the number of animals proposed to be manipulated the <u>minimum</u> necessary to provide a scientifically interpretable result, consistent with the level of statistical precision required? What consideration has been given to the design of the study with regard to:

- **The level of precision necessary in the results?**

The purpose of the small trial is to establish if there is a species-specific sensitivity to the vaccine and its adjuvant. For this purpose, we require only a small number of birds to extrapolate a species sensitivity. Similarly, for determining vaccine response by antibody response levels, a sample size of 10 will provide sufficient individual variation to establish an overall species response level. Additionally if a bird is removed from the trial for any reason (e.g. other health issues, injury, behavioural), starting with 10 birds allows sufficient number to still be able to make a reasonable conclusion on the vaccine efficacy for future management purposes.

A larger sample size would ensure a more nuanced examination of the species' response to vaccination; however we are examining a general level of impact/effect, rather than subtle differences. Thus, if results which showed >1 bird having a safety issue, or the majority or average antibody response to be low, that would be sufficient to inform the next steps for decision making regarding kākāriki vaccination.

- **The possible confounding effects of animal variation?**

We expect some individual variation since the immune response is affected by individual health status and biological variation. This sample size is sufficient to ensure we have a range of individual responses to examine.

- **The needs of statistical analysis?**

There is likely to be individual variation, which, for the antibody response, requires a reasonable sample size. We determined that 10 was the maximum which was feasible to include in the trial, and also sufficient to allow for individual variation to establish some baseline parameters of antibody response.

Ultimately, in an outbreak situation, the results of a sample size of 10 will be sufficient to make reasonably informed decisions about the use of a commercially produced killed vaccine which has a good history of safety and efficacy across a wide range of species.

7. WELFARE OF ANIMALS DURING PROPOSED MANIPULATION:

7a. What measures will be taken to ensure: the general health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of over-crowding, and prevention and control of disease?

Kākāriki will be caught and handled by experienced staff as per usual kākāriki protocols at Natureland Wildlife Trust where staff already maintain appropriate husbandry practices and monitoring of all the birds. Each bird will be held within its normal enclosure so that there is minimum disturbance to their daily lives. Staff will continue to monitor birds throughout the trial, including food consumption and behaviour.

Each bird will receive a veterinary examination at the start of the trial. Equipment will be disinfected between individuals, or new equipment will be used. Once blood has been collected and vaccination undertaken the bird will be re-released in their home aviary.

7b. What movement and transportation measures will be followed for the animals to be manipulated to ensure their welfare and humane treatment?

Birds will be vaccinated on site, in their aviary where they are captured, therefore there will be no transport required.

However, if a bird requires specialist veterinary care e.g. in the event of an injury or serious reaction, then the bird will be taken to the local veterinary clinic of Rachel Stayner, the veterinarian who provides care for the Natureland animal collection.

Birds will be transported using the standard transport boxes, and in accordance with normal transportation procedures. Briefly, birds will have non-slip flooring the box, be transported via car to the veterinary clinic Transport will be managed to reduce noise and allow for temperature control. Radio will be off and driver/passenger will ensure minimal noise. Travel will be direct and the clinic will be alerted ahead of time to enable a fast hand-over a and rapid care.

Supportive therapy may be provided prior to transport which may include pain relief and fluids by the veterinarian if on site, otherwise the bird will be rapidly transferred to the clinic for immediate vet care.

7c. What measures are to be taken to minimise the pain or distress of any animal manipulated? *Stating there will not be any impact is not acceptable. The AEC is looking for the Applicant to (1) provide analysis about the potential for pain and/or distress to the animal(s), and (2) describe how they will manage that pain or distress. Identify how you would ascertain pain or distress animal's behaviour, environmental conditions likely to lead to pain or distress.*

Birds will be captured and handled by experienced staff using their routine techniques. Only experienced staff will handle the birds. Initial physical examination, vaccination and blood collection will be undertaken by a veterinarian.

Any bird detected to have abnormalities will be examined and rejected from the trial, and receive normal veterinary investigation/intervention.

Subsequent examination and blood collection may be undertaken by staff trained in blood collection from kākāriki, provided the initial results (0,1, and 2-3 month check) are normal across the cohorts.

The subcutaneous injection is not considered painful, and the vaccine dose will be warmed to room temperature prior to injection. Blood collection is associated with a minorly painful pin-prick when the needle is inserted. This will be minimised by careful planning and handling.

If birds are observed to have any pain response to the vaccination, the staff will report it to the veterinarian who will investigate. In the event that there is an injection site reaction (painful inflammation) then an anti-inflammatory such as Metacam may be prescribed by the attending veterinarian, as well as antibiotics if infection is also present.

As noted earlier, if any serious adverse reactions occur, veterinary care by the attending veterinarian will be undertaken, and transfer to local veterinary clinic of Rachel Stanyer undertaken if required for more intensive specialist care.

8. CONTINGENCY PLAN:

8a. What arrangements have been made for the abandonment of any manipulation and/or the euthanasia of animals where pain or distress cannot be held within reasonable levels?

If pain or distress is apparent, during handling or following the procedure, the veterinarian will investigate. If the veterinarian deems the level to be unreasonable, then the manipulation will be abandoned and all efforts made to ameliorate the event e.g. anti-inflammatory, pain relief medication, antibiotics.

In the unlikely event that the pain is not temporary and cannot be managed, transfer to the local veterinary clinic of Rachel Stayner will allow for intensive veterinary intervention and care.

Supportive therapy would be provided during any transport which may include pain relief and fluids.

9. PEOPLE TO UNDERTAKE PROPOSED MANIPULATION:

9a. Who are the person(s) primarily involved in carrying out the proposed manipulation?
Veterinarians Kate McInnes, Lydia Uddstrom and Rachel Stayner are the primary persons.

9b. What is the experience and qualifications of the person primarily responsible (9a) for the undertaking and supervising the manipulation (including selection of animals, their care and disposal?)

Kate McInnes has been the DOC vet since 2000 and has worked across a range of avian species , and is currently the lead technical advisor for the DOC HPAI response.

Lydia Uddstrom is contracted full time to the DOC kākāpō team, has undertaken postgraduate training as a zoo veterinarian and has experience with a wide range of New Zealand native species veterinary care.

Both Kate and Lydia have previously been involved in capture and handling of threatened species undertaking vaccination and blood collection for a range of threatened species, and have trained multiple DOC staff to safely and effectively undertake these procedures.

Rachel Stayner is a local veterinarian in Nelson with post-graduate training in avian medicine, and currently provides veterinary care to the animal collection at Natureland Wildlife Trust. She is also contracted to DOC to assist with the DOC Avian Influenza preparedness and response work.

9c. Who else is in the team undertaking the manipulation? State their role in the team, and their relevant experience with the procedure(s) proposed in the application? Include DOC and non-DOC staff in the team.

Name of Manipulation Team member	*Role in the manipulation*	*Experience and qualifications relevant to the manipulation*
Leah Foster	Team leader for capture, handling and monitoring of birds	Manager and Keeper at Natureland Wildlife Trust. 11 Years at Australia Zoo. 2 years as Wildlife carer for Fauna Rescue North QLD. 6 years as Veterinary Nurse at Belmont Veterinary Hospital. Experience in handling, medicating, and rehabilitation of native Australian Birds.
Alix Rimmer	Assist in capture handling and monitoring of birds	Certificate in Captive Wild Animal Management. Care Team Leader at Natureland Wildlife Trust. 7+ years at Auckland Zoo and Ti Point Reptile Park. Breed for release: Yellow crowned kākāriki, Kiwi, Kākā, Kōkako, Pāteke, Tuatara and rehab. In situ breeding monitoring of wild native birds. Split band banding for 3 years. Safe capture and handling of native and introduced/exotic birds. Mentoring and training Tertiary students for Unitec, Vet Nursing, Animal Care, college students, new staff. Coordinating volunteers.
Claire Daniel	Assist in capture handling and monitoring of birds	Certificate in Captive Wild Animal Management, BSc and Msc in Biological Science. Keeper at Natureland Wildlife Trust. Five years at Birdcare Aotearoa husbandry and medical treatment of wild native, introduced and captive exotic birds. Two years with WIRES (Sydney) rescue, husbandry

		and medical treatment of Australian native birds. Thesis fieldwork including capture, blood sampling, banding and measurements of 100+ Australasian gannets.
Hani Fern	Assist in capture handling and monitoring of birds	Certificate in Captive Wild Animal Management Keeper at Natureland Wildlife Trust. I have experience with safe capture, restraint and handling techniques for native bird species such as Kaka and Red crowned Kakariki for medical treatment, banding and transportation.
Natalie Kerr	Assist in capture handling and monitoring of birds	Diploma in animal Management. Keeper at Natureland Wildlife Trust. 6 years experience in training, handling and restraining birds of prey in England. Trained in administering oral medication and topical treatment.

9d. What training will be given to the people identified in 9c to help them undertake the manipulation proposed in the application?

The capture and handling will be undertaken according to the direction of the team leader.

Vaccination will be undertaken by the DOC veterinarian.

10. COMPLIANCE WITH CONDITIONS of the APPROVAL:

- Please outline any opportunities for a member, or members, of the DOC Animal Ethics Committee to observe this work.

10a. Identify ways that the manipulation(s) can be monitored by the AEC.

AEC members could attend a vaccination session at Nelson to see the procedure in kākāriki and/or receive a video or photographs of the manipulation being undertaken.

11. Are there any other aspects which ought to be brought to the attention of the DOC Animal Ethics Committee?

No

12. Does the research, testing or teaching involve a species which is covered by a Department of Conservation Species Recovery Plan and if so, has the Recovery Group been consulted and their endorsement for the work received? Please provide a summary of communication.

Yes. Kākāriki karaka management is guided by the kākāriki karaka Recovery Group which has been consulted and are supportive of this trial. The use of a surrogate species is acknowledged as a desirable alternative to the additional capture and handling which would be required for the captive kākāriki karaka population.

This application has been discussed with the kākāriki karaka RG at a captive management meeting in August. 2023, and again with the kākāriki karaka captive management coordinator on 15th November 2023.

13. What month of year is most useful to report back to the AEC (depending on the project schedule and the animal's biology)?

September

13. Manipulation Grading

Please work through the document '*Grading of Manipulations*' (Please refer to DOCDM-870472), and determine the grading you believe best applies to the manipulation proposed in this application. Please also provide a rationale for the grading.

Grade A: No impact or virtually no impact.
Grade B: Little impact. Manipulations of minor impact and short duration.
Grade C: Moderate impact. Includes manipulations of minor impact and long duration or moderate impact and short duration.
Grade D: High impact. Includes manipulations of moderate impact and long duration or high impact and short duration.
Grade E: Very high impact. Manipulations of high impact and long duration.

Grading determined by the Applicant: B

Your rationale for the grading:
Grade B includes "**Disease/injury/functional impairment:** Studies of vaccines using killed pathogens." The animals will be kept in their normal husbandry conditions for the duration of the study. There will be capture and handling for blood collection and vaccination, and two doses of a killed vaccine administered. Handling time & stress will be minimised by using only skilled staff and it will be undertaken at site.

Note: The grading determined by the Applicant is not the grading assigned by the AEC. The Applicant will be advised of the AEC's grading and any conditions in writing.

DECLARATION by the APPLICANT

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I declare that the information in this Application is correct; and
[☑] I agree to comply with the conditions imposed by DOC's AEC for the manipulation; and
[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be aware of the contents of this AEC application; and
[☑] I declare the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff
[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application.
[☑] I agree to comply with the reporting requirements stipulated by the AEC on approval of this research project.

9(2)(a) [redacted]

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāriki

Signed by the Applicant _____

Full Name: Catherine McInnes Date: 13/11/2023

DECLARATION by the ACCOUNTABLE MANAGER

Tick boxes [☑] to indicate your agreement to conditions: *[Copy and paste this tick object ☑]*

[☑] I agree to ensure my staff member complies with the conditions imposed by DOC's AEC for this manipulation; and

[☑] I agree to ensure all personnel involved in this manipulation will be properly trained and/or qualified to undertake the manipulation and will be made aware of the contents of this AEC application; and

[☑] I agree the proposed manipulation has the necessary resources to undertake the manipulation with regard to the health and safety of the animals and staff

[☑] I agree to oversee this Application via MORs, PDPs and other means to ensure the manipulation remains within the scope of the Application and the Approval, and all reporting required by the AEC is delivered on time;

[☑] I agree to advise the AEC of any changes in the details of the manipulation as described in this Application, and to advise the AEC if the Applicant leaves the Department, or if the work should be transferred to another staff member for operational reasons' or if the manipulations is abandoned for any reason.

Signed by the Manager: 9(2)(a)

Full Name: John Lyall

Role: Fauna Advice Manager

Date: 17/11 / 2023

Application Number DOCDM	AEC447 APPLICATION DOC-7483661
Applicant	Kate McInnes
Key Words	avian influenza, vaccine, safety, efficacy, kākāriki

Appendix 1: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.
• Use contents of each vial within 6 hours of opening

Appendix 2: General Instructions for subcutaneous injection of vaccine

- The vaccine is supplied in a 500mL bottle and is given to the bird using a needle and syringe.
- The vaccine is injected under the skin but NOT into the muscle below.
- The vaccine should be drawn up into the syringe and then allowed to warm to room temperature (this is more comfortable for the bird).

EQUIPMENT NEEDED

1. Vaccine container
2. 1 mL syringe
3. 25 gauge 5/8th inch needle
4. alcohol swab (mediswab or cotton wool and meths)
5. dry swab (gauze or cotton wool)
6. Sharps container for needle disposal
7. Bird
8. Bird handler
9. Veterinarian

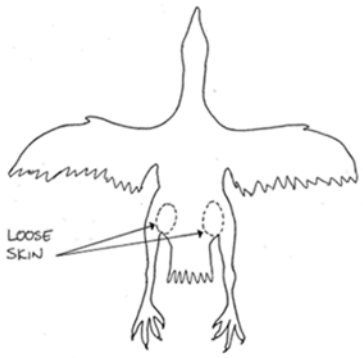
PREPARING THE VACCINATION

1. Store the vaccine in the fridge at 2-8 degrees C in the dark. Do not Freeze.
2. When ready to use, take the vaccine out of the fridge and shake well to mix.
3. Write the date on the vaccine bottle.
4. Break off the metal seal on the top of the rubber injection port.
5. Swab the injection port on the vaccine with alcohol to sterilise it with a mediswab or cotton ball soaked in methylated spirits.
6. Firmly attach the needle to the syringe – 25 gauge 5/8th inch needle to a 1mL syringe.
7. Insert the needle through the centre of the rubber stopper CAREFULLY.
8. Hold the vaccine upside down and slowly suck vaccine into the syringe until you have a little more than the prescribed dose of vaccine.
9. Flick the syringe to dislodge any air bubbles and squirt them slowly back into the vaccine bottle.
10. Keep squirting until all the bubbles are gone and you have the prescribed dose of vaccine left in the syringe.
11. Pull the needle out of the vaccine bottle and CAREFULLY recap the needle.
12. Leave the syringe and needle to warm to room temperature.
13. Repeat this procedure to draw up all the doses you need for your vaccination session.
14. Put the vaccine back in the fridge.
15. Once open, the vaccine can be used for 30 days. (Note that this expiry is based on Zoetis technical advice for limited use of the vaccine in this trial, and only applies when following the above instructions for maintaining sterility of the product and correct storage.)
16. If you are in doubt that the vaccine has been stored correctly (kept refrigerated), then discard it and get a new bottle.

GIVING THE INJECTION

1. Have the following equipment ready for use:
    - The correct dose of vaccine drawn up in syringe with needle attached and warmed to room temperature. (the cap should be on the needle to avoid accidental stabbing or contamination of the needle)
    - One alcohol swab (mediswab or cotton wool in meths)
    - One dry swab (gauze or cotton wool)
2. Have an assistant restrain the bird on its back or side with its legs restrained to provide access to the groin (where the bird's leg joins its belly).

Diagram of ventral (belly) of a bird showing the groin region for subcutaneous vaccination sites:



3. Spread the feathers in the groin area.
4. Wet down the feathers with the swab to clear a patch of skin and swab the skin.
5. Lift the loose skin 1-2cm off the body to make a "tent".

Diagram of the skin being lifted to make a "tent" for a subcutaneous injection

6. Take the cap off the needle and aim the needle about halfway down the side of the tent. Keep the needle parallel to the body wall. When the needle goes through the skin, it should still be above the muscle of the groin i.e. you are injecting into the space inside the tent, not into the muscle.
7. Suck back on the syringe to check for blood. This is to avoid injecting into a blood vessel.
8. Inject the vaccine with a steady firm pressure.
9. Withdraw the needle and place it into the Sharps container.
10. Use the dry swab to press over the injection site if there is any bleeding.
11. Release the bird.

12. Record:	Bird ID	Date	Dose	L or R side	Vaccinator	Holder	Vaccine Batch	Expiry Date	Notes

13. Transfer this data to the vaccination record spreadsheet
14. Note any other specifics about the injection process not described above. E.g. if there was bleeding at the injection site.

Approvals Group
New Zealand Food Safety
Ministry for Primary Industries
Charles Fergusson Building, 34-38 Bowen St, Pipitea
PO Box 2526, Wellington, New Zealand 6140
Tel: 04 894 2550
Email: approvals@mpi.govt.nz

New Zealand Food Safety
Haumaru Kai Aotearoa

Research Approval Product Data Sheet
(or Variation of Existing Research Approval) of Agricultural Chemical or Veterinary Medicine or Vertebrate Toxic Agent
ACVM 5 (July 2021)

- **This form is to be completed by the Applicant or their nominated Agent/Consultant.**
- A research approval, which is an "Approval in special circumstances" with the Director-General, MPI, is required under section 8(C) of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- If you wish to make an application for research approval of an agricultural compound (i.e. agricultural chemical, veterinary medicine or vertebrate toxic agent), under section 10 of the ACVM Act you must fill out this form.
- If the agricultural compound is being imported and it contains an ingredient originating from an organism (such as from a plant, animal, fungus, bacteria, virus), you must also submit the Biosecurity Assessment of ACVMs application form, which is attached as Appendix 1.
- Send the completed application form electronically together with any fee and other required documentation (see section D1 of this form) to the Ministry for Primary Industries at the above email address.
- If there are any changes to the details provided in this application form subsequent to approval, you must inform MPI in writing at the above address.
- Refer to the Privacy Act 2020 and Official Information Act 1982 notices at the end of this form regarding collection of information by MPI.

Processing time is up to 40 working days from the time we determine that your application is complete.

Part A: General Information

Refer to ACVM Information Requirements for Research Approval in New Zealand and the Research Standard

Depending on your product type, use the veterinary medicine, agricultural chemical or vertebrate toxic agent product data sheet guideline (on our website) to help you complete this form.

A1 Trade Name or Company Code of the Product	
Trade Name	**Approval number** (if assigned)
Threatened Native Species HPAI Vaccine Trial	A012074

A2 Applicant Information		
Full Legal Name Registered company name or partnership names (including the trading name) or individual name.		
Ministry for Primary Industries		
Applicant's New Zealand Business Number (NZBN)		
Overseas applicants, provide Companies Act reference number		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Charles Fergusson Tower 34-38 Bowen Street Wellington 6011		
Contact Name	**Tel**	9(2)(a)
	Mobile	9(2)(a)
Grant Matthews	**Email**	Grant.matthews@mpi.govt.nz

A3 New Zealand Agent

Complete only if you have appointed an agent in New Zealand. (This is compulsory for overseas companies.) Any official MPI documents (such as certificates of registration, suspension of registration, prohibition notices, recall notices) will be sent to this person/organisation. Note that a Letter of Authorisation is required.

If you are in New Zealand, you may also nominate an agent to accept service of documents on your behalf.

This agent is only a contact person and is not legally responsible for the product. The responsibility remains with the registrant.

Name of Organisation/Company		
Agent's New Zealand Business Number (NZBN)		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Nominated Contact's Name	**Tel**	
	Mobile	
Is the person named above the primary contact for this product? (delete one) YES NO	**Email**	

A4 Consultant

Complete only if a consultant is managing the application process for you and is the point of contact during the process. Note that a Letter of Authorisation is required.

Name of Organisation/Company		
Consultant's New Zealand Business Number (NZBN) (if applicable)		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Contact Name	**Tel**	
	Mobile	
	Email	

A5 Study

Detailed reason for carrying out this study.

To assess the safety and efficacy of an inactivated avian influenza vaccine on five nationally critically endangered species; kakī/black stilt (*Himantopus novaezelandiae)*, kakariki karaka/orange-fronted parakeet (*Cyanoramphus malherbi*), tūturuatu/shore plover (*Thinornis novaeseelandiae*), kākāpō (*Strigops habroptilus*) and takahē (*Porphyrio hochstetteri*) for use in the protection against extinction from highly pathogenic avian influenza (HPAI).

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain of HPAI has had severe impacts on wild bird populations overseas. It is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia in the southern Atlantic aub-antarctic region in October 2023.

Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and a high mortality rate from HPAI in an endangered species could result in extinction.

Population persistence for the five species in this trial is either dependent on captive rearing, or they are flightless birds undergoing intensive management in a confined area (off-shore island). Protection of captive/confined breeding birds from HPAI morbidity and mortality, and reduction of viral shedding is essential to mitigate against risk of extinction of these species.

Data from commercial vaccine use in other avian species in zoos indicates a high level of safety for use of avian influenza vaccines across a range of avian species, however different species have shown a variable immune response to the vaccine (as measured by antibody titer peak levels and duration). See EFSA 2007 & Vergara-Alert et al 2011.

We aim to determine the safety and efficacy of the vaccine in these five species. We will establish if there are any adverse events associated with vaccination which can be mitigated or which indicate the vaccine is not suitable for use in these species.

We will measure the antibody response (elevation and duration) to a standard vaccine regime. This will determine the effectiveness of the dosage and the duration of expected protection (using antibody titer as a proxy for protection).

The results will inform the species recovery programmes of any safety issues relating to the vaccine which might affect its use in these species, the duration of protective antibody titers which may determine if vaccination is feasible and effective as a protection against HPAI morbidity and mortality, and any the requirements for subsequent booster vaccination to extend the level of protection.

Overall, the results will inform any future use of vaccination to provide a small insurance population against the risk of extinction from HPAI, and the potential for use in birds bred for release into the wild which might be considered at risk in the face of a major mortality event.

References:

EFSA 2007. Vaccination against avian influenza of H5 and H7 subtypes as a preventative measure carried out in Member States in birds kept in zoos under Community approved programmes. ESFA journal, 450. https://doi.org/10.2903/j.efsa.2007.450

Vergara-Alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706 https://europepmc.org/article/PMC/PMC3122527

Anticipated start date (Month and year)	February 2024
Anticipated duration of study (Length)	13 months

A6 Identification of Investigational Product See relevant guideline (as mentioned before question A1).	
Product type	Vaccine
Formulation type	Inactivated virus, oil emulsion
Application/Administration method	Subcutaneous injection
Target species/host For veterinary medicines or VTAs, state animal species. For agricultural chemicals, state target host species.	kakī/black stilt (*Himantopus novaezelandiae)* tūturuatū/shore plover (*Thinornis novaeseelandiae*) kākāpō (*Strigops habroptilus*) takahē (*Porphyrio hochstetteri*) red-crowned parakeet *(Cyanoramphus novaezelandiae novaezelandiae*) (as a surrogate species for kākāriki karaka/orange-fronted parakeet (*Cyanoramphus malherbi))*
Trial design Provide a description of the trial design. State clearly the plot size/number of experimental animals, and justification of dose/ application rate and treatment frequency.	The dose volume and frequency of the vaccine is based on dosages used in Vergara-Alert et al 2011 for a range of avian species, whereby birds <1.5kg will receive 0.2ml per dose and birds >1.5kg will receive 0.5ml per dose of vaccine subcutaneously one month apart to stimulate humoral immunity and antibody production. For each species, ten individuals held at the captive facility/offshore island will be selected for the trial by the lead husbandry expert. Birds will be chosen based on normal behaviour and appearance, and suitability for capture and handling. Bird will be permanently banded with individual identifying leg bands or microchips. The birds will be divided into two cohorts of roughly 5 birds each (this may be cohorts of 4 and 6, depending on the birds available and their aviary distribution e.g. birds in a pair would be kept as a pair during the trial). Cohort 1 commences the trial and if all results/observations are favourable, then one month later cohort 2 commences the trial. This allows initial results from cohort 1 to be received and reviewed, prior to starting cohort 2. Time point: 0 months Each animal receives a physical examination by an experienced wildlife veterinarian. A dose of vaccine of 0.2ml for kākāriki, tūturuatu & kakī, or 0.2-0.5ml for takahē and kākāpō (depending on bodyweight) is delivered by subcutaneous injection in the left groin region. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Tracheal/choanal and cloacal swabs from each bird on day 0 of their vaccine trial. It will be stored in RNAshield, and tested at PacificVet/BioPacifica laboratory Birds are monitored daily as per normal husbandry practices, and any abnormalities are reported to the veterinarian and thoroughly investigated. Time point: 1 month Approximately one month later, the birds are re-examined for any abnormalities. (3-6 weeks is the range to allow for weather conditions to be suitable to capture the birds) If none are detected which indicate a safety issue from the vaccine, the second dose of vaccination is administered at 0.2ml for kākāriki, tūturuatu & kakī, or 0.2-0.5ml for takahē and kākāpō (depending on bodyweight), in the right groin region.

	If any abnormalities are detected, these are documented and thoroughly investigated. The bird may be removed from the trial if its welfare is compromised. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Time point: 2-3 months One to 2 months later, the birds are re-examined for any abnormalities. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Antibody titer results are reviewed. If a species has a low antibody response at the 2-3 month blood sample, the veterinarian may decide to administer a third dose. The birds will receive the same dose as previously given to that species according to the size of the individual bird (either 0.2 or 0.5ml). Time points: 6 months & 12 months If any abnormalities are detected, these are documented and thoroughly investigated. The bird may be removed from the trial if its welfare is compromised. Blood samples are taken for serum antibody titer.
Amount of product State clearly the total amount and unit (i.e. the total to be used in all trial work).	The product is produced in 500ml bottles. Each species will be dosed from a separate bottle. 5 species x 5 bottles = 2500ml total product.
Justification for amount of product Explanation should include full amount needed, taking into consideration trial numbers, design, and application rates, as well as practical considerations (such as overage or container sizes).	The product is supplied in 5 x 500ml bottles = 2500ml total. There will be 30 birds in the trial which will receive two doses each of 0.2ml per dose: 60 doses x 0.2ml = 12 ml. There will be 20 birds in the trial which will receive two doses each of up to 0.5ml per dose (dependent on body weight): 40 doses x 0.5ml = 20 ml. There may be a third dose given to any of the species, based on antibody response results. This additional volume could be up to 16 ml if all 5 species require the third dose: (30 x 0.2ml) + (20 x 0.5ml) = 16 ml Sterile practices will be used to draw up aliquots of 2 mL of vaccine from the main bottle and stored in sterile glass 5 mL vials to enable the product to be broken down into smaller doses. 50 aliquots will be made, with up to 3 birds vaccinated from each vial. The total used as a result of the trial is 2500ml because the five full bottles will be partly used and the remainer is discarded as medical waste at the end of the trial.

A7 Formulation Details See relevant guideline.			
Ingredient Name (Common or Chemical)	**CAS Number**	**Quantity (g/kg or g/L)**	**Function**
See registration data for this product: Poulvac Flufend I AI H5N3 RG (ACVM Reg. No. A009733)			
Specific gravity			
Other information about formulation (for example, overage, isomers)			

Part B: Other Approvals

B1 Biosecurity Approval (only applies to imported products)	
Does the product contain any ingredient of biological (animal, plant, or micro-organism) origin?	☐ ~~No~~ ☐ Yes If yes, you will need a Biosecurity approval. Submit a completed **Biosecurity Assessment of ACVMs** application (appended to this form) with the information you have available. If necessary we will contact you or the manufacturer for further information. Note this incurs a biosecurity processing fee in addition to the fee for processing this research approval application. Both fees will be invoiced together. If you have questions, contact animal.imports@mpi.govt.nz

B2 Importation Approval	
Do you require an Approval to Import for goods being imported under your research approval?	☒ ~~No~~ ☐ Yes
If yes, physical address to which goods must be released from the border	
kākāpō and takahē - 2x 500ml bottles Department of Conservation, Kakapo Recovery Team, Level 7, 33 Don Street, Invercargill, 9810. ATTN Dr Lydia Uddstrom **kakī: 1 x 500ml bottle** Department of Conservation, 15 Wairepo Road, Twizel 7901. ATTN Liz Brown **tūturuatu: 1 x 500ml bottle** Isaac Conservation and Wildlife Trust, Isaac Construction, McArthurs Road, Harewood, Christchurch, 8051 ATTN Anne Richardson/Leigh Percasky **kākāriki: 1 x 500ml bottle** Dr Rachel Stanyer, Nelson Vets - Saxton, 2 Findlay Place, Stoke. 7011	

B3 HSNO Approval HSNO status must be obtained before MPI approval will be issued. (See note at end of form, before appendices.) **Tick one box below.**	
Status of a Substance issued by the EPA or section 26 declaration under the Hazardous Substances and New Organisms Act 1996 **Provide a copy of the approval with your application.**	☐ SOS # ☐ section 26 declaration ☐ EPA Approval Code: HSR
OR Self-determination that the product fits an existing HSNO or group standard approval	☐ EPA Approval Code: ☐ EPA Group Standard: HSR100757
OR Self-determination that the trade name product is non-hazardous	☐
OR EPA generic containment **Provide written confirmation from EPA that your trials**	☐ EPA Approval Code: HSC

have been notified for use under this approval.	

B4 Animal Ethics Committee Approval Animal Ethics Committee approval is required for all animal-based trial work and must be obtained before that trial can commence. A copy of that approval must be provided to the ACVM team. The Animal Ethics Committee approval must remain current for all trials conducted under this approval for the duration of the approval period.		
Has Animal Ethics Committee Approval been obtained? (Put an X next to correct answer and add other information as indicated.)		
✓	Yes	A letter from the chairperson of the AEC or other proof of AEC approval has been provided. AEC Approval Numbers: AEC443 – DOC7522196 AEC444 – DOC7522200 AEC445 – DOC7522201 AEC446 – DOC7522198 AEC447 – DOC7522199.
	No	Attach information on the status of the approval (e.g. a letter from the AEC chairperson that the application is pending or other information on the status of the application).
	Not applicable	

Part C: Security of Product, Place and People

Refer to ACVM Information Requirements for Research Approval in New Zealand

If appropriate, provide references from your research documentation that will enable the following information to be found during an audit.

C1 Personnel	
Name of Study Director	Grant Matthews
Names of personnel involved in the study and their responsibilities	Catherine (Kate) McInnes BVSc DOC Veterinarian, HPAI response work Vet lead Responsible for design and oversight of the trials, Animal Ethics Committee application, delivery of veterinary services including physical examination, vaccination and blood collection and records pertaining to this, adverse event investigation, collating and reporting data. Lydia Uddstrom, BVSc DOC veterinarian (kakapo team), assisting with HPAI vaccination trial Assist with design and oversight of the trials, Animal Ethics Committee application, delivery of veterinary services including physical examination, vaccination and blood collection and records pertaining to this, adverse event investigation, collating and reporting data. The site lead will be responsible for the product while stored at the site, direct staff for catching, handling, monitoring & follow-up blood collection at 2-3, 6 & 12 months post vaccination. Site leads: Kakī: DOC Twizel breeding centre, Liz Brown Tūturuatu: Isaacs Conservation and Wildlife Trust, Christchurch. Anne Richardson Kākāriki: Natureland Wildlife Trust, Leah Foster, Manager (on site activities), Dr Rachel Stanyer (veterinarian responsible for product storage) Takahē: Burwood Takahē Centre: James Bohan Kākāpō: Whenua Hou/Codfish Island: Petrus Hedman

C2 Site
Identify the study location/site, the method used to select it, and the means by which access to it is limited.

Kaki: Department of Conservation Twizel breeding centre. This is a purpose-built site for captive breeding of kakī, operated by the Department of Conservation at 6199 Tekapo-Twizel Road, Pukakai, 7999. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. The site is surrounded by an electric fence, and security swipe pass is needed to enter the grounds. Only persons authorised by DOC are permitted to enter the site.

Tūturuatu: Isaacs Conservation and Wildlife Trust, Christchurch. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. The site is surrounded by a security fence and security swipe pass is needed to enter the grounds. Only persons authorised by Isaacs Construction are allowed to enter the site, via security sign in at the front office.

Kākāriki: Natureland Wildlife Trust, Nelson. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. It is a Zoo and Aquarium Association (ZAA) accredited facility. The site is surrounded by a security fence and meets MPI zoo containment requirements.

Takahē: Burwood Takahē Centre: holds takahē in enclosures for breeding. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. It is located at 3860 Te Anau-Mossburn Highway, Centre Hill. Only persons authorised by DOC are permitted to enter the site. The site is not marked and not widely known. There are DOC rangers living on-site to monitor people accessing the location.

Kākāpō: Whenua Hou/Codfish Island: is a 1396 ha island located 3km off the north-west coast of Rakiura/Stewart Island. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff available to work on site. Whenua Hou is a nature reserve under the Reserves Act 1977 – access is by permit only. There is no public access to this site.

C3 Security	
Give assurance that persons who have access to the product are suitably qualified or trained to use it and that they have had any conditions specified on the research approval given to them in writing	The product will only be directly handled and administered by a registered veterinarian. This will be either Dr Catherine (Kate) McInnes BVSc or Dr Lydia Uddstrom BVSc or Dr Rachel Stanyer who are all employed by the Department of Conservation. Access to the product by other staff only relates to the storage in the refrigerator at the captive facility. See below for more details.

Measures implemented to limit access to the investigational product	This process is outlined in the document: "SOP for receiving, storing and access to Poulvac Flufend vaccine DOC-7521640" which will be provided to the veterinarians and site leads for all species/sites. The product will be delivered via courier from the supplier to the facility, or it will be directly collected from the supplier by the veterinarian. If delivered by courier, the local DOC ranger/ facility staff member will receive the package and store it in the captive facility refrigerator in a closed container which is clearly labelled "Veterinary Access Only – keep refrigerated" in accordance with the SOP. If collected form the facility, the Veterinarian will maintain the cold chain until it is delivered to the captive facility where it will be stored. The refrigerator at the facility has access limited to authorised staff only. All staff will be made aware of the restricted access to the vaccine.
Measures implemented to limit off-target exposure to the investigational product by animals or plants	The vaccine will be administered by the veterinarian directly to the test subject only. Care will be taken in all handling of the product to ensure no spillage, breakage or contamination of the environment occurs. Used needles and syringes will be disposed of directly into Sharps containers for disposal via medical waste. If a bird dies, it will be detected by staff and collected immediately. It will be double bagged and chilled, then sent for necropsy examination at Massey University (takahē, kakariki, kakī & tūturuatu) or Auckland Zoo (kākāpō). Its remains will be disposed of via medical waste or held frozen for genetic, cultural or conservation purposes. Bodies will not enter the food chain.

Describe the method of disposal of any unused investigational product	Any unused product will be disposed of by placing in a medical waste container for disposal by a commercial medical waste company. Disposal will be recorded by the veterinarian in a shared document record in the DOC Document Content system, which will also be used to record delivery of the vaccine, and all use of the vaccine including vet ID, animal ID, date, dose given, injection site, and any relevant notes. "HPAI vaccination safety and efficacy trial VACCINE USE DOCCM-7521354" A stock audit (similar to the controlled drug register audit) will be undertaken each time the vaccine is accessed – that is monthly for 3 months. Once the final audit is complete, the disposal will occur.

C4 Residues

Describe how residues in treated crops/animals will be managed, including animal transfer if crops are to be used as animal feed.

The animals receiving the vaccine will not enter the food chain.

Site residues

Describe measures implemented to ensure that the study site(s) are free from residues that might compromise further use of the site(s), including the period of time for which the site will remain secure to avoid residues affecting its further use.

In addition, for agricultural chemicals only, discuss management of potential residues in soil and subsequent crops.

There will be no site residues. The vaccine is administered directly into the bird and is not excreted via urine/urates or faeces.

C5 Approval for Sale of Treated Produce or Declaration

If you do not seek an approval for sale* of treated produce (animal or plant matter), you must indicate YES in the declaration below and confirm by your signature (section D2).

*Definition of 'sale' under the ACVM Act:

Sale includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes—

(a) delivering or disposing of by way of gift, loan, or otherwise; and

(b) giving or distributing, in the course of business, as a sample or otherwise, without charge

Will the treated crop/animals be destroyed? (Put an X next to correct answer.)	Yes	
	No	X
I confirm that the treated plants or animals or their produce will NOT be sold or used for human/ animal consumption or enter the food chain at any time. (Put an X next to correct answer.)	Yes	X
	No	

If NO, provide information to support sale

Part D: Documentation, Applicant Statement and Payment

D1 Additional Documentation Requirements

Provide electronic copies of the following documents with this application:

- Letter of authorisation for agent/consultant (if applicable)
- Letter of consent (Confidential Supporting Information) (if applicable)
- Biosecurity assessment application if a product being imported contains an ingredient of biological origin
- Status of substance (SOS) advice or non-hazardous declaration from EPA (if applicable)
- Animal Ethics Committee approval documentation (if applicable)
- Request for import approval (if applicable)
- Existing import approval if application is for a variation

D2 Applicant Statement

I confirm that:

- I am authorised to make this application as the applicant OR a person with legal authority to act on behalf of the applicant noted in section A2; and
- the information supplied in and with this application is truthful and accurate to the best of my knowledge; and
- I understand that any change to the information provided in this application must go through MPI's 'variation' process or I will be in breach of the research approval conditions.

Name	Grant Matthews	**Tel**	9(2)(a)
		Email	Grant.matthews@mpi.govt.nz
Signature	9(2)(a)	**Date**	13/12/23

D3 MPI Service Charge

ON PAYMENT THIS BECOMES A TAX INVOICE GST No: 64-558-838

APPLICATION FEE: Refer to schedule of fees on website.

PAYMENT OPTIONS:

Payments comprising multiple fees must be supported by a remittance advice. Please attach your payment confirmation to this application or send it separately to: **approvals@mpi.govt.nz**

MPI does not accept cash. Payment must be made using **credit/debit card or direct credit**. (Please mark your choice with an X and fill in the appropriate section.)

APPROVED CREDITOR ☒ MPI Cost Centre 1935

CREDIT /DEBIT CARD (preferred option): ☐

Go to https://www.mpi.govt.nz/food-safety/payments and follow the instructions.

☐ I have attached my credit card payment receipt

DIRECT CREDIT ☐

1. Pay into Bank Account no. **03 0049 0001709 002**
2. In the 'Reference' details, put the code: **RESAPP**
3. Enter the date of deposit and the payer name on this form below:

Date of Deposit		**Payer Name**	

Collection of Information

Collection of Personal Information

Pursuant to Principle 3 of the Privacy Act 2020, we advise that:

1. This information is being collected for the purpose of approval in special circumstances (research) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997; and
2. The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, Wellington 6140; and
3. The collection of information is authorised under section 10 of the ACVM Act; and
4. The provision of this information is necessary in order to process this application; and
5. The supply of this information is voluntary; and
6. Failure to provide the requested information is likely to result in a return of the application form to the applicant, and in accordance with the ACVM Act, may ultimately result in a refusal of this application; and
7. Under Principles 6 and 7 of the Privacy Act 2020, you have the right of access to, and correction of, any personal information which you have provided.

Collection of Official Information

All information provided to the Ministry for Primary Industries is official information and may be subject to a request made under the Official Information Act 1982.

If a request is made under that Act for information you have provided in this application, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation.

Note on HSNO Approval

Section 21(5) of the ACVM Act states: "Where a trade name product contains an agricultural compound that is also a hazardous substance or new organism, the Director-General must not register that product under this section, unless an approval for that substance or organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996".

Hazardous substances or new organisms

If your product contains a hazardous substance or a new organism, or if you are unsure whether it does, contact the Environmental Protection Authority (http://www.epa.govt.nz/). EPA NZ will provide informal advice, based on information provided, on whether or not a substance is hazardous and/or whether it is covered by an existing approval. If you choose this option, provide a status of substance (SOS) number, or section 26 declaration, and the EPA approval code on the PDS, and attach a copy of the SOS letter.

If you have self-determined that the product matches an existing substance, you must provide the HSNO number and ensure that you have filled out Section B2. Your signature on this form serves as confirmation.

Alternatively, you may make the determination that a product may be assigned to a group standard approval. If you have self-determined that a product fits a group standard, MPI will require evidence of the determination process to justify the use of the group standard. If you choose this option, provide the reference number of the group standard.

Non-hazardous substances

MPI will accept a declaration if you have self-determined that the agricultural compound you wish to register is not a hazardous substance*. We may require you to provide a technical argument why the ingredients in the product are non-hazardous to support your declaration. If MPI is not certain that the determination is correct, we will advise you to obtain a determination by EPA NZ.

* For a product to be considered non-hazardous, it must either contain no hazardous substances as defined under the HSNO Act OR contain a hazardous substance at a low enough level that the product as a whole is considered non-hazardous.

Appendix 1

Biosecurity Assessment of Agricultural Compounds or Veterinary Medicines (ACVMs) Application Form for Research Approval

- If the agricultural compound contains an ingredient of a biological (animal, plant, or micro-organism) origin, this information is required by the Biosecurity Act 1993 to undertake a risk assessment for biosecurity approval. Provide as much information requested in the form as you have. We will contact you if we need further information.
- Time for assessment: If all the information requirements are met, then the assessment will be processed within the timeframe of the ACVM process.
- Cost of assessment: NZ$117.61 (inc GST) per hour. The fee will be invoiced in conjunction with the ACVM charges.
- If you have questions about this biosecurity assessment, contact animal.imports@mpi.govt.nz

1. Trade Name or Company Code of the Product	
Trade name	**Poulvac Flufend i AI H5N3 RG**
Approval number (if assigned)	Registration number A009733
List countries where product is registered	New Zealand,

2. Manufacturer(s) of the Formulated Product

Complete for all manufacturers

Company name	Site address

3. Is your product a vaccine?

☐ No
☒ Yes

If yes, skip section 4 below and complete the information requirements outlined in Appendix 2. Ensure you take note of section 5 and complete the Applicant Statement (section 6).

4. If your product is not a vaccine but contains ingredients of bacterial, fungal, viral, plant or animal origin

For products containing live organisms provide:

- systematic name and strain of the bacteria, protozoa, fungi, rickettsia, nematode or virus and the taxonomic description of the agent, serotype, strain or mutant;
- common name or alternative and superseded names;
- composition of the unformulated material, microbiological purity, nature and identity of any culture media, impurities and content of extraneous organisms.

For processed products provide:

Origin of the ingredient(s) of plant and animal origin

Complete for each ingredient (raw material) and for each manufacturer if more than one manufacturer:

Identify the raw materials used, the species and country of origin. Include health certification referring to disease country freedom and herd or flock of origin disease testing.

Describe the manufacturing processes for preparing the product.

Briefly outline the processes designed to render the product(s) sterile (e.g. heat treatment, filtration, acid or alkali treatment, irradiation, long term maturation etc). Include relevant parameters (e.g. temperature, pH level, radiation dose) and the time the product is maintained at these levels.

Each major step in the production process should be shown in a flow-chart diagram.
Each step on the flowchart should be cross-referenced to the application, which should contain details of the materials used and results of any tests conducted.

Describe the operational environment, quality systems and controls used for manufacturing. The manufacturer's GMP may include SOPs and/or specifications of the approved source, sterilisation procedure (if applicable) and pathogen testing applied to each product.

Expert opinion

If available, the applicant shall provide an opinion on the likelihood of the product containing associated organisms from an independent expert authority who is familiar with the manufacturing process. Include the following information:
Name:
Postal address:
Street address (if different from above):
Tel:
E-mail:

5. Confidential Information

If information is confidential, please ensure that you have contacted the manufacturer/supplier to arrange for information to be supplied to us directly.

6. Applicant Statement

I confirm that the information supplied in and with this application for biosecurity assessment is truthful and accurate to the best of my knowledge.

Name	Grant Matthews	**Tel**	9(2)(a)
Job Title	Manager Animal Disease Team (Acting)	**Email**	Grant.matthews@mpi.govt.nz
Signature	9(2)(a)	**Date**	13/12/23

Appendix 2
Additional Information Required for a Biosecurity Assessment of a Veterinary Vaccine

- Information identified below is additional to that required in the Application for Biosecurity Assessment of Agricultural Compounds or Veterinary Medicines (Appendix 1).
- Provide information in a format consistent with these requirements or as a summary document cross-referenced to registration dossiers and/or drug master files which should also be submitted.
- Provide the information you have available. If necessary we will contact you or the manufacturer for further information.
- If you have questions about this biosecurity assessment, contact animal.imports@mpi.govt.nz.

Additional information required for products that are veterinary vaccines
Materials of biological origin Provide detailed information on all components of biological origin used directly or indirectly in production of the vaccine. Such components include viral/bacterial seeds, cell lines, trypsin, nutritive factors (e.g. serum), fermentation broths/culture media and excipients. List every ingredient of animal origin contained in or used in the production of the product, the country and species of origin, approximate date of collection if available, processing/treatment and testing specified.
Testing standards MPI will normally accept procedures to test for pathogens that are specified in the Code of Federal Regulations (9CFR 113) or other standards. Submit details of all testing protocols with the application.
Certification and audit trails Provide information to show that an audit trail can track the country, species and date of origin of each product of animal origin used in production of the vaccine. Such audits should be able to correlate batches of finished product with all raw ingredients.
Other pathogens held and vaccines produced at the facility List of all pathogens held and vaccines produced within the vaccine manufacturing facility. List of other activities on the same site (e.g. vaccine research involving challenge trials, veterinary pathology and diagnostic services) and on neighbouring sites (e.g. intensive livestock production, abattoirs, animal research facilities).
Sterilisation of components of animal origin Sterilisation procedures must be validated. Submit a copy of the appropriate SOP with the application.
Master seeds (virus, bacteria and cells) A well-documented history of the master seed must be made available. Provide the origin, date of isolation, passage history, reversion to virulence, purity and identity confirmation studies. Provide details of cell lines and nutritive media used for the transport, storage and propagation of the master seed. For master seeds created many years ago, detailed information on the initial nutritive factors used may not be available. In this situation, it may be possible in some circumstances to establish the safety of the master seed by additional testing and a history of safe use over many years in live vaccines. Frequent use and extensive pathogen testing over many years in research laboratories and inactivated vaccine manufacture may also provide an additional level of biosecurity confidence. Provide details of the testing methods used to establish freedom from contamination by bacteria, fungi, mycoplasma, viruses and pathogens.
Working and production seeds (virus, bacteria and cells) Describe the tests used to identify potential pathogens in working and production seeds.

Nutritive factors Nutritive factors include serum, foetal serum, serum albumin and other serum products. Detail the country and species of origin, processing and/or any pathogen testing.
Trypsin and other enzymes of animal origin Provide details on the country of origin, species of origin, processing and any pathogen testing.
Fermentation broths and culture media List all ingredients used in the fermentation broth/production culture media in the import application. Specify country and species of origin of each ingredient of biological origin along with details of any processing, treatments or testing of either the ingredients or the final culture media/fermentation broth.
Final product testing – live vaccines Describe the testing used on live vaccines.

Approvals Group
New Zealand Food Safety
Ministry for Primary Industries
Charles Fergusson Building, 34-38 Bowen St, Pipitea
PO Box 2526, Wellington, New Zealand 6140
Tel: 04 894 2550
Email: approvals@mpi.govt.nz

New Zealand Food Safety
Haumaru Kai Aotearoa

Research Approval Product Data Sheet
(or Variation of Existing Research Approval) of Agricultural Chemical or Veterinary Medicine or Vertebrate Toxic Agent
ACVM 5 (July 2021)

- **This form is to be completed by the Applicant or their nominated Agent/Consultant.**
- A research approval, which is an "Approval in special circumstances" with the Director-General, MPI, is required under section 8(C) of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- If you wish to make an application for research approval of an agricultural compound (i.e. agricultural chemical, veterinary medicine or vertebrate toxic agent), under section 10 of the ACVM Act you must fill out this form.
- If the agricultural compound is being imported and it contains an ingredient originating from an organism (such as from a plant, animal, fungus, bacteria, virus), you must also submit the Biosecurity Assessment of ACVMs application form, which is attached as Appendix 1.
- Send the completed application form electronically together with any fee and other required documentation (see section D1 of this form) to the Ministry for Primary Industries at the above email address.
- If there are any changes to the details provided in this application form subsequent to approval, you must inform MPI in writing at the above address.
- Refer to the Privacy Act 2020 and Official Information Act 1982 notices at the end of this form regarding collection of information by MPI.

Processing time is up to 40 working days from the time we determine that your application is complete.

Part A: General Information

Refer to ACVM Information Requirements for Research Approval in New Zealand and the Research Standard

Depending on your product type, use the veterinary medicine, agricultural chemical or vertebrate toxic agent product data sheet guideline (on our website) to help you complete this form.

A1 Trade Name or Company Code of the Product	
Trade Name	**Approval number** (if assigned)
Threatened Native Species HPAI Vaccine Trial	A012074

A2 Applicant Information		
Full Legal Name Registered company name or partnership names (including the trading name) or individual name.		
Ministry for Primary Industries		
Applicant's New Zealand Business Number (NZBN)		
Overseas applicants, provide Companies Act reference number		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Charles Fergusson Tower 34-38 Bowen Street Wellington 6011		
Contact Name	**Tel**	9(2)(a)
	Mobile	9(2)(a)
Grant Matthews	**Email**	Grant.matthews@mpi.govt.nz

A3 New Zealand Agent Complete only if you have appointed an agent in New Zealand. (This is compulsory for overseas companies.) Any official MPI documents (such as certificates of registration, suspension of registration, prohibition notices, recall notices) will be sent to this person/organisation. Note that a Letter of Authorisation is required. If you are in New Zealand, you may also nominate an agent to accept service of documents on your behalf. This agent is only a contact person and is not legally responsible for the product. The responsibility remains with the registrant.		
Name of Organisation/Company		
Agent's New Zealand Business Number (NZBN)		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Nominated Contact's Name	**Tel**	
	Mobile	
Is the person named above the primary contact for this product? (delete one) YES NO	**Email**	

A4 Consultant Complete only if a consultant is managing the application process for you and is the point of contact during the process. Note that a Letter of Authorisation is required.		
Name of Organisation/Company		
Consultant's New Zealand Business Number (NZBN) (if applicable)		
Street/Physical Address (for service)	**Postal Address** (for communication)	
Contact Name	**Tel**	
	Mobile	
	Email	

A5 Study

Detailed reason for carrying out this study.

To assess the safety and efficacy of an inactivated avian influenza vaccine on five nationally critically endangered species; kakī/black stilt (*Himantopus novaezelandiae)*, kakariki karaka/orange-fronted parakeet (*Cyanoramphus malherbi*), tūturuatu/shore plover (*Thinornis novaeseelandiae*), kākāpō (*Strigops habroptilus*) and takahē (*Porphyrio hochstetteri*) for use in the protection against extinction from highly pathogenic avian influenza (HPAI).

Avian influenza is a viral disease which can cause mass mortality events in birds. The current strain of HPAI has had severe impacts on wild bird populations overseas. It is predicted to reach the Southern Ocean by 2024/25 and was confirmed in South Georgia in the southern Atlantic aub-antarctic region in October 2023.

Population size is a key factor which can mitigate against extinction due to disease, however where the population is already low, has low genetic diversity or recovery is slow, a disease outbreak could have a significant impact, including loss of genetic diversity, and a high mortality rate from HPAI in an endangered species could result in extinction.

Population persistence for the five species in this trial is either dependent on captive rearing, or they are flightless birds undergoing intensive management in a confined area (off-shore island). Protection of captive/confined breeding birds from HPAI morbidity and mortality, and reduction of viral shedding is essential to mitigate against risk of extinction of these species.

Data from commercial vaccine use in other avian species in zoos indicates a high level of safety for use of avian influenza vaccines across a range of avian species, however different species have shown a variable immune response to the vaccine (as measured by antibody titer peak levels and duration). See EFSA 2007 & Vergara-Alert et al 2011.

We aim to determine the safety and efficacy of the vaccine in these five species. We will establish if there are any adverse events associated with vaccination which can be mitigated or which indicate the vaccine is not suitable for use in these species.

We will measure the antibody response (elevation and duration) to a standard vaccine regime. This will determine the effectiveness of the dosage and the duration of expected protection (using antibody titer as a proxy for protection).

The results will inform the species recovery programmes of any safety issues relating to the vaccine which might affect its use in these species, the duration of protective antibody titers which may determine if vaccination is feasible and effective as a protection against HPAI morbidity and mortality, and any the requirements for subsequent booster vaccination to extend the level of protection.

Overall, the results will inform any future use of vaccination to provide a small insurance population against the risk of extinction from HPAI, and the potential for use in birds bred for release into the wild which might be considered at risk in the face of a major mortality event.

References:

EFSA 2007. Vaccination against avian influenza of H5 and H7 subtypes as a preventative measure carried out in Member States in birds kept in zoos under Community approved programmes. ESFA journal, 450. https://doi.org/10.2903/j.efsa.2007.450

Vergara-Alert J, Ferhandez-Bellon H, Busquets B, Alcantara G, Delclaux M, Pizarro B, Sandchez C, Sanchez A, Majo N, Darju A. Comprehensive serological analysis of two successive heterologous vaccines against H5N1 Avian Influenza virus in exotic birds in zoos. Clinical and Vaccine Immunology, 2011. P. 697-706 https://europepmc.org/article/PMC/PMC3122527

Anticipated start date (Month and year)	February 2024
Anticipated duration of study (Length)	13 months

A6 Identification of Investigational Product See relevant guideline (as mentioned before question A1).	
Product type	Vaccine
Formulation type	Inactivated virus, oil emulsion
Application/Administration method	Subcutaneous injection
Target species/host For veterinary medicines or VTAs, state animal species. For agricultural chemicals, state target host species.	kakī/black stilt (*Himantopus novaezelandiae)* tūturuatū/shore plover (*Thinornis novaeseelandiae*) kākāpō (*Strigops habroptilus*) takahē (*Porphyrio hochstetteri*) red-crowned parakeet *(Cyanoramphus novaezelandiae novaezelandiae*) (as a surrogate species for kākāriki karaka/orange-fronted parakeet (*Cyanoramphus malherbi))*
Trial design Provide a description of the trial design. State clearly the plot size/number of experimental animals, and justification of dose/ application rate and treatment frequency.	The dose volume and frequency of the vaccine is based on dosages used in Vergara-Alert et al 2011 for a range of avian species, whereby birds <1.5kg will receive 0.2ml per dose and birds >1.5kg will receive 0.5ml per dose of vaccine subcutaneously one month apart to stimulate humoral immunity and antibody production. For each species, ten individuals held at the captive facility/offshore island will be selected for the trial by the lead husbandry expert. Birds will be chosen based on normal behaviour and appearance, and suitability for capture and handling. Bird will be permanently banded with individual identifying leg bands or microchips. The birds will be divided into two cohorts of roughly 5 birds each (this may be cohorts of 4 and 6, depending on the birds available and their aviary distribution e.g. birds in a pair would be kept as a pair during the trial). Cohort 1 commences the trial and if all results/observations are favourable, then one month later cohort 2 commences the trial. This allows initial results from cohort 1 to be received and reviewed, prior to starting cohort 2. Time point: 0 months Each animal receives a physical examination by an experienced wildlife veterinarian. A dose of vaccine of 0.2ml for kākāriki, tūturuatu & kakī, or 0.2-0.5ml for takahē and kākāpō (depending on bodyweight) is delivered by subcutaneous injection in the left groin region. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Tracheal/choanal and cloacal swabs from each bird on day 0 of their vaccine trial. It will be stored in RNAshield, and tested at PacificVet/BioPacifica laboratory Birds are monitored daily as per normal husbandry practices, and any abnormalities are reported to the veterinarian and thoroughly investigated. Time point: 1 month Approximately one month later, the birds are re-examined for any abnormalities. (3-6 weeks is the range to allow for weather conditions to be suitable to capture the birds) If none are detected which indicate a safety issue from the vaccine, the second dose of vaccination is administered at 0.2ml for kākāriki, tūturuatu & kakī, or 0.2-0.5ml for takahē and kākāpō (depending on bodyweight), in the right groin region.

	If any abnormalities are detected, these are documented and thoroughly investigated. The bird may be removed from the trial if its welfare is compromised. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Time point: 2-3 months One to 2 months later, the birds are re-examined for any abnormalities. Blood samples are taken for a blood smear for white cell count and differential, and serum antibody titer. Antibody titer results are reviewed. If a species has a low antibody response at the 2-3 month blood sample, the veterinarian may decide to administer a third dose. The birds will receive the same dose as previously given to that species according to the size of the individual bird (either 0.2 or 0.5ml). Time point: 10-14 weeks Blood sample taken for serum antibody titre Time points: 6 months & 12 months If any abnormalities are detected, these are documented and thoroughly investigated. The bird may be removed from the trial if its welfare is compromised. Blood samples are taken for serum antibody titer. Time point: up to 12 months from last vaccination Up to two opportunistic blood samples within a 12 month period - taken during routine handline for serum antibody titres
Amount of product State clearly the total amount and unit (i.e. the total to be used in all trial work).	The product is produced in 500ml bottles. Each species will be dosed from a separate bottle. 5 species x 5 bottles = 2500ml total product.

Justification for amount of product Explanation should include full amount needed, taking into consideration trial numbers, design, and application rates, as well as practical considerations (such as overage or container sizes).	The product is supplied in 5 x 500ml bottles = 2500ml total. There will be 30 birds in the trial which will receive two doses each of 0.2ml per dose: 60 doses x 0.2ml = 12 ml. There will be 20 birds in the trial which will receive two doses each of up to 0.5ml per dose (dependent on body weight): 40 doses x 0.5ml = 20 ml. There may be a third dose given to any of the species, based on antibody response results. This additional volume could be up to 16 ml if all 5 species require the third dose: (30 x 0.2ml) + (20 x 0.5ml) = 16 ml Sterile practices will be used to draw up aliquots of 2 mL of vaccine from the main bottle and stored in sterile glass 5 mL vials to enable the product to be broken down into smaller doses. 50 aliquots will be made, with up to 3 birds vaccinated from each vial. The total used as a result of the trial is 2500ml because the five full bottles will be partly used and the remainer is discarded as medical waste at the end of the trial.

A7 Formulation Details See relevant guideline.			
Ingredient Name (Common or Chemical)	**CAS Number**	**Quantity (g/kg or g/L)**	**Function**
See registration data for this product: Poulvac Flufend I AI H5N3 RG (ACVM Reg. No. A009733)			
Specific gravity			
Other information about formulation (for example, overage, isomers)			

Part B: Other Approvals

B1 Biosecurity Approval (only applies to imported products)	
Does the product contain any ingredient of biological (animal, plant, or micro-organism) origin?	☐ ~~No~~ ☐ Yes If yes, you will need a Biosecurity approval. Submit a completed **Biosecurity Assessment of ACVMs** application (appended to this form) with the information you have available. If necessary we will contact you or the manufacturer for further information. Note this incurs a biosecurity processing fee in addition to the fee for processing this research approval application. Both fees will be invoiced together. If you have questions, contact animal.imports@mpi.govt.nz

B2 Importation Approval	
Do you require an Approval to Import for goods being imported under your research approval?	☒ ~~No~~ ☐ Yes
If yes, physical address to which goods must be released from the border	
kākāpō and takahē - 2x 500ml bottles Department of Conservation, Kakapo Recovery Team, Level 7, 33 Don Street, Invercargill, 9810. ATTN Dr Lydia Uddstrom **kakī: 1 x 500ml bottle** Department of Conservation, 15 Wairepo Road, Twizel 7901. ATTN Liz Brown **tūturuatu: 1 x 500ml bottle** Isaac Conservation and Wildlife Trust, Isaac Construction, McArthurs Road, Harewood, Christchurch, 8051 ATTN Anne Richardson/Leigh Percasky **kākāriki: 1 x 500ml bottle** Dr Rachel Stanyer, Nelson Vets - Saxton, 2 Findlay Place, Stoke. 7011	

B3 HSNO Approval HSNO status must be obtained before MPI approval will be issued. (See note at end of form, before appendices.) **Tick one box below.**	
Status of a Substance issued by the EPA or section 26 declaration under the Hazardous Substances and New Organisms Act 1996 **Provide a copy of the approval with your application.**	☐ SOS # ☐ section 26 declaration ☐ EPA Approval Code: HSR
OR Self-determination that the product fits an existing HSNO or group standard approval	☐ EPA Approval Code: ☐ EPA Group Standard: HSR100757
OR Self-determination that the trade name product is non-hazardous	☐
OR EPA generic containment **Provide written confirmation from EPA that your trials**	☐ EPA Approval Code: HSC

have been notified for use under this approval.	

B4 Animal Ethics Committee Approval Animal Ethics Committee approval is required for all animal-based trial work and must be obtained before that trial can commence. A copy of that approval must be provided to the ACVM team. The Animal Ethics Committee approval must remain current for all trials conducted under this approval for the duration of the approval period.		
Has Animal Ethics Committee Approval been obtained? (Put an X next to correct answer and add other information as indicated.)		
✓	Yes	A letter from the chairperson of the AEC or other proof of AEC approval has been provided. AEC Approval Numbers: AEC443 – DOC7522196 AEC444 – DOC7522200 AEC445 – DOC7522201 AEC446 – DOC7522198 AEC447 – DOC7522199.
	No	Attach information on the status of the approval (e.g. a letter from the AEC chairperson that the application is pending or other information on the status of the application).
	Not applicable	

Part C: Security of Product, Place and People

Refer to ACVM Information Requirements for Research Approval in New Zealand

If appropriate, provide references from your research documentation that will enable the following information to be found during an audit.

C1 Personnel	
Name of Study Director	Grant Matthews
Names of personnel involved in the study and their responsibilities	Catherine (Kate) McInnes BVSc DOC Veterinarian, HPAI response work Vet lead Responsible for design and oversight of the trials, Animal Ethics Committee application, delivery of veterinary services including physical examination, vaccination and blood collection and records pertaining to this, adverse event investigation, collating and reporting data. Lydia Uddstrom, BVSc DOC veterinarian (kakapo team), assisting with HPAI vaccination trial Assist with design and oversight of the trials, Animal Ethics Committee application, delivery of veterinary services including physical examination, vaccination and blood collection and records pertaining to this, adverse event investigation, collating and reporting data. The site lead will be responsible for the product while stored at the site, direct staff for catching, handling, monitoring & follow-up blood collection at 2-3, 6 & 12 months post vaccination. Site leads: Kakī: DOC Twizel breeding centre, Liz Brown Tūturuatu: Isaacs Conservation and Wildlife Trust, Christchurch. Anne Richardson Kākāriki: Natureland Wildlife Trust, Leah Foster, Manager (on site activities), Dr Rachel Stanyer (veterinarian responsible for product storage) Takahē: Burwood Takahē Centre: James Bohan Kākāpō: Whenua Hou/Codfish Island: Petrus Hedman

C2 Site
Identify the study location/site, the method used to select it, and the means by which access to it is limited.

Kaki: Department of Conservation Twizel breeding centre. This is a purpose-built site for captive breeding of kakī, operated by the Department of Conservation at 6199 Tekapo-Twizel Road, Pukakai, 7999. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. The site is surrounded by an electric fence, and security swipe pass is needed to enter the grounds. Only persons authorised by DOC are permitted to enter the site.

Tūturuatu: Isaacs Conservation and Wildlife Trust, Christchurch. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. The site is surrounded by a security fence and security swipe pass is needed to enter the grounds. Only persons authorised by Isaacs Construction are allowed to enter the site, via security sign in at the front office.

Kākāriki: Natureland Wildlife Trust, Nelson. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. It is a Zoo and Aquarium Association (ZAA) accredited facility. The site is surrounded by a security fence and meets MPI zoo containment requirements.

Takahē: Burwood Takahē Centre: holds takahē in enclosures for breeding. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff on site. It is located at 3860 Te Anau-Mossburn Highway, Centre Hill. Only persons authorised by DOC are permitted to enter the site. The site is not marked and not widely known. There are DOC rangers living on-site to monitor people accessing the location.

Kākāpō: Whenua Hou/Codfish Island: is a 1396 ha island located 3km off the north-west coast of Rakiura/Stewart Island. It was chosen because it holds a sufficient number of birds to complete the trial and has experienced staff available to work on site. Whenua Hou is a nature reserve under the Reserves Act 1977 – access is by permit only. There is no public access to this site.

C3 Security	
Give assurance that persons who have access to the product are suitably qualified or trained to use it and that they have had any conditions specified on the research approval given to them in writing	The product will only be directly handled and administered by a registered veterinarian. This will be either Dr Catherine (Kate) McInnes BVSc or Dr Lydia Uddstrom BVSc or Dr Rachel Stanyer who are all employed by the Department of Conservation. Access to the product by other staff only relates to the storage in the refrigerator at the captive facility. See below for more details.

Measures implemented to limit access to the investigational product	This process is outlined in the document: "SOP for receiving, storing and access to Poulvac Flufend vaccine DOC-7521640" which will be provided to the veterinarians and site leads for all species/sites. The product will be delivered via courier from the supplier to the facility, or it will be directly collected from the supplier by the veterinarian. If delivered by courier, the local DOC ranger/ facility staff member will receive the package and store it in the captive facility refrigerator in a closed container which is clearly labelled "Veterinary Access Only – keep refrigerated" in accordance with the SOP. If collected form the facility, the Veterinarian will maintain the cold chain until it is delivered to the captive facility where it will be stored. The refrigerator at the facility has access limited to authorised staff only. All staff will be made aware of the restricted access to the vaccine.
Measures implemented to limit off-target exposure to the investigational product by animals or plants	The vaccine will be administered by the veterinarian directly to the test subject only. Care will be taken in all handling of the product to ensure no spillage, breakage or contamination of the environment occurs. Used needles and syringes will be disposed of directly into Sharps containers for disposal via medical waste. If a bird dies, it will be detected by staff and collected immediately. It will be double bagged and chilled, then sent for necropsy examination at Massey University (takahē, kakariki, kakī & tūturuatu) or Auckland Zoo (kākāpō). Its remains will be disposed of via medical waste or held frozen for genetic, cultural or conservation purposes. Bodies will not enter the food chain.

Describe the method of disposal of any unused investigational product	Any unused product will be disposed of by placing in a medical waste container for disposal by a commercial medical waste company. Disposal will be recorded by the veterinarian in a shared document record in the DOC Document Content system, which will also be used to record delivery of the vaccine, and all use of the vaccine including vet ID, animal ID, date, dose given, injection site, and any relevant notes. "HPAI vaccination safety and efficacy trial VACCINE USE DOCCM-7521354" A stock audit (similar to the controlled drug register audit) will be undertaken each time the vaccine is accessed – that is monthly for 3 months. Once the final audit is complete, the disposal will occur.

C4 Residues

Describe how residues in treated crops/animals will be managed, including animal transfer if crops are to be used as animal feed.

The animals receiving the vaccine will not enter the food chain.

Site residues

Describe measures implemented to ensure that the study site(s) are free from residues that might compromise further use of the site(s), including the period of time for which the site will remain secure to avoid residues affecting its further use.

In addition, for agricultural chemicals only, discuss management of potential residues in soil and subsequent crops.

There will be no site residues. The vaccine is administered directly into the bird and is not excreted via urine/urates or faeces.

C5 Approval for Sale of Treated Produce or Declaration

If you do not seek an approval for sale* of treated produce (animal or plant matter), you must indicate YES in the declaration below and confirm by your signature (section D2).

*Definition of 'sale' under the ACVM Act:

Sale includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes—

(a) delivering or disposing of by way of gift, loan, or otherwise; and

(b) giving or distributing, in the course of business, as a sample or otherwise, without charge

Will the treated crop/animals be destroyed? (Put an X next to correct answer.)	Yes	
	No	X
I confirm that the treated plants or animals or their produce will NOT be sold or used for human/ animal consumption or enter the food chain at any time. (Put an X next to correct answer.)	Yes	X
	No	

If NO, provide information to support sale

Part D: Documentation, Applicant Statement and Payment

D1 Additional Documentation Requirements

Provide electronic copies of the following documents with this application:

- Letter of authorisation for agent/consultant (if applicable)
- Letter of consent (Confidential Supporting Information) (if applicable)
- Biosecurity assessment application if a product being imported contains an ingredient of biological origin
- Status of substance (SOS) advice or non-hazardous declaration from EPA (if applicable)
- Animal Ethics Committee approval documentation (if applicable)
- Request for import approval (if applicable)
- Existing import approval if application is for a variation

D2 Applicant Statement

I confirm that:

- I am authorised to make this application as the applicant OR a person with legal authority to act on behalf of the applicant noted in section A2; and
- the information supplied in and with this application is truthful and accurate to the best of my knowledge; and
- I understand that any change to the information provided in this application must go through MPI's 'variation' process or I will be in breach of the research approval conditions.

Name	Grant Matthews	**Tel**	9(2)(a)
		Email	Grant.matthews@mpi.govt.nz
Signature	9(2)(a)	**Date**	13/12/23

D3 MPI Service Charge

ON PAYMENT THIS BECOMES A TAX INVOICE GST No: 64-558-838

APPLICATION FEE: Refer to schedule of fees on website.

PAYMENT OPTIONS:

Payments comprising multiple fees must be supported by a remittance advice. Please attach your payment confirmation to this application or send it separately to: **approvals@mpi.govt.nz**

MPI does not accept cash. Payment must be made using **credit/debit card or direct credit**. (Please mark your choice with an X and fill in the appropriate section.)

APPROVED CREDITOR ☒ MPI Cost Centre 1935

CREDIT /DEBIT CARD (preferred option): ☐

Go to https://www.mpi.govt.nz/food-safety/payments and follow the instructions.

☐ I have attached my credit card payment receipt

DIRECT CREDIT ☐

1. Pay into Bank Account no. **03 0049 0001709 002**
2. In the 'Reference' details, put the code: **RESAPP**
3. Enter the date of deposit and the payer name on this form below:

Date of Deposit		**Payer Name**	

Collection of Information

Collection of Personal Information

Pursuant to Principle 3 of the Privacy Act 2020, we advise that:

1. This information is being collected for the purpose of approval in special circumstances (research) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997; and
2. The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, Wellington 6140; and
3. The collection of information is authorised under section 10 of the ACVM Act; and
4. The provision of this information is necessary in order to process this application; and
5. The supply of this information is voluntary; and
6. Failure to provide the requested information is likely to result in a return of the application form to the applicant, and in accordance with the ACVM Act, may ultimately result in a refusal of this application; and
7. Under Principles 6 and 7 of the Privacy Act 2020, you have the right of access to, and correction of, any personal information which you have provided.

Collection of Official Information

All information provided to the Ministry for Primary Industries is official information and may be subject to a request made under the Official Information Act 1982.

If a request is made under that Act for information you have provided in this application, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation.

Note on HSNO Approval

Section 21(5) of the ACVM Act states: "Where a trade name product contains an agricultural compound that is also a hazardous substance or new organism, the Director-General must not register that product under this section, unless an approval for that substance or organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996".

Hazardous substances or new organisms

If your product contains a hazardous substance or a new organism, or if you are unsure whether it does, contact the Environmental Protection Authority (http://www.epa.govt.nz/). EPA NZ will provide informal advice, based on information provided, on whether or not a substance is hazardous and/or whether it is covered by an existing approval. If you choose this option, provide a status of substance (SOS) number, or section 26 declaration, and the EPA approval code on the PDS, and attach a copy of the SOS letter.

If you have self-determined that the product matches an existing substance, you must provide the HSNO number and ensure that you have filled out Section B2. Your signature on this form serves as confirmation.

Alternatively, you may make the determination that a product may be assigned to a group standard approval. If you have self-determined that a product fits a group standard, MPI will require evidence of the determination process to justify the use of the group standard. If you choose this option, provide the reference number of the group standard.

Non-hazardous substances

MPI will accept a declaration if you have self-determined that the agricultural compound you wish to register is not a hazardous substance*. We may require you to provide a technical argument why the ingredients in the product are non-hazardous to support your declaration. If MPI is not certain that the determination is correct, we will advise you to obtain a determination by EPA NZ.

* For a product to be considered non-hazardous, it must either contain no hazardous substances as defined under the HSNO Act OR contain a hazardous substance at a low enough level that the product as a whole is considered non-hazardous.

Appendix 1

Biosecurity Assessment of Agricultural Compounds or Veterinary Medicines (ACVMs) Application Form for Research Approval

- If the agricultural compound contains an ingredient of a biological (animal, plant, or micro-organism) origin, this information is required by the Biosecurity Act 1993 to undertake a risk assessment for biosecurity approval. Provide as much information requested in the form as you have. We will contact you if we need further information.
- Time for assessment: If all the information requirements are met, then the assessment will be processed within the timeframe of the ACVM process.
- Cost of assessment: NZ$117.61 (inc GST) per hour. The fee will be invoiced in conjunction with the ACVM charges.
- If you have questions about this biosecurity assessment, contact animal.imports@mpi.govt.nz

1. Trade Name or Company Code of the Product	
Trade name	**Poulvac Flufend i AI H5N3 RG**
Approval number (if assigned)	Registration number A009733
List countries where product is registered	New Zealand,

2. Manufacturer(s) of the Formulated Product

Complete for all manufacturers

Company name	Site address

3. Is your product a vaccine?

☐ No
☒ Yes

If yes, skip section 4 below and complete the information requirements outlined in Appendix 2. Ensure you take note of section 5 and complete the Applicant Statement (section 6).

4. If your product is not a vaccine but contains ingredients of bacterial, fungal, viral, plant or animal origin

For products containing live organisms provide:

- systematic name and strain of the bacteria, protozoa, fungi, rickettsia, nematode or virus and the taxonomic description of the agent, serotype, strain or mutant;
- common name or alternative and superseded names;
- composition of the unformulated material, microbiological purity, nature and identity of any culture media, impurities and content of extraneous organisms.

For processed products provide:

Origin of the ingredient(s) of plant and animal origin

Complete for each ingredient (raw material) and for each manufacturer if more than one manufacturer:

Identify the raw materials used, the species and country of origin. Include health certification referring to disease country freedom and herd or flock of origin disease testing.

Describe the manufacturing processes for preparing the product.

Briefly outline the processes designed to render the product(s) sterile (e.g. heat treatment, filtration, acid or alkali treatment, irradiation, long term maturation etc). Include relevant parameters (e.g. temperature, pH level, radiation dose) and the time the product is maintained at these levels.

Each major step in the production process should be shown in a flow-chart diagram.
Each step on the flowchart should be cross-referenced to the application, which should contain details of the materials used and results of any tests conducted.

Describe the operational environment, quality systems and controls used for manufacturing. The manufacturer's GMP may include SOPs and/or specifications of the approved source, sterilisation procedure (if applicable) and pathogen testing applied to each product.

Expert opinion

If available, the applicant shall provide an opinion on the likelihood of the product containing associated organisms from an independent expert authority who is familiar with the manufacturing process. Include the following information:
Name:
Postal address:
Street address (if different from above):
Tel:
E-mail:

5. Confidential Information

If information is confidential, please ensure that you have contacted the manufacturer/supplier to arrange for information to be supplied to us directly.

6. Applicant Statement

I confirm that the information supplied in and with this application for biosecurity assessment is truthful and accurate to the best of my knowledge.

Name	Grant Matthews	**Tel**	9(2)(a)
Job Title	Manager Animal Disease Team (Acting)	**Email**	Grant.matthews@mpi.govt.nz
Signature	9(2)(a)	**Date**	13/12/23

Appendix 2
Additional Information Required for a Biosecurity Assessment of a Veterinary Vaccine

- Information identified below is additional to that required in the Application for Biosecurity Assessment of Agricultural Compounds or Veterinary Medicines (Appendix 1).
- Provide information in a format consistent with these requirements or as a summary document cross-referenced to registration dossiers and/or drug master files which should also be submitted.
- Provide the information you have available. If necessary we will contact you or the manufacturer for further information.
- If you have questions about this biosecurity assessment, contact animal.imports@mpi.govt.nz.

Additional information required for products that are veterinary vaccines
Materials of biological origin Provide detailed information on all components of biological origin used directly or indirectly in production of the vaccine. Such components include viral/bacterial seeds, cell lines, trypsin, nutritive factors (e.g. serum), fermentation broths/culture media and excipients. List every ingredient of animal origin contained in or used in the production of the product, the country and species of origin, approximate date of collection if available, processing/treatment and testing specified.
Testing standards MPI will normally accept procedures to test for pathogens that are specified in the Code of Federal Regulations (9CFR 113) or other standards. Submit details of all testing protocols with the application.
Certification and audit trails Provide information to show that an audit trail can track the country, species and date of origin of each product of animal origin used in production of the vaccine. Such audits should be able to correlate batches of finished product with all raw ingredients.
Other pathogens held and vaccines produced at the facility List of all pathogens held and vaccines produced within the vaccine manufacturing facility. List of other activities on the same site (e.g. vaccine research involving challenge trials, veterinary pathology and diagnostic services) and on neighbouring sites (e.g. intensive livestock production, abattoirs, animal research facilities).
Sterilisation of components of animal origin Sterilisation procedures must be validated. Submit a copy of the appropriate SOP with the application.
Master seeds (virus, bacteria and cells) A well-documented history of the master seed must be made available. Provide the origin, date of isolation, passage history, reversion to virulence, purity and identity confirmation studies. Provide details of cell lines and nutritive media used for the transport, storage and propagation of the master seed. For master seeds created many years ago, detailed information on the initial nutritive factors used may not be available. In this situation, it may be possible in some circumstances to establish the safety of the master seed by additional testing and a history of safe use over many years in live vaccines. Frequent use and extensive pathogen testing over many years in research laboratories and inactivated vaccine manufacture may also provide an additional level of biosecurity confidence. Provide details of the testing methods used to establish freedom from contamination by bacteria, fungi, mycoplasma, viruses and pathogens.
Working and production seeds (virus, bacteria and cells) Describe the tests used to identify potential pathogens in working and production seeds.

Nutritive factors Nutritive factors include serum, foetal serum, serum albumin and other serum products. Detail the country and species of origin, processing and/or any pathogen testing.
Trypsin and other enzymes of animal origin Provide details on the country of origin, species of origin, processing and any pathogen testing.
Fermentation broths and culture media List all ingredients used in the fermentation broth/production culture media in the import application. Specify country and species of origin of each ingredient of biological origin along with details of any processing, treatments or testing of either the ingredients or the final culture media/fermentation broth.
Final product testing – live vaccines Describe the testing used on live vaccines.

SOP for receiving, storing, & access to Poulvac Flufend vaccine

Receiving vaccine:

Vaccine is sent directly from PacificVet, Christchurch using standard cold chain transport methods to the nominated address. This will be either direct to the veterinarian or to the site where the vaccine will be used, depending on which is the more favourable cold-chain option.

In some circumstances the vaccine may be collected directly from the supplier by the veterinarian.

Species	Recipient	Address	Number of vials
kākāpō	Dr Lydia Uddstrom	Department of Conservation, Kakapo Recovery Team, Level 7, 33 Don Street, Invercargill, 9810	1
takahē	Nichollete Brown	Department of Conservation Te Anau Office, Lakefront Drive, Te Anau, 9600	1
kakī	Liz Brown	Department of Conservation, 15 Wairepo Road, Twizel, 7901	1
tuturuatū	Anne Richardson/Leigh Percasky	Isaac Conservation and Wildlife Trust, Isaac Construction, McArthurs Road, Harewood, Christchurch,	1
kākāriki	Dr Rachel Stanyer	Nelson Vets - Saxton, 2 Findlay Place, Stoke, 7011	1

Storing Vaccine

The vaccine will be stored in a closed plastic container in the refrigerator.

The container will be labelled with the information label in Appendix 1

Access to vaccine

Only the Authorised Veterinarian will be allowed to access the vaccine, as per the DOC AEC approvals 443, 444, 445, 446, 447 and MPI New Zealand Food Safety approval.

The authorised veterinarian will access and re-store the vaccine when undertaking the administration.

The veterinarian will record all details of use in the document: HPAI vaccination safety and efficacy trial VACCINE USE DOCCM-7521354.

SOP Updates or changes:
15 January 2024 to reflect updated distribution of vaccine to Te Anau site, as per NZFS approval

Appendix 1

Vaccine container label to be printed and attached to the outside of the vaccine container.

Veterinary Access Only – keep refrigerated

ANIMAL VACCINE

Poulvac Flufend i AI H5N3 RG

Store in the dark between 2 °C and 8 °C

Do not freeze

Protect from direct sunlight

Only for administration by a veterinarian in accordance with DOC AEC APPROVALS 443, 444, 445, 446, 447 and MPI New Zealand Food Safety approval.

Contact Kate McInnes 9(2)(a) or Lydia Uddstrom 9(2)(a)

Mitigation Options for Highly Pathogenic Avian Influenza in Threatened Species

About this document

Disclaimer	For Department of Conservation (DOC) internal use only.
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Department of Conservation
Te Papa Atawhai

Policy
Standard Operating Procedure
Guideline

New Zealand Government

Contents

1 Purpose and scope

The purpose of this document is to provide information, intelligence and guidance to support a Controlled Incident Management System (CIMS) response to Highly Pathogenic Avian Influenza (HPAI).

It describes trigger-points, readiness, and response actions which could be undertaken when there is a heightened concern of risk of HPAI arrival or following detection within Aotearoa New Zealand.

This document helps inform a CIMS response, but the suite of actions undertaken will depend on decision making within the CIMS response team, and the overall Biosecurity Response by Biosecurity New Zealand (BNZ) which is a business unit within the Ministry for Primary Industries (MPI).

Note: Biosecurity New Zealand Ministry for Primary Industries is the lead agency for Biosecurity Response.

Figure 1: Roles and Responsibilities in a Biosecurity Response, taken from The New Zealand Government Biosecurity Reponse Guide 2018

2 Background

Avian Influenza ("bird flu") is an infectious viral disease which can cause severe illness and death, generally in poultry but also occasionally in other bird species.

The virus is continually changing, and new and existing strains may pose a risk to Aotearoa New Zealand's indigenous avifauna.

Low Pathogenic Avian Influenza (LPAI) virus is sporadically detected by the MPI surveillance programme, but Highly Pathogenic Avian Influenza (HPAI) has never been detected in Aotearoa New Zealand.

Mitigation of avian influenza infection is difficult in wild birds, and response actions are situationally dependent and need to be carefully considered to avoid unintended consequences.

This document replaces the 2006 document "HPAI Vaccination of Threatened Indigenous Birds against Avian Influenza" WGNHO-259625 which was prepared in response to HPAI circulating in Asia.

3 Virus information

3.1 What is Avian Influenza (AI)?

Avian Influenza is a contagious viral disease that affects both domestic and wild birds and is caused by avian influenza A viruses.

Most wild birds infected with the virus are asymptomatic. Strains of this virus are classed as either Low Pathogenic Avian Influenza A virus (LPAI) (causing no or minimal illness) or Highly Pathogenic Avian Influenza A viruses (HPAI) which refers to the virus' molecular characteristics and ability to cause disease and mortality in poultry in a laboratory setting (WHO 2005).

Although AI viruses usually do not infect people, there have been some rare cases of human infection with these viruses.

HPAI viruses appear to emerge in two ways, mutation and recombination. The most common way is when a Low Pathogenic Avian Influenza (LPAI) infects chickens and mutates to HPAI causing high mortalities in poultry. The other way is when different strains of avian influenza virus recombine within a host with an HPAI emerging.

3.2 How is it named?

Subtypes of AI viruses are named based on two surface proteins - hemagglutinin (H) and neuraminidase (N), and these surface proteins have different versions – in birds 16 H and 9 N have been identified. The name of a strain is based on the combination of those subtypes of protein – so H5N1 has a subtype 5 for H, and subtype 1 for N. Those subtypes also indicate the likelihood of the AI strain being low or high pathogenic in poultry.

AI viruses are continuously changing through mutation and recombination with other AI viruses, so the strain is identified according to the genetic analysis which traces it back to species, location & year it was first detected. The 2021/22 strain of concern is identified in the literature as HPAI H5N1 Clade 2.3.4.4.b which emerged from the strain A/goose/Guangdong/1/1996 (Gs/GD) H5N1 influenza A virus. It may also be referred to as the 2021 Eurasian strain.

3.3 How is it spread?

Avian influenza is mainly spread by direct contact between infected birds and healthy birds. It can also be transmitted when birds come in contact with equipment or materials (including water and feed) that have been contaminated with faeces or secretions from the nose or mouth of infected birds. Movement of farm workers/researchers could contribute to spread between sites if strict disinfection measures are not undertaken. Scavenging birds can also contract AI from contact with infected corpses.

Species in the orders Anseriformes (ducks, geese, swans) and Charadriiformes (shorebirds, waders, gulls) are regarded as important reservoir hosts for avian influenza. This means the virus tends to multiply in the intestine of these species and can be shed in large amounts in faeces, especially of juvenile ducks. Other bird species that succumb to disease are likely to be spill-over hosts – i.e. they don't harbour the disease like a reservoir species, but they can pass it to other birds they come in contact with and they will either die or recover.

Spread of the disease is considered to be predominantly faecal-oral in wild birds, however the virus has been found in tracheal samples, suggesting airborne transmission may be important in some species when in close contact (CIDRP 2013). Overseas experience has shown that avian influenza can spread very rapidly and can be carried over long distances by contaminated clothing, equipment, and vehicles. Avian influenza virus can survive in the environment for days to a few weeks particularly at lower temperatures in damp conditions (Nazir et al 2011). The virus may remain infective in lake water for up to 14 days at 10◦C and for over 30 days at 0◦C, (Nazir 2010) and the virus can remain viable for longer periods in lake sediment particularly at low temperatures, allowing it to survive through winter (Nazier et al 2011).

Consumption of carcasses by predation and cannibalism is another source of virus transmission to susceptible birds and other animals (Swayne et al 2003).

3.4 What are the clinical signs of Avian Influenza?

Clinical signs can vary. In poultry flocks, it may cause acute death with mass mortalities wiping out a flock within hours or days. Silent infections of H5N1 have occurred in commercial chicken broiler flocks in Europe during 2021/22. There are no typical signs of HPAI which would allow a field diagnosis, however certain signs can raise a strong suspicion including:

- Sudden death,
- neurological signs (tremors, convulsions, torticollis/twisted neck, opisthotonos/backward-arching head, nystagmus/eye rolling, paresis/weakness, drooping wings and paralysis),
- respiratory signs (nasal discharge, coughing, sneezing, respiratory distress/gasping for air),
- diarrhoea and
- skin bruising may occur.
- In captive birds decreased activity, food or water consumption and weight loss may be observed.

Incubation periods are extremely variable for AI, dependent on the bird's species, virus subtype and virulence (CIDRP 2013) and may vary from a few hours to 7 days (WHA 2022).

Although avian influenza viruses do not normally infect humans, some subtypes have been associated with disease in humans, ranging from mild illness to severe respiratory disease. (WHA 2022)

3.5 Viral strains of concern - distribution and transmission (updated 2022)

In 2006 multiple outbreaks of Highly Pathogenic Avian Influenza (HPAI) occurred in Asia. In general, only poultry or wild waterfowl in close contact with poultry were affected. A vaccination plan for threatened species in Aotearoa New Zealand was developed to mitigate risk. HPAI did not reach Aotearoa New Zealand and no further action was required.

Since December 2021, HPAI H5N1 "Clade 2.3.4.4 B" viruses have been circulating in the northern hemisphere with detections and outbreaks reported in domestic and wild birds across Europe, Asia, Africa, and North America. This virus has been detected in apparently healthy wild birds which enables its spread; however, it has also contributed to a number of mortality events in wild birds including ducks, red knots, cranes, barnacle geese, northern gannets, and great skuas.

Detections in 2022 in the northern hemisphere indicate it is widespread. The nature of the mortality events in wild birds suggest the main risk factors are extended periods of close contact in crowded circumstances (e.g. colony nesting birds and possibly communal feeding and roosting areas e.g. mud flats and shell banks) or scavenging on infected carcasses. Colony nesting birds which spend significant time in close contact and birds which scavenge are possibly the most likely to be at risk of mortalities, and waterfowl and Charadriiformes which share feeding and roosting sites are possibly the most likely to transmit the infection.

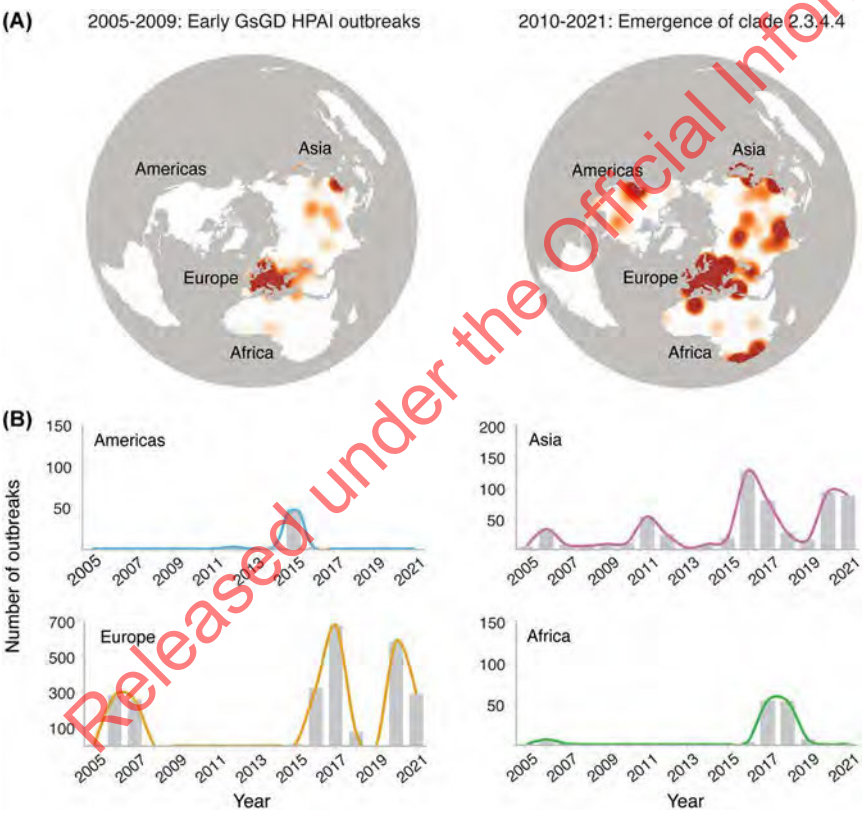

Figure 2: Outbreaks of HPAI 2005-2021

Occurrence of outbreak events for highly pathogenic avian influenza (HPAI) in wild and captive birds (i.e., non-poultry) from 2 August 2005–22 March 2021 as reported to the World Organisation for Animal Health (OIE).
Panel A depicts the relative occurrence of detection events (red) geographically during the period following spread of emergent A/goose/Guangdong/1/1996-like (GsGD) highly pathogenic HPAI

viruses to wild and captive birds (left) and subsequent to the evolution of Clade 2.3.4.4 viruses (right), many of which may be adapted to wild birds.
Panel B depicts the relative occurrence of HPAI outbreak detections by year. Data courtesy of the World Organisation for Animal Health (OIE 2021*a*) Ramey et al, 2022

To date, mortalities from HPAI H5N1 have been reported in a wide range of species – see Appendix 1.

3.6 Arrival scenarios for HPAI virus in NZ

HPAI could arrive in NZ in the following ways:

a) Arrival by migratory birds (see Appendix 2 for migratory paths for waders)

b) Arrival in smuggled birds/products

c) Carried on faeces, contaminated objects (fomites)

d) Mutates by genetic drift or recombination from current LPAI strains already present in Aotearoa New Zealand.

Current pre-border and border biosecurity measures mitigate most of these risks (b, c & e).

The majority of waders (e.g. red knots, pacific golden plovers, and ruddy turnstones) arriving in Aotearoa New Zealand in spring are expected to have travelled along the East Asian coast to reach Australia before flying to Aotearoa New Zealand, and may spend time along this pathway in "hotspots" around the Yellow Sea coast to feed and sometimes molt (Melville 2022). Bar-tailed godwits/kuaka mostly fly direct from Alaska in an 8-9 day single flight.

New Zealand is not on any waterfowl migration pathway, and New Zealand's waterfowl population is isolated from all others, except occasional Australian vagrants (Williams et al 2006). There are no regular international movements of waterfowl that have been tracked to/from Aotearoa New Zealand, although arrivals of rare vagrants do occur (Troy Makan pers comm).

Pelagic seabirds will return to Aotearoa New Zealand in spring to breed on offshore islands and subantarctic archipelagos having spent their non-breeding period in the waters of the Pacific, e.g. sooty shearwaters. Due to their pelagic behaviour these birds likely have a low risk of infection with HPAI. Scavenging birds such as Southern skua and giant petrels have previously tested seropositive demonstrating exposure to AI viruses (Melville 2022) however the pathway of infection has not been established.

Two cuckoo species migrate annually between New Zealand forests and islands in the tropical southwestern Pacific.

3.7 Spread scenarios for HPAI virus in NZ

If HPAI H5N1 is detected in Aotearoa New Zealand it would most likely be seen as either deaths in poultry and/or wildlife species. The extent of an outbreak is difficult to forecast as the current strain of H5N1 Clade 2.3.4.4 B has been behaving in new ways, with outbreaks continuing beyond the normal northern hemisphere winter seasonal pattern, and a wider range of wild bird's species affected than normal.

It is likely that if the disease is first seen in poultry, then MPI will instigate an immediate response to eradicate the disease. In this situation as long as biosecurity measures are sufficient in keeping wild birds away from affected poultry, and the disease is eradicated, then there may be no or minimal deaths in wild birds.

If HPAI is first seen in wild birds either as an initial outbreak or subsequent to disease in poultry, it is difficult to predict a likely outcome. If the disease is confined to spill-over hosts (birds which contract the virus but do not spread it further) and does not become carried in reservoir species (birds which contract the virus and survive but still shed the virus), then it is likely that an initial wave of mortalities could occur, confined both spatially and temporally, then 'die out' as the virus kills its hosts or they develop immunity before it has time to spread. If it becomes established in reservoir species, more widespread and recurrent outbreaks could result.

H5N1 Clade 2.3.4.4 B may have a higher transmissibility to wild birds than previous outbreaks which increases uncertainty about arrival, spread, and impact on indigenous avian species.

Dowding and Moore (2006) describe the habitat networks of seven endemic shorebirds species in Aotearoa New Zealand, describing movement pathways and identifying significant sites of species congregation with migratory shorebirds. This can inform possible pathogen transmission pathways and hotspots for infection and detection of HPAI during outbreaks.

3.8 Surveillance and testing

Surveillance and testing for HPAI is routinely undertaken in targeted programmes by the Ministry for Primary Industries and opportunistically on birds which undergo a mass mortality/morbidity event.

Arrival in Aotearoa New Zealand of HPAI and subsequent outbreak in birds would most likely be detected by the passive surveillance network of birders, conservation workers, vets, and the public.

Reporting to the BNZ exotic pest and disease hotline (0800 80 99 66) would result in an Incursion Investigator investigating the report and arranging for appropriate testing. BNZ would be the lead agency on the overall response. DOC's focus would be to undertake actions to protect indigenous avifauna, particularly threatened species.

4 Trigger-points for mitigation actions:

4.1 Readiness trigger-points

Detection of a new strain of concern in other countries

Continual monitoring of information on overseas strains of HPAI is undertaken by the DOC Vet.

A strain of concern is a strain which is more;

- Persistent: the outbreaks extend over a longer period than normal for that location
- Transmissible: there are outbreaks in a wider range of species than normal
- Pathogenic: a higher rate of morbidity and mortality is seen in affected species

When these three criteria are met it will trigger Readiness Actions as described in Section 5.1.

4.2 Mitigation action trigger-points

Detection of HPAI in Aotearoa New Zealand

HPAI is a notifiable disease and if detected in Aotearoa New Zealand must be immediately reported to Biosecurity New Zealand. All veterinarians and veterinary laboratories are aware and able to undertake that reporting, including suspected cases.

Upon receiving a report, BNZ Incursion Investigators will undertake sampling and testing to determine a diagnosis. Clinical signs are insufficient to make such a diagnosis as these can be confused with other diseases. The MPI laboratory will make the diagnosis.

Once MPI reports the confirmed diagnosis of HPAI to DOC, this should trigger a DOC CIMS response to assess the situation and determine appropriate mitigation actions (as described in Section 5.2), working with BNZ.

5 Potential mitigation actions:

Mitigation actions listed here aim to reduce the risk of extinction of threatened species in Aotearoa New Zealand.

For a wider discussion of the pros and cos of a range of different options in more detail see:

Department Environment, Food and Rural Affairs, Mitigation Strategy for Avian Influenza in Wild Birds in England and Wales 31 August 2022 Version: 1.0 Mitigation Strategy for Avian Influenza in Wild Birds in England and Wales (publishing.service.gov.uk)

5.1 Readiness actions

Readiness actions are undertaken when a heightened level of risk is suspected e.g. increased outbreaks overseas, a new strain of HPAI is detected etc.

These steps are preferably undertaken prior to arrival of HPAI in Aotearoa New Zealand to ensure planning has occurred to enable a fast effective response.

5.1.1 Biosecurity & reporting

Prepare and distribute an Avian Influenza Advisory for conservation managers and bird banders.

This advisory provides

- background information on the current event, and
- a reminder to undertake biosecurity/hygiene measures at all times, and to
- report sick or dead birds to BNZ's Exotic Pest and Disease Hotline: 0800 80 99 66 for investigation and testing.

The biosecurity/hygiene and reporting actions described are contained within the DOC Wildlife Health Management SOP and are therefore routine actions for DOC staff and Wildlife Authority holders where handling of wildlife occurs.

Additional biosecurity/hygiene measures are described In the Island Biosecurity SOP and species-specific SOPs.

Additional reporting guidelines are also provided on the DOC website (https://www.doc.govt.nz/nature/native-animals/sick-injured-and-dead-wildlife/)

and on the DOC Intranet

(http://intranet/natural-heritage/terrestrial/wildlife-health-management/get-help-with-sick-injured-or-dead-wildlife/)

Disseminate this advisory to DOC Operations Directors and Recovery Group Leaders.

[In August 2022 DOC staff, bird banders, Operations Directors, and Recovery Group leaders were asked via a DOC Advisory (DOC-7109612) to undertake biosecurity and hygiene measures (already part of the Wildlife Health Management Standard Operating Procedure) and to report cases of sick or dead birds to the BNZ exotic pest and disease hotline.]

5.1.2 Identify sites for early detection and pathways of spread

Identify locations or species at high risk of entry and early detection for increased monitoring vigilance.

Monitor points of entry for migratory birds to target the more likely sites of mortality events shortly after arrival. These flocks can amount to 20-50,000 birds.

These sites also contain indigenous species which may disperse during or post-breeding, and transient juvenile non-breeding birds, all of which represent pathways of spread.

- Significant entry points for returning Arctic migrants are Pūkorokoro/Miranda, Manukau Harbour, Kaipara Harbour, Foxton Beach, and Farewell Spit, which provide wader roosts for returning Arctic migrants (top 5 are: bar-tailed godwit/kuaka, red knots, little tern, Pacific golden plover, ruddy turnstone).
- These migratory birds share feeding and roosting areas with resident NZ endemic species such as oystercatchers, wrybill/ngutu pare, gulls, terns, herons, shags, and waterfowl.
- Internal migration of resident birds reaches most mainland areas e.g black-backed gulls, mallard ducks, indigenous waders and non-breeding migratory waders.
- Migratory seabirds do not tend to overlap with migratory waders and return to offshore islands with minimal contact so estimated risk of infection is lower.

5.1.3 Monitor bird populations

The HPAI Advisory from DOC includes a call for vigilance and reporting of bird mortality events. This provides a strong wide-spread network of experts who can assist with detection and reporting.

Targeted monitoring can also be undertaken, involving specific visits by DOC staff or bird observers to report on a regular basis from sites with congregations of species which may introduce, transmit or be affected by HPAI. This is more likely to be instituted following detection of HPAI within Aotearoa New Zealand.

5.1.4 Identify at-risk species and sites of concern

a) Review overseas evidence and affected species lists

b) Convene an avian expert TAG to discuss relevance to NZ species

c) Consider risk factors appropriate to the current situation/strain

d) Assess the risk to bird species at risk of extinction i.e. those species with small populations namely Nationally Critical, Nationally Endangered and Nationally Vulnerable species.

e) Assess the risk to bird species which congregate for extended periods of time during feeding, roosting or breeding e.g. colony nesting birds, birds which feed in estuaries

f) Identify any other factors which increase risk to a species e.g. scavenger behaviour increasing likelihood of infection

g) Identify sites of concern which may benefit from some level of intervention such as sites which

   a. have dense bird populations e.g. seabird islands;

   b. overlap of transmission to rare birds e.g. black-backed gulls and tara iti/fairy tern; or

   c. where public visitors overlap with bird congregation e.g. Taiaroa Head and red-billed gull breeding colony.

h) Consider any specific mitigation measures which would benefit species survival and/or reduce pathogen transmission for risk species and sites of concern.

i) Collate this data to inform the CIMS process if HPAI arrives and spreads in Aotearoa New Zealand.

[See Appendix 3 for at-risk species, sites of concern, and mitigation measures as of September 2022.]

5.2 Response actions

DOC will work with BNZ (as the lead agency) to implement measures to reduce risk of spread and protect critically endangered species in the event that HPAI is detected in Aotearoa New Zealand.

Decision making regarding undertaking the following actions will take into account the outbreak situation. For example, if the outbreak is restricted to a manageable location/species such as commercial chickens, with no further spread of the virus detected or anticipated, then lower-level mitigation actions would be sufficient.

5.2.1 Implement enhanced biosecurity actions for at-risk species and sites:

a) Disinfection of all equipment and personnel on arrival and departure to conservation areas or facilities - similar to island biosecurity measures for kākāpō islands, including disinfection of all clothing and equipment, showering and washing hair, prior to working with birds and this is undertaken enroute to avoid recontamination in a home environment

b) Within a field site ensure separation of field equipment, clothing & staff between species where possible

c) Use of full PPE when handling birds (alive or dead) during an outbreak

5.2.2 Implement enhanced monitoring actions for at-risk species and sites:

a) Specific monitoring programme to detect sick/dead birds quickly for fast diagnosis

b) Use remote monitoring tools where possible e.g. drones &/or cameras

c) Report all dead/dying birds immediately to BNZ for investigation

d) Assist BNZ investigation where appropriate

5.2.3 Reduce risk of transmission:

These actions may be applied locally, in the event of a contained outbreak, or on a wider scale, dependent on the outbreak situation. Anticipating the spread and instigating mitigation ahead of the affected area is important to prevent spread.

Preventative actions need to be balanced against impacts on species to ensure best outcomes for species survival.

a) Suspend translocations in affected areas, and a wider risk zone and/or high value conservation areas.

b) Suspend wildlife rehabilitation work, including uplift, veterinary care, and release

c) Suspend wild bird feeding (consider impacts of supplementary food dependent species such as hihi and kākāpō, or feeding for soft release techniques such as kakī).

d) Increase biosecurity measures for captive facilities including exclusion of wild birds and pest species, management of food and water sources

e) Conservation workers with chickens/other poultry undertake specific biosecurity measures prior to and after contact with other birds

f) Site closure to restrict public access and/or conservation access to high-risk species or sites

g) Carcass removal (effectiveness of carcass removal is still under investigation).1

h) Suspend egg collection from wild nests (consider impacts for high-risk species reliant on egg collection and instead consider disinfecting all arriving eggs and incubating separately from captive facilities and testing for avian influenza virus immediately after hatch and regularly during rearing.

BNZ has powers to close areas and restrict access through a Controlled Area Notice under the Biosecurity Act 1993.

DOC is able to undertake these actions for its own staff through normal decision-making processes.

Wildlife Act Authorities may contain conditions which allow the Department to limit access to public conservation land for reasons of public safety or emergency; and to terminate the authority if carrying out the Authorised Activity causes of is likely to cause any unforeseen or unacceptable effects.

5.2.4 Mitigate extinction risk through captive management

Captive management actions might include:

a) Transfer of birds into a breeding facility for an insurance population

b) Hold back birds from planned release to ensure a viable captive population

c) Distribute breeding birds across additional facilities as insurance populations

[1] There is limited evidence to indicate whether removal of carcasses reduces transmission risk within seabird colonies given the significant levels of environmental contamination that will remain in the area where carcasses have been removed from and the close contact between birds in these colonies. There is however emerging evidence from seabird colonies in Continental Europe that carcass removal may be effective in reducing incidence in some species when the risk of movement of the virus around the colonies by carcass collectors can be mitigated, together with the welfare impacts of entering the colony areas. DEFRA 2022.

d) Release of juveniles to reduce stress and density within a captive population (to avoid overcrowding in aviaries as birds mature)

e) Reduced captive holding of non-threatened species

European Association of Zoo and Wildlife Veterinarians HPAI fact sheet recommends for prevention and control in zoos:

a) Vaccination of all susceptible birds

b) Reduction of food supply for wild birds

c) Avoidance of direct contact between susceptible birds and persons

d) Control suppliers, enterprises, personnel for their contacts with potentially infected premises (cave: food suppliers are believed to have transferred the virus in The Netherlands and Germany in 2003)

e) Quarantine of susceptible birds and animals in case of a nearby outbreak

f) Complete isolation of the zoo in case of an outbreak inside the zoo, potentially culling of infected birds, subdivision of the zoo into epidemiological units

g) General measures of epidemiological control, like increased rodent control etc.

5.2.5 Undertake vaccination of threatened species

Use of avian influenza vaccine is managed by the Ministry for Primary Industries. MPI have internal policies regarding emergency use of vaccination. DOC is consulting (as of August 2022) with MPI regarding approval for use of the vaccine for the current strain of HPAI for protection of threatened species.

5.2.5.1 Why consider vaccination?

Effective vaccination reduces susceptibility to infection. When infection does occur, it reduces clinical signs of disease and the amount of virus shed into the environment. Vaccination may be considered to assist in managing particular compartments of birds that are at risk of infection, such as captive endangered species. (Ausvetplan)

5.2.5.2 What is known about vaccine efficacy in non-poultry?

Use of vaccine in zoo collections has demonstrated high efficacy and safety in a number of outbreak situations overseas and according to Philippa (2007b) vaccination should be regarded as a beneficial component of the preventive measures (including increased biosecurity and monitoring) that can be undertaken in zoos to prevent an outbreak of and decrease environmental contamination by HPAI H5N1 virus, while alleviating confinement measures.

Most information on vaccination in non-poultry avian species comes from zoo vaccination and consists solely of serological data. Whenever experimental challenge was performed in birds other than chickens and turkeys, vaccination using inactivated vaccines always protected against disease and mortality, provided the vaccine was sufficiently matched antigenically with the challenge virus (Koch et al 2009). Inactivated vaccines induce good antibody titres in most species when applied twice and when body weight is taken into account (Koch et al 2009).

In one zoo study, to compensate for body weight, birds under 1.5 kg were given two doses of 0.25 ml and those over 1.5 kg were inoculated with two doses of 0.5 ml, using average published body weights for each species.

In the Netherlands, ten zoos vaccinated birds with an inactivated, adjuvanted H7N1 virus vaccine previously used in poultry, giving two doses. Of 211 birds in 13 orders tested, 81.5% developed an antibody titre of 40 or higher, which is considered protective in chickens (Philippa et al 2005).

According to Pitman (2006) more than 36,000 birds kept in ~250 zoos have been vaccinated. Vaccination was performed twice in intervals between 3-8 weeks. Three different commercial AI vaccines have been used: Nobilis H5N2 (Intervet) in 10 countries, Gallimune H5N9 (Merial) in 2 countries, H5N9 (Fort Dodge) in 2 countries. In general, no adverse reactions to vaccination were noted. Losses and reduced reproduction rate occurred due to stress and trauma (handling, identification, temporary confinement). Most birds produced a significant immune response following two administrations of vaccine. In some countries poor immune response was experienced in certain species (e.g. ratites) which might be related to vaccine dosage or way of vaccine administration (e.g. in penguins it was given subcutaneously). Indications are that antibody titres substantially wane after 2 years (H7N1 vaccination). There was no data on protective immunity.

The 2003 Dutch H7N7 outbreak and vaccination response, and subsequent 2005 EU Decision to allow vaccination in zoos against the encroaching H5N1 subtype are further discussed in Philippa 2007a and Philippa et al 2007b. The vaccination campaign involved >3000 zoo birds and experienced only 5 mortality events due to catching or handling stress. Vaccination with a commercial H5N2 vaccine with vaccine doses adapted to mean body weight per species was safe, and proved immunogenic throughout the range of species tested, with some variations between and within taxonomic orders. After booster vaccination the overall homologous geometric mean titre (GMT) to the vaccine strain, measured in 334 birds, was 190 (95% CI: 152–236), and 80.5% of vaccinated birds developed a titre of ≥40. Titres to the HPAI H5N1 virus followed a similar trend but were lower (GMT: 61 (95% CI: 49–76); 61% ≥ 40). The breadth of the immune response was further demonstrated by measuring antibody titres against prototype strains of four antigenic clades of currently circulating H5N1 viruses. (Philippa et al 2007)

Additional work in Singapore's Jurong Bird Park showed all species responded but at differing levels with some species requiring a third vaccination (pers comm 2005.)

5.2.5.3 Criteria for vaccination to be considered are:

a) Iwi engagement regarding vaccine use is undertaken and has resulted in agreement for use of vaccination for each species in the prescribed circumstances.

b) The vaccine is likely to be effective, based on epidemiological information from overseas events e.g. the European zoo data described in 5.2.5.2.

c) Processes that import, store, distribute and administer the vaccine are appropriate to ensure vaccine safety and efficacy.

d) Individual birds have permanent identification markings e.g. band or internal PIT tag.

e) Birds are in a captive facility or are flightless on an offshore island and are managed individually with transmitters or other marks to enable recapture and monitoring.

f) Birds are either part of a threatened species breeding programme or are held in the same facility as birds in a breeding programme.

g) The bird can receive at least two injections of the vaccine according to manufacturer's instructions.

5.2.5.4 Risks and limitations of vaccination

a) A veterinarian is required to administer the vaccine.

b) A Chief Technical Officer (CTO) or person authorised by the CTO must approve the use of the vaccine in the specific circumstances, requiring DOC to obtain this approval before the vaccine can be used.

c) Administering a vaccine may cause significant stress and risk of injury during capture and handling, which must be performed twice within a short period of time.

d) Birds may suffer an adverse reaction resulting in illness or death (anaphylaxis, injection site granuloma, but this is low risk based on European zoo data).

e) Vaccination efficacy is not known for most species; therefore it is not possible to predict the degree of protections afforded by the vaccine, however it appears effective in European zoo data.

f) It is important to vaccinate for the outbreak type (or as close as genetically possible to type). If the outbreak was H5N1, then the ideal vaccine would not be H5N1 but one with a different N protein, such as H5N2 so that birds with immunity from vaccination could be differentiated from natural immunity as a result of infection with the avian influenza virus of concern (DIVA vaccination strategy). There is good cross protection, as long there are high antigen levels in the vaccine, and the H proteins are the same.

g) There are strict requirements for vaccine use, record keeping, animal tracing to meet MPI requirements.

5.2.5.5 Vaccine availability for indigenous wildlife

PacificVet NZ Christchurch has Poulvac Flufend i AI H5N3 RG inactivated (killed) vaccine (Zoetis) available to supply to the Department at no cost. This vaccine is registered in Aotearoa New Zealand by MPI ACVM registration number **A009733**.

By law the distribution and use of this product must comply with the requirements of the relevant operating plan. (MPI registration label)

See Appendix 5 for vaccine label details.

5.2.5.6 Proposed vaccination protocol

Based on vaccine use in European Zoos, the following protocol is proposed, pending MPI approval.

Vaccine: Flufend I AI H5N3 RG (Zoetis)

A veterinarian will administer the vaccine.

Each individually permanently marked (leg band or PIT) captive bird will receive two doses by subcutaneous injection into the inguinal (groin) region no less than 2 weeks apart and a maximum of 6 weeks apart. The first vaccination will be into the left inguinal region, and the second vaccination into the right inguinal region.

Birds <1.5kg will receive 0.25ml per dose. Birds >1.5kg will receive 0.5ml per dose.

Vaccination will be administered by a registered veterinarian or trained personnel under the direction of the DOC Veterinarian.

5.2.5.7 Birds in priority list for vaccination of species which have captive breeding programmes

Species	Reason	Population
Kakī/black stilt	Species survival is reliant on captive breed for release	<200
Tūturuatu/shore plover	Species survival is reliant on captive breed for release	<250
Kākāriki karaka/orange fronted parakeet	Species survival is reliant on captive breed for release	<250
Takahē (Burwood Bush breeding facility)	Breed for release is a significant component of species management	<500

5.2.5.8 Birds in priority list for vaccination of species which have intensive management programmes

Species	Reason	
Kākāpō	Nationally critical, intensively managed individually identified birds with transmitters for monitoring, restricted to 2 main breeding populations, flightless, contained on islands	252

6 Related documents

- Advisory for wildlife managers and bird banders DOC-7109612 link
- Migratory birds technical review DOC-7109097
- Ausvetplan Avian Influenza https://animalhealthaustralia.com.au//wp-content/uploads/dlm_uploads/2021/11/AUSVETPLAN-_Response_Avian-influenza.pdf
- World Organisation for Animal Health /avian-influenza-and-wildlife-risk-management-for-people-working-with-wild-birds.pdf
- Department Environment, Food and Rural Affairs (DEFRA), Mitigation Strategy for Avian Influenza in Wild Birds in England and Wales 31 August 2022 Version: 1.0 Mitigation Strategy for Avian Influenza in Wild Birds in England and Wales (publishing.service.gov.uk)
- Vaccination of Threatened Indigenous Birds against Avian Influenza 2006 WGNHO-259625
- The New Zealand Government Biosecurity Response Guide https://www.mpi.govt.nz/dmsdocument/31917-The-New-Zealand-Government-Biosecurity-Response-Guide
- Wildlife Health Australia, Avian influenza in wild birds in Australia Fact Sheet September 2022. https://www.wildlifehealthaustralia.com.au/Portals/0/Documents/FactSheets/Avian/Avian_Influenza_in_Wild_Birds_in_Australia.pdf

7 International organisations' Avian Influenza information

Food and Agriculture Organization of the United Nations	http://www.fao.org/ag/againfo/programmes/en/empres/Global_AIV_Zoonotic_Update/situation_update.html
World Organisation of Animal Health	https://www.oie.int/en/disease/avian-influenza/
Canadian Wildlife Health Cooperative	http://www.cwhc-rcsf.ca/avian_influenza.php
U.S. Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/avian-influenza/ai
U.S. Geological Survey	https://www.usgs.gov/ecosystems/fish-wildlife-disease/wildlife-diseases-and-agriculture/avian-influenza
U.S. Geological Survey National Wildlife Health Center	https://www.usgs.gov/centers/nwhc/science/avian-influenza
International Society for Infectious Diseases (ProMED)	https://promedmail.org/
Occupational Safety and Health Administration	https://www.osha.gov/avian-flu
U.S. Department of the Interior	https://pubs.er.usgs.gov/publication/tm15C2
Centers for Disease Control and Prevention	https://www.cdc.gov/flu/avianflu/groups.htm
Wildlife Health Australia	https://wildlifehealthaustralia.com.au/ProgramsProjects/WildBirdSurveillance.aspx
Wetlands International	Waterbird Population Estimates (wetlands.org)

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Philippa J, Bass C, Beyer W, Bestebroer T, Fouchier R, Smith D, Schaftenaar W, Osterhaus, A.Vaccination against highly pathogenic avian influenza H5Na virus in zoos using an adjuvanted inactiviated H5N2 vaccine. Vaccine, 2007b, 25: 3800-3808.

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9 Document history

Date	Details	Document ID and version	Amended by
31/10/2022	DRAFT for approval	doc-7111177 version 14	Michael Harbrow

10 Appendix 1: Affected species

Species reported affected by H5N1 2021/22 in Northern Hemisphere.

Outbreak numbers included where noted, up to date information available on WAHIS (woah.org)

Date	Location	Species affected	Number affected
April 2021	Netherlands	Barnacle geese	large groups
November 2021	India	Demoiselle cranes	>300
December 2021	Netherlands	Red knots	¬300
December 2021	Israel	Common cranes	>5-8000
Early 2022		Marbled teal	
	Greece	Dalmatian pelicans	40%
	UK	Great skua	80%
	Solway	Barnacle geese	>4000
		Northern gannets	
		Great skua	
		Eider ducks	
	Netherlands	Sandwich terns	80%
	Netherlands	Peregrine falcons	30%
	Farne Islands	Guillemots, kittiwakes, puffins	
Dec 21/Jan 22	Canada & USA	Northern gannets	>20,000
		Snow geese	>1000
		Lesser scaup	>1000
		Black vultures	¬100
		Bald eagles, great horned owls, red-tailed hawks, turkey vultures	
	Maine	Harbour seals	
		Foxes, bobcats, skink, otters	

List of birds tested positive in US

Alive and dead as at 03/09/2022 on APHIS database aphis avian-influenza/hpai-2022.

Species	Count	Species	Count	Species	Count
American black duck	31	Dunlin	1	Pelican (unidentified)	2
American crow	30	Eared grebe	3	Peregrine falcon	10
American green-winged teal	44	Eastern screech owl	2	Pheasant (unidentified)	3
American kestrel	1	Fish crow	1	Redhead duck	10
American robin	1	Gadwall	35	Red-Necked Grebe	1
American white pelican	57	Glaucous gull	8	Red-shouldered hawk	2
American wigeon	65	Goose (unidentified)	22	Red-tailed hawk	102
American wood stork	1	Great black-backed gull	20	Red-winged blackbird	1
Arctic tern	2	Great blue heron	5	Ring-billed gull	4
Bald eagle	222	Great horned owl	104	Ring-necked duck	5
Barred owl	8	Greater white-fronted goose	1	Ross's goose	63
Black vulture	245	Gull (unidentified)	6	Rough-legged hawk	4
Black-billed magpie	3	Harris hawk	1	Royal tern	2
Blue-winged teal	11	Hawk (unidentified)	12	Ruddy duck	2
Brant	4	Heron (unidentified)	1	Sabine's gull	3
Broad-winged hawk	1	Herring gull	27	Sanderling	11
Brown pelican	3	Hooded merganser	20	Sandhill crane	5
Canada goose	191	Horned grebe	2	Sharp-shinned hawk	3
Caspian tern	12	Laughing gull	1	Short-Billed Gull	1
Cinnamon teal	4	Lesser scaup	25	Snow goose	228
Common eider	24	Mallard	197	Snowy egret	1
Common goldeneye	2	Merganser (unidentified)	6	Snowy owl	15
Common grackle	1	Muscovy duck	11	Swainson's hawk	3
Common loon	5	Mute swan	4	Swan (unidentified)	2
Common raven	13	Neotropic cormorant	3	Tree swallow	1
Common tern	9	Northern gannet	1	Trumpeter swan	7
Cooper's hawk	6	Northern harrier	2	Tundra swan	5
Cormorant (unidentified)	7	Northern pintail	4	Turkey vulture	52
Crested caracara	1	Northern shoveler	14	Vulture (unidentified)	1
Dark-eyed junco	1	Osprey	1	Western screech owl	1
Double-crested cormorant	20	Owl (unidentified)	8	Wild turkey	15
Duck (unidentified)	2	Parasitic jaeger	2	Wood duck	47

11 Appendix 2: Key migratory routes for waders that visit NZ

Aotearoa New Zealand lies at the southern end of the East Asian - Australasian Flyway for waders (Fig.1)

Figure 1. From: MIGRATIONS AND MOVEMENTS OF BIRDS TO NEW ZEALAND AND SURROUNDING SEAS, compiled by Murray Williams, Helen Gummer, Ralph Powlesland, Hugh Robertson, Graeme Taylor. September 2004. A report prepared by Department of Conservation, Science and Research Unit for the Ministry of Agriculture and Fisheries, Biosecurity Authority under MOU BIF/58/2003
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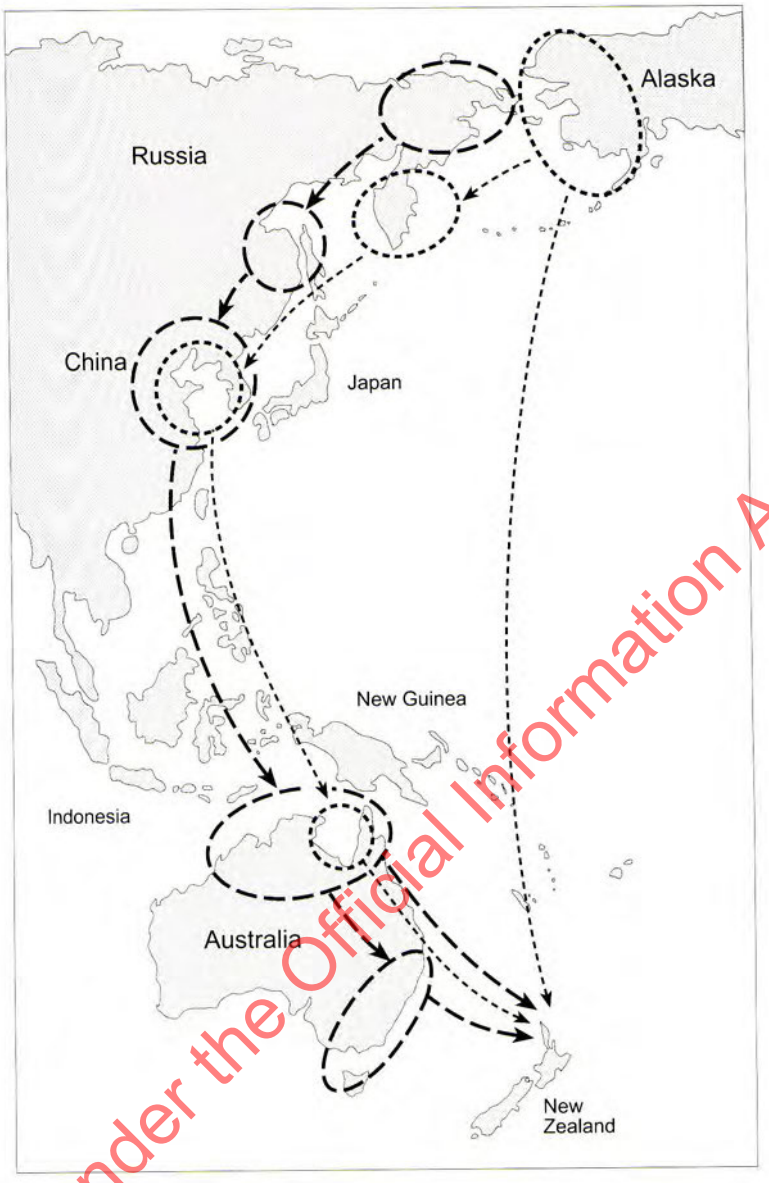

Figure 2. Southward migration route and principal stop-over areas for lesser knots (dashed) and bar-tailed godwits/kuaka (dotted). Northern Australia is a key stop-over for all birds moving down through Asia en route to Aotearoa New Zealand (from Reigen 1999).

12 Appendix 3: At risk species and sites

On 9th September 2022, a TAG consisting of Kate McInnes, Science Advisor Threats, Troy Makan, Technical Advisor Terrestrial Science Unit, Graeme Taylor, Principal Science Advisor Marine Species Team, Johannes Fischer, Technical Advisor Seabirds, Aquatic Unit undertook an assessment to identify at-risk species and sites of concern.

Using the 2021 NZ Threat Classifications list, species were ranked based on the risk to the species of severe impact on the population if HPAI spreads in Aotearoa New Zealand. Factors considered were

a) Vulnerability of the species to extreme decline which might result in extinction
    a. Species within the nationally critical, endangered and vulnerable categories were assessed based on total population number and the distribution of the population(s) number of populations. Birds with low number of individuals and a single population were considered most at risk.

b) Risk of infection.
    a. Birds were assessed based on behaviours which make transmission of virus more likely such as colony nesting, communal feeding and/or roosting, scavenging ,
    b. Bird were assessed for susceptibility to infection based on genus/family/order using current HPAI infection/mortality data from the northern hemisphere.

12.1 At-risk species

Preferred Common Name	Preferred Māori Name	Status	low number	single population	colony nesting	communal roosting	communal feeding	Scavenger	risk of infection	risk to the species (II = individual infections)	Species is reliant on captive management CM, feeders F, Operation Nest Egg ONE
Antipodean wandering albatross	toroa	Nationally Critical	Y	Y	Y	N	N		low	moderate	
Australasian bittern	matuku hūrepo	Nationally Critical	Y	N	N	N	N		moderate	low (II)	
Black robin		Nationally Critical	Y	N	N	N	N		low	low (II)	
Black stilt	kakī	Nationally Critical	Y	N	N	N	N		high	high	CM, ONE
Chatham Island oystercatcher	tōrea tai	Nationally Critical	Y	N	N	N	N		high	high	
Chatham Island taiko	taiko	Nationally Critical	Y	Y	N	N	N		low	high	
Gibson's wandering albatross	toroa	Nationally Critical	Y	Y	Y	N	N		low	moderate	
Kākāpō	kākāpō	Nationally Critical	Y	N	N	N	N		low	high	
Kermadec white-faced storm petrel		Nationally Critical	Y	N	Y	N	N		low	high	
New Zealand fairy tern	tara iti	Nationally Critical	Y	N	N	Y	N		high	high	
Northern rock wren		Nationally Critical	Y	N	N	N	N		low	low (II)	
Orange-fronted parakeet	kākāriki karaka	Nationally Critical	Y	N	N	N	N		low	high	CM, F
Pacific white tern		Nationally Critical	Y	Y	Y	N	N		low	low/moderate	
Salvin's mollymawk	toroa	Nationally Critical	Y	N	Y	N	N		low	high	
Shore plover	tuturuatu	Nationally Critical	Y	N	N	N	N		high	high	CM
Southern New Zealand dotterel	tūturuatu	Nationally Critical	Y	Y	N	Y	Y		high	high	
Whenua Hou diving petrel		Nationally Critical	Y	Y	Y	N	N		low	high	
White heron	kōtuku	Nationally Critical	Y	Y	Y	N	N		moderate	low/moderate	
Black-fronted tern	tarapirohe	Nationally Endangered	N	N	Y	Y	Y		high	moderate/high	
Chatham Island tit		Nationally Endangered	N	N	N	N	N		low	low	

Chatham Island yellow-crowned parakeet		Nationally Endangered	N	Y	N	N	N	Y	low	high	
Hoiho	hoiho	Nationally Endangered	N	N	N	N	N		low	low	
Kea	kea	Nationally Endangered	N	N	N	N	N	Y	moderate	low (II*)	
Kermadec petrel "summer"		Nationally Endangered	N	N	Y	N	N		low	low	
King shag	kawau	Nationally Endangered	N	N	Y	N	N		high	high	
Masked booby		Nationally Endangered	N	N	Y	N	N		moderate	low	
Reef heron	matuku moana	Nationally Endangered	N	N	N	N	N		moderate	low	
Rowi, Okarito brown kiwi	rowi	Nationally Endangered	N	Y	N	N	N		low	low (II)	ONE
Southern falcon		Nationally Endangered	N	N	N	N	N		moderate	low (II)	
Southern Fiordland tokoeka	tokoeka	Nationally Endangered	N	N	N	N	N		low	low (II)	
Southern rock wren		Nationally Endangered	N	N	N	N	N		low	low (II)	
White-bellied storm petrel		Nationally Endangered	N	N	N	N	N		low	low	
Antarctic tern		Nationally Increasing	N	N	Y	Y	N		moderate	low	
Brown teal	pāteke	Nationally Increasing	N	N	N	Y	Y		high	moderate	CM
Bush falcon	kārearea	Nationally Increasing	N	N	N	N	N	?	moderate	low (II)	
Campbell Island teal		Nationally Increasing	N	N	N	N	N	Y	low	low	
Little spotted kiwi	kiwi pukupuku	Nationally Increasing	N	N	N	N	N		low	low	
New Zealand dabchick		Nationally Increasing	N	N	N	N	N		moderate	low	
North Island kōkako	kōkako	Nationally Increasing	N	N	N	N	N		low	low	
Northern New Zealand dotterel		Nationally Increasing	N	N	N	Y	N		high	low	
Otago shag		Nationally Increasing	N	N	Y	N	N		high	moderate	
Red-tailed tropicbird		Nationally Increasing	N	N	Y	N	N		low	low	
Wrybill	ngutu-pare	Nationally Increasing	N	N	N	Y	Y		high	high	
Auckland Island shag		Nationally Vulnerable	N	N	Y	Y	N		moderate	high	
Auckland Island teal		Nationally Vulnerable	N	N	N	N	N		low	low	
Australasian crested grebe		Nationally Vulnerable	N	N	N	N	N		moderate	low	
Black petrel	taiko	Nationally Vulnerable	N	N	Y	N	N		low	low (II)	
Campbell Island snipe		Nationally Vulnerable	N	Y	N	N	N		low	low	
Caspian tern	taranui	Nationally Vulnerable	N	N	Y	Y	Y		high	high	
Chatham Island pigeon	pārea	Nationally Vulnerable	N	Y	N	N	N		low	low	
Chatham Island shag		Nationally Vulnerable	N	N	Y	Y	N		high	high	

Chatham Island snipe		Nationally Vulnerable	N	N	N	N	N		low	low	
Chatham Island tui		Nationally Vulnerable	N	N	N	N	N		low	low	
Chatham petrel	ranguru	Nationally Vulnerable	N	N	Y	N	N		low	low	
Eastern falcon	kārearea	Nationally Vulnerable	N	N	N	N	N	?	moderate	low (II)	
Eastern rockhopper penguin		Nationally Vulnerable	N	N	Y	N	N		moderate	low	
Foveaux shag		Nationally Vulnerable	N	N	Y	Y	N		high	moderate	
Great spotted kiwi	roroa	Nationally Vulnerable	N	N	N	N	N		low	low	
Grey duck	pārera	Nationally Vulnerable	N	N	N	N	Y		moderate	low	
Grey-headed mollymawk		Nationally Vulnerable	N	Y	N	N	N		low	high	
Haast tokoeka		Nationally Vulnerable	N	Y	N	N	N		low	low (II)	ONE
Hihi, stitchbird	hihi	Nationally Vulnerable	N	N	N	N	N		moderate	moderate	F
Hutton's shearwater		Nationally Vulnerable	N	Y	Y	N	N		low	low	
Lesser fulmar prion		Nationally Vulnerable	N	Y	Y	N	N		low	low	
Light-mantled sooty albatross	toroa pango	Nationally Vulnerable	N	N	N	N	N		low	low	
Long-tailed cuckoo	koekoeā	Nationally Vulnerable	N	N	N	N	N		low	low	
New Zealand storm petrel		Nationally Vulnerable	N	Y	N	N	N		low	low	
Northern Fiordland tokoeka		Nationally Vulnerable	N	N	N	N	N		low	low	
Northern royal albatross	toroa	Nationally Vulnerable	N	N	Y	N	N		high	moderate	
Pitt Island shag		Nationally Vulnerable	N	N	Y	N	N		high	moderate	
South Island kākā	kākā	Nationally Vulnerable	N	N	N	N	N		low	low	
South Island takahē	takahē	Nationally Vulnerable	N	N	N	N	N		low	low (II)	CM, F
Southern royal albatross	toroa	Nationally Vulnerable	N	N	Y	N	N		low	moderate	
Southern white-fronted tern	tara	Nationally Vulnerable	N	N	Y	Y	Y		moderate	moderate	
Spotted shag	kawau pāteketeke	Nationally Vulnerable	N	N	Y	N	N		high	low	
Stewart Island fernbird		Nationally Vulnerable	N	N	N	N	N		low	low	
Stewart Island weka	weka	Nationally Vulnerable	N	N	N	N	N	Y	moderate	low	
Subantarctic skua	hākoakoa	Nationally Vulnerable	N	N	N	N	N	Y	high	high	
Whio, blue duck	whio	Nationally Vulnerable	N	N	N	N	N		low	low	
White-capped noddy		Nationally Vulnerable	N	N	N	Y	Y		moderate	low	

12.2 Sites of concern

Sites with dense seabird populations

Location	Notes
Kermadec Islands	Pelagic species with rare tattler or turnstone arrival, terns, noddies, boobies, petrels
Subantarctic Islands	Pelagic species, skua, shags, waterfowl, vagrants
Chatham Islands	Skua, dense populations of seabirds
Titi Islands	Pelagic spp, weka, skua scavengers
Manawatāwhi/Three Kings Islands	Gannet, RBG, seabirds
Whaakari/White Island	Gannet, gull islands
Codfish Island/Whenua Hou	Seabirds, teal, penguins, kākāpō interaction with everything

Sites with at-risk species overlapping with high transmission species

Location	Species at-risk
Mangawhai spit	Tara iti/fairy tern
Kaipara	Tara iti/fairy tern
Awarua Bay	Southern NZ dotterel/tūturiwhatu

Sites with species overlap of shorebirds, gulls, terns, waterfowl AND public access

Muriwai	Avon Heathcote Estuary/Ihutai
Taiaroa head	Motueka Sandspit
Cape Kidnappers	Jacobs River Estuary, Riverton/Aparima
Farewell Spit	Big Sand, Kaipara
Sulphur Bay, Rotorua	Ahuriri Wetland, Napier
Pūkorokoro/Miranda	Maketu
Māngere, at Manukau, Ambury Heights	Mangawhai
Foxton	Ōhope
Lake Ellesmere (Te Waihora)	Tip lagoon, Invercargill
Awarua Bay	Oamaru wharf
Waikanae River Estuary	Kaikoura Peninsula
Matiu Somes Island	

12.3 Mitigation options

Mitigation options were discussed to identify special actions for individual species.

For all species, the following actions were determined to be important to stop spread of the virus within common and threatened species:

- monitoring & reporting,
- hygiene,
- biosecurity (restricted access),
- cessation of wildlife rehabilitation activities,
- cessation of bird feeding, and
- cessation of translocations.

For species reliant on management interventions to maintain the population, these activities should continue where possible. E.g.

- captive management for breeding, or
- supplementary feeding or
- Operation Nest Egg.

For species reliant on captive breeding for species persistence, vaccination of captive breeding birds should be undertaken, if possible, to reduce the risk of mortality.

For species with very small wild populations, vaccination should be undertaken if

- individual birds are permanently marked, and
- access is maintained via monitoring of individual via transmitters, and
- the birds are restricted from dispersal e.g. a flightless bird on an island.

13 Appendix 4: Hygiene & PPE

BNZ MPI will provide requirements for working with birds if HPAI is detected in Aotearoa New Zealand as part of their response. The following information provides current recommendations from the DOC Wildlife Health SOP for use when HPAI is not known in Aotearoa New Zealand, and recommendations from international organisations for wildlife and human health for locations where HPAI outbreaks are occurring.

Review up-to-date recommendations from the US Centers for Disease Control https://www.cdc.gov/flu/avianflu/h5/worker-protection-ppe.htm

Standard Precautions for DOC staff when handling birds:

DOC staff who handle apparently healthy wild birds when HPAI has not been detected in Aotearoa New Zealand should:

Complete and undertake the actions in the Hygiene Checklist DOCDM-635558, this includes;

- Clean and disinfect all clothing, footwear and equipment used with animals (before and after use).
- When possible, wear gloves that can be disinfected or disposed of while handling animals.
- Wash hands with soap and water often and disinfect work surfaces and equipment between sites.
- Do not eat, drink, or smoke while handling animals.
- Report any sick or dead animals.
- Work in well-ventilated areas if working indoors.
- Ensure facilities provided to wild animals are clean and hygienic e.g food stations.
- Ensure food storage and quality is appropriate.
- Captive facilities have good hygiene, disease, and pest control measures.
- Prevent zoonotic infections (animal to human).

DOC staff who handle sick or dead birds associated with a mortality event should:

- Report the event to BNZ 0800 80 99 66 and follow their instructions.
- Wear protective clothing, including coveralls, rubber boots, latex or rubber gloves that can be disinfected or disposed of.
- Minimize exposure to mucosal membranes by wearing protective eyewear (goggles) and a particulate surgical mask (NIOSH N95 respirator/mask is preferable).
- Decontaminate and properly dispose of potentially infectious material including carcasses.
- Do not eat, drink, or smoke while handling animals.
- Wash and disinfect hands and any exposed skin.
- Immediately consult a medical practitioner if illness occurs.

DOC staff working with wild birds in areas where HPAI H5N1 has been detected should:

- Follow instructions from BNZ.
- At a minimum follow the above instructions for handling sick or dead birds.
- Consult with a health care provider and follow the latest guidelines from the Ministry of Health for prophylactic medications and precautions for persons involved in avian influenza disease control.

14 Appendix 5: Avian Influenza vaccine information

Registration number A009733: **Poulvac Flufend i AI H5N3 RG**

Link to Entry in ACVM register Registrant: Ministry for Primary Industries

Draft label information:

PRESENTATION

Bottles of 500 mL (1000 doses). Packs of 1 or 10 bottles.

DIRECTIONS FOR USE

By law the distribution and use of this product must comply with the requirements of the relevant operating plan.

General:
• Inject 0.5 mL (0.5 cc) subcutaneously, using aseptic technique, into healthy birds at 3 to 4 weeks of age or older.
• Shake well before use.
• Allow the vaccine to reach room temperature (18-29°C) before use.

Chickens:
• Administer another dose of 0.5 mL not less than 2 weeks later, if required.
• The second dose should be administered at least 4 weeks before point of lay.

Ducks:
• Ducks less than two weeks of age:
• Administer 0.2 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.
• Ducks two or more weeks of age:
• Administer 0.5 mL of vaccine subcutaneously at the back of the neck.
• Administer another dose of 0.5 mL not less than 2 weeks later.

ADVERSE EFFECTS, CAUTIONS AND CONTRAINDICATIONS

ADVERSE EFFECT
• Vaccinate only healthy chickens or ducks and avoid stressing the birds at the time of vaccination.
• Do not mix with any other vaccine or injectable product.
• The use of this product in laying birds has not been evaluated.
• Local or systemic post-vaccination reactions can occur due to the use of oily vaccines. Symptoms observed are generally transitory and can include oedema and granulation at the injection site, anorexia and dehydration. Such reactions can be minimised by good aseptic vaccination technique.

CAUTIONS
• Destroy any unused vaccine and containers after vaccination (including syringes and needles) by burning.
• Do not mix the vaccine with other vaccines or administer another vaccine shortly before or after vaccination with this product.
• Consult a physician immediately for an accidental self-injection and show this package insert to the physician.
• KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS

CONTRAINDICATIONS
• None.

WITHHOLDING PERIODS
Meat: Nil.

STORAGE
• Store in the dark between 2 °C and 8 °C. Do not freeze.
• Protect from direct sunlight.

• Use contents of each vial within 6 hours of opening

15 Appendix 6: Vaccination considerations

Any vaccination programme for exotic disease needs to be approved by the MPI Chief Technical Officer, Biosecurity.

There may be some advantages in commencing a prophylactic vaccination programme as soon as staff are trained and protocols are in place. For instance:

1. HPAI has a short incubation phase from infection to disease (4hrs – 2 days) whereas it takes 2 to 3 weeks for protection from vaccination. Immediate vaccination would remove the risk of the virus arriving and spreading before a vaccine programme has had time to produce effective immunity.
2. Vaccinating prior to arrival of HPAI decreases the risks of staff handling infected birds during the vaccination programme, thus reducing risk of humans catching bird flu and of spreading the disease via contaminated equipment etc.
3. Stress to the birds from capture/handling/vaccination could make them more susceptible to disease should they become exposed soon after.
4. It would be possible to monitor vaccine efficacy and duration of immunity prior to any risk of exposure (by collection of blood samples after vaccination, looking for an antibody response).
5. It would be possible to employ a staggered vaccination programme to assess the safety of the vaccine i.e. vaccinate a subset of the species and monitor for adverse effects before vaccinating the population.

However, there are several disadvantages to acting immediately:

1. The duration of protection from the vaccine is not known, therefore protection may have waned before the arrival of HPAI.
2. There are risks of injury from capture and handling some species and of side effects from the vaccine, and if the virus never arrives in NZ these species would have been put at unnecessary risk.
3. A vaccination programme is resource hungry and while the threat of arrival of HPAI is low, it may be difficult to justify channelling resources away from other priority programmes.
4. Once commenced, in the absence of the arrival of HPAI, it will be difficult to determine when it would be appropriate to stop (booster vaccinations are be necessary to maintain immunity in the long term).
5. A vaccination programme may actually encourage mutation of avian influenza virus into more pathogenic types if the birds are already carrying low pathogenic avian influenza.

16 Appendix 7: Additional references

This is a living Appendix which will be updated with additional references which provide useful background information relevant to HPAI response in Aotearoa New Zealand.

Last updated 23/09/2022

National Surveillance Program shows Australia is a 'global sink' for diversity of AIV (May 2022)

WOAH and IUCN Wildlife Health Specialist Group Guidelines: Avian influenza and Wildlife: Risk management for people working with wild birds(Sept 2022)

Bird Flu advisory for wildlife managers and bird banders: New Zealand Department of Conservation (in collaboration with Ministry for Primary Industries)

FAO alert for Central America and South America: *H5 high pathogenicity avian influenza – risk for introduction and spread* – with a summary of the situation, recommendations and links for further reading.

UK guidance on mitigating the impact of avian influenza in wild birds: Guidance to support land managers and ornithologists.

Dewar et al (2022). The Risk of Avian Influenza in the Southern Ocean: A practical guide: SCAR Antarctic Wildlife Health Working Group.

WHO Global Influenza Programme Monthly Risk assessment summaries of influenza at the human-animal interface: https://www.who.int/teams/global-influenza-programme/avian-influenza

Caliendo et al (2022). Long-Term Protective Effect of Serial Infections with H5N8 Highly Pathogenic Avian Influenza Virus in Wild Ducks. *Journal of Virology*, e01233-22.

Guinat et al (2022). Disentangling the role of poultry farms and wild birds in the spread of highly pathogenic avian influenza virus in Europe. *Virus Evolution*, *8*(2), veac073.

Pohlmann et al (2022). Has Epizootic Become Enzootic? Evidence for a Fundamental Change in the Infection Dynamics of Highly Pathogenic Avian Influenza in Europe, 2021. *Mbio*, e00609-22.

Alkie et al (2022). A threat from both sides: Multiple introductions of genetically distinct H5 HPAI viruses into Canada via both East Asia-Australasia/Pacific and Atlantic flyways. *Virus Evolution*, *8*(2), veac077.

Adverse Event Report

Animal Ethics Committee

Animal Ethics Committee

V5 prepared 15/09/23 DOCDM-871369

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Application/Approval number	AEC445
Title	Avian Influenza vaccination safety and efficacy trial Kakī Black stilt
Approval holder	Kate McInnes
Date of incident	7th May 2024
Time/ Weather Other environmental conditions	Cool still morning becoming warmer during the day. This event occurred at just before 1300hrs
Location	DOC kakī aviaries, Old Iron Bridge Road, Twizel.
Describe what happened	We caught an adult kakī in its aviary for a physical examination, blood sample and second vaccination for Avian Influenza. The capture was routine, but the bird evaded the nets for a reasonable period of time (<5 minutes). This was a longer capture than previously with this pair of birds or any other kaki in the trial, but within the standard time frame for capture of kakī in an aviary setting. Capture was undertaken by DOC staff listed on the AEC approval who have considerable experience in kakī capture. They did not indicate that this capture event was unusual. The bird was examined and then blood collected by wing stab/capillary tube method according to the DOC SOP. Blood flowed freely and it was difficult to control bleeding when the sample had been obtained.
What action did you take?	It took longer than normal to control the bleeding (~15 minutes). However, it was achieved with standard techniques of pressure, a cool pack under the wing, styptic powder, and finally use of a silver nitrate stick. These were all items in our standard collection kit, however we had not needed to use all these methods previously, and in the past, the bleeding was stopped much more rapidly (~2-3 minutes). The bird was held in a kakī transport box after the event to allow it calm down and to ensure we could recheck it to see that the bleeding did not reoccur.

	It was re-examined, vaccinated, and released approximately 10 minutes later and no further adverse effects of the sampling event were noted. The bird behaved normally on release into the aviary and was seen bathing and preening as expected after handling.
What samples, photos or materials were taken?	nil
What advice did you seek? From whom, and what was the advice?	The DOC veterinarian and the DOC aviary manager were undertaking the procedure. A stop was called and the situation assessed to ensure the best outcome for the bird. The transport box was obtained for holding the bird to reduce stress.
Is further follow up action needed or recommended? By whom?	Consider options which could include treating or isolating potentially affected animals, closer monitoring, changes to routine husbandry, techniques or experimental procedures, termination, or suspension of a study. Kakī staff rechecked and monitored the bird during the day and no ongoing adverse reactions were noted.
What recommendations could <u>you</u> make to the AEC about how this manipulation could be improved/modified?	1. If birds take longer to capture than normal, they will be held in a transport box for 5 to 10 minutes to let them calm down before sampling. Transport boxes are large enough to allow the bird to stand comfortably, and are dark and quiet, which reduces stress. 2. We will use a smaller gauge needle. Currently 25g. We will try 26g and can go smaller to 30g if necessary. 3. We will use the hematocrit tubes to collect blood if the flow is slow or switch up a microtainer if it is fast. That will allow rapid collection and stopping the bleeding sooner. 4. Ambient temperatures will be considered a potential factor in increased bleeding, so on sunny, hot days, collection will be undertaken early in the day to avoid the warmer periods. 5. The period between bleeding events should be maximised to reduce stress related to repeated capture in a short period of time, particularly adult birds which may have more of a stress reaction.

Any other comments or observations of thoughts?	This event shows the importance of good planning, equipment and experienced people to do this work. The mix of vet & husbandry experience was essential in ensuring this event had a successful outcome. It also highlights the need to reconsider techniques/practices when repeated manipulations are undertaken, as we feel it was the memory of past experiences of capture/handling of the adult bird which made them more prone to this event.

Approval holder name:

Signed: 9(2)(a) Date: 30 May 2024

Animal Ethics Committee Use

Follow up actions:

#	Actions /Comments	Follow Up By /when

Recommendations:

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Animal Ethics Committee

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<table>
<tr><td>Application/Approval number</td><td>AEC446</td></tr>
<tr><td>Title</td><td>Avian Influenza vaccination safety and efficacy trial tūturuatu</td></tr>
<tr><td>Approval holder</td><td>Kate McInnes</td></tr>
<tr><td>Date of incident</td><td>27/4/25</td></tr>
<tr><td>Time/ Weather
Other environmental conditions</td><td>Normal weather/temperatures, 8-10 degrees overnight, up to 18 during the day for past 3 days, some whind but not extreme</td></tr>
<tr><td>Location</td><td>Isaac Conservation & Wildlife Trust, Christchurch</td></tr>
<tr><td>Describe what happened</td><td>The affected birds is El, an adult female tuturuatu/shore plover.
El was captured for blood collection on 25th March. It was a routine procedure and no abnormal events occurred. She was noted to be low body weight. She had produced 2 clutches of eggs and all birds were in lower body weight/condition at the end of the breeding season.
Apart form that, there were no indications of ill health to suggest any risk of illness or death.
No abnormalities were observed post release to the aviary or that afternoon or on the following day when all birds were visited and the aviary serviced (am and pm).
48 hours after handling later she was found dead in the aviary.

<table>
<tr><td>Date</td><td>Weight</td><td>Condition score (1-5)</td><td>Activity undertaken</td></tr>
<tr><td>2/2/24</td><td>57g</td><td>2.5</td><td>Vax & blood & swab</td></tr>
<tr><td>5/3/24</td><td>59g</td><td>3</td><td>Vax & blood</td></tr>
<tr><td>5/4/24</td><td>56g</td><td>2</td><td>Blood</td></tr>
<tr><td>8/8/24</td><td>58g</td><td>2.5</td><td>Blood</td></tr>
<tr><td>25/3/25</td><td>50g</td><td>2.5</td><td>Blood</td></tr>
</table>

At the time of handling we did note that her weight was low, and looked at historic weights and the other birds' weights. Based on her good levels of activity , her bright alert demeanour, and no evidence of illness, we decided this was normal post-breeding weight loss which would resolve now that breeding was over (as is normally seen with tuturuatu).</td></tr>
</table>

What action did you take?	Body was sent to Massey for necropsy. Other birds were visually checked.
What samples, photos or materials were taken?	Body submitted for necropsy. Report: Pathology_64621 El shore plover https://doccm.doc.govt.nz/cwxv4/wcc/faces/wccdoc?dDocName=DOC-10337050 The bird was in moderate body condition, i.e. she was not emaciated. Really the only microscopic abnormalities were small areas of haemorrhage over the heart and the early death of small groups of cardiomyofibers (heart muscle). There was no associated inflammation so an infectious cause seems unlikely. This type of damage can be seen with sudden/acute stress which can result in large amounts of adrenaline which can damage the cells of the heart and result in sudden death. The damage to the heart looks to be several hours old, if not shorter. There was also no evidence of a capture myopathy-type of injury to the pectoral muscles.
What advice did you seek? From whom, and what was the advice?	Necropsy results did not detect any issues which were considered likely to be related to the handling or the blood collection. The necropsy suggests a sudden death due to a spike of extreme stress. One possible scenario is an aerial predator may have spooked the bird. That is speculative and there is no definitive explanation for this bird's death.
Is further follow up action needed or recommended? By whom?	Consider options which could include treating or isolating potentially affected animals, closer monitoring, changes to routine husbandry, techniques or experimental procedures, termination, or suspension of a study. There is no evidence that the stress of handling contributed to the death of this bird - from the observations of normal behaviour for 48 hours after blood collection, or from the necropsy. Additionally other management work with the birds has previously involved handling at a similar regularity and that has not been associated with mortality.

What recommendations could you make to the AEC about how this manipulation could be improved/modified?	Undertake observations for any aerial predator or other disturbance which may be causing significant stressful events in the aviaries. Also: Avoid handling tuturuatu. Consider carefully risks/benefits of any handling event. (this is standard approach normally). Consider if nutritional changes are needed to boost body condition as multiple clutches appear to be having a significant impact on body weight (10% loss). (although the necropsy showed the bird was in a moderate body condition)
Any other comments or observations of thoughts?	

Approval holder name:

Signed: 9(2)(a) Date: 26/5/2025

Animal Ethics Committee Use

Follow up actions:

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Recommendations:

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<tr><td>Title</td><td>Avian Influenza vaccination safety and efficacy trial tūturuatu</td></tr>
<tr><td>Approval holder</td><td>Kate McInnes</td></tr>
<tr><td>Date of incident</td><td>5th September 2024</td></tr>
<tr><td>Time/ Weather
Other environmental conditions</td><td>Indoors, flocking aviary/smaller insect proof aviary at</td></tr>
<tr><td>Location</td><td>Wildbase Hospital, Massey University, Palmerston North
And
Isaacs Conservation & Wildlife Trust, Christchurch</td></tr>
<tr><td>Describe what happened</td><td>The affected birds is Badger, an adult male tuturuatu/shore plover.
He was caught twice, 1 month apart, for sampling and vaccination.
At his third capture, he was noted to have lost 6g and had a decreased condition score. No health abnormalities were detected on physical examination or blood testing.

<table>
<tr><td>Date</td><td>Weight</td><td>Condition score (1-5)</td><td>Activity undertaken</td></tr>
<tr><td>2/2/24</td><td>56g</td><td>2.5</td><td>Vax & blood & swab</td></tr>
<tr><td>5/3/24</td><td>56g</td><td>2.5</td><td>Vax & blood</td></tr>
<tr><td>5/4/24</td><td>50g</td><td>2</td><td>Blood</td></tr>
<tr><td>8/8/24</td><td>56g</td><td>2</td><td>Blood</td></tr>
</table>
</td></tr>
<tr><td>What action did you take?</td><td>Based on his weight loss it was decided to release him into a smaller insect proof aviary on 5th April for closer monitoring and more shelter.
On 17th April the team at Isaacs reported: “Badger appears to be well but we haven’t had him in the hand since you were here. Its definitely an easier life in there and he’s behaving normally, hoovering down mealworms when he gets the chance.”
He was recaptured on 8th August for the 6 month blood test and noted to have gained weight but not condition. He was also noted to have poor waterproofing, however this can happen from time-to-time in tuturuatu. We discussed keeping him for longer in the smaller aviary until he regained waterproofing, however, because the breeding season had commenced and it was hoped he would pair up, he was returned to a normal aviary at this</td></tr>
</table>

	time with the hope/expectation that he would improve in a more normal aviary with better water-bath access. Closer observation continued and it was noted that he was not regaining his waterproofing so he was transferred to Massey University on Monday 2nd Sept for veterinary workup. He appeared stable initially but then died suddenly overnight on the Wednesday 4th Sept. Massey report on Wednesday 4th Sept: *Just a quick update on badger - yesterday we performed xrays, bloods and faecal smears. The xrays and bloods were unremarkable. The faecal smear yesterday had a lot of weird looking "bacteria" or other organism that predominated, whereas today the smear was a mixed population that doesn't warrant any major investigation. Tomorrow I will repeat a fresh faecal smear - if the weird organisms are back I will perform a faecal culture, otherwise we can just ignore whatever was there the first day! We are currently collecting serial faecal samples for parasitology which I hope we will be able to send away in a couple of days so I will let you know once we have a result. Other than that he is doing well in hospital, eating like a champ, gaining weight and has well formed faeces with little vent feather staining. If you have any more questions, please don't hesitate to email me.* Massey report on Thursday 5th Sept: *Unfortunately I am emailing you with bad news regarding Badger. Following a relatively positive update yesterday, we've come in to the clinic this morning with Badger looking very sad, with very little faecal output overnight, and a very wet/faecal stained vent. He crashed quickly throughout the morning even with supportive care, and following an attempt by Megan to resuscitate, he unfortunately died. I'm sorry to have to pass on that news, it was a bit of a surprise to us considering how well he was doing yesterday. It even looked like he was active and eating after afternoon treatments yesterday but declined through the night. We have sent his body to Stu for post-mortem and I will get back to you with any results from that.* He was 37g at necropsy. The necropsy revealed abnormal gut bacterial overgrowth.
What samples, photos or materials were taken?	Blood samples for health parameters which were normal. Body submitted for necropsy. Pathology_63886 shore plover.pdf

What advice did you seek? From whom, and what was the advice?	Massey vet Brett Gartrell provided this summary for the team at Isaacs: *Stu has just finalised the PM report on the shore plover that died in hospital (see attached). The pattern of disease in the gut is very similar to the nebulous cases we have seen before and haven't been able to pin down a primary cause. The overall feeling is that this bird has chronically declined in bodyweight to the point where it wasn't able to cope anymore. There is nothing here that connects the death with the vaccination.* *I have asked Stu to do some bacterial cultures of the gut content, and we are going to put some material aside in case Jemma Geoghan is interested in running more her molecular pathogen discovery techniques.* *The only new thing in the post mortem report is the finding of spironucleus organisms. These are single celled protozoa that parasitise the gut and for most species don't cause much disease. However in King Parrots in Australia they can cause a severe diarrhoea and wasting syndrome. Its most likely these were simply present in the shore plover as opportunists with the bird being run down, but there's a small possibility they may be more important than that. These protozoa die quickly out of the bird, or when the bird is dead, so they are often hard to find in post mortem samples. The best way to detect them is to fresh faecal wet mounts and examine them immediately under the microscope. I suggest that if you are doing catchups after the breeding season let me know and I'll come and visit with my microscope and see what we can find.*
Is further follow up action needed or recommended? By whom?	Consider options which could include treating or isolating potentially affected animals, closer monitoring, changes to routine husbandry, techniques or experimental procedures, termination, or suspension of a study. Abnormal gut microbiome with mortality events has been noted before in tūturuatu from this facility and investigations at the time looking at gut microbiome and water quality testing(water quality was good) did not determine a cause of the gut bacterial overgrowth. Around the same time, treatment at the veterinary clinic of a group of tūturuatu from a different facility which had experienced a poor water quality event following flooding had a mixed result for the birds being treated, with a high mortality rate despite intervention. There is no guarantee that earlier intervention would have changed the outcome. The impact of stress of handling cannot be ruled out as a potential influence in this event, however there is no direct cause and effect evident in the symptoms of generally a bit unwell, or the results of testing or necropsy. Additionally other management work with the birds has previously involved handling at a similar regularity and that has not been associated with mortality.

	As noted by Dr Gartrell, in the event that a bird suffers weight/condition loss and is noted to be abnormal, earlier transfer to the veterinary clinic could be useful. This can be a difficult decision to make, with movement of birds disturbing pair bonds or interfering with breeding season plans, particularly when there is nothing specific to identify as an issue. We will continue to follow up on the gut microbiome to attempt to identify the "weird" bacteria and establish if there is any management or treatment which can/should be instigated now or in the future if this problem reoccurs.
What recommendations could <u>you</u> make to the AEC about how this manipulation could be improved/modified?	Set a weight loss % and if a bird drops below that, strongly consider sending to a veterinary clinic for work-up. This would be discussed in conjunction with the animal managers and in consideration of all the measurable health parameters and history of the bird, time of year, weather, availably of aviaries and closer observation. Earlier intervention is recommended to potentially improve the outcomes for individual birds in the future.
Any other comments or observations of thoughts?	In essence, we followed the process discussed above, however with the outcome in this instance, I feel that faced with a similar situation in the future, the decision would be made to transfer the bird to a vet earlier in the process. It is not clear if this would change the outcome as we are unclear what illness resulted in the bird's demise.

Approval holder name:

Signed: 9(2)(a) Date: 10/9/2024

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Application/Approval number	AEC446
Title	Avian Influenza vaccination safety and efficacy trial in tūturuatu shore plover
Approval holder	Kate McInnes
Date of incident	Friday 17th May 2024
Time/ Weather Other environmental conditions	Friday: -0.7 overnight, 14C daytime max. NE 33. Previous day was strong southerlies, but temperature range had been consistent for the previous week. Prior to that, 3 days of sub-zero overnight temperatures (-3.2, -4.2, -6.3) with strong winds and showers on the 8th, 9th & 10th May. 
Location	Isaacs Wildlife and Conservation Trust, Harewood, Christchurch

Describe what happened

Zara C-14643, an adult female, was part of cohort 2 in the HPAI trial. She had received blood tests and vaccinations on 5/3/24 &5/4/24.
Her physical exams were normal on both occasions and her blood results were:

	5/3/24	5/4/24
Weight	57	56
PCV (red cells)%	50	50
Total Protein	38	40
WBC	5.7	6.4
Lymphocyte %	71	61
Lymphocyte count	4.0	3.9
Monocyte %	5	8
Monocyte count	0.3	0.5
Eosinophil %	0	5
Eosinophil count	0	0.3
Basophils %	1	3
Basophil count	0.1	0.2
Heterophil %	23	23
Heterophil count	1.3	1.5
	Erythrocyte morphology appears normal. White cell count is an estimate from the blood film Leukocyte morphology appears normal. Thrombocytes appear adequate in number and normal in morphology No blood parasites seen	Erythrocyte morphology appears normal. White cell count is an estimate from the blood film Leukocyte morphology appears normal. Thrombocytes appear moderately reduced in number and normal in morphology No blood parasites seen

History provided by the captive facility staff:
Held with 3 other females for flock mating in spring. Noticed on Friday she was puffed up and quiet, also the same the following day.
Could not find Zara in the am, but she came out of the bushes eventually. Puffed up, and being pecked by other shore plover. I was able to corner her and pick her up, she couldn't fly and was struggling to run. Seemed like she was also struggling to breathe when in my hand. Put in a brooder for now. Died around midday, weighed 44.5g (down from 56gm 4/4/24)

What action did you take?

Captive facility undertook their normal procedures for health issues in birds which involved isolating the animal in a warm brooder to provide supportive conditions. Bird died on the same day.

What samples, photos or materials were taken?	The body was sent to Massey for a necropsy on Monday 20th May. Preliminary findings (pending histopathology results) are: Gross Findings 63479 The bird weighed 44grams and was in poor body condition. There was minimal to no subcutaneous fat, and also reduced pectoral muscle coverage. The right cranial and caudal thoracic air sac was very thickened and filled with fluffy white mould, and the wall of the air sac had adhered to sections of the coelomic organs. The right abdominal air sac was also white and thickened. There were a couple of focal white mouldy lesions in the left cranial thoracic air sac as well. Pathologist: S.A. Hunter
What advice did you seek? From whom, and what was the advice?	I have reviewed the blood results from samples taken from this bird prior to this event, and the bird had perfectly normal results. There was no indication of either an infection or immunosuppression. Body weight had not changed across the two handling events. This event was discussed by the Tūturuatu Captive Management Group at their annual meeting on 22nd May. The history of susceptibility to aspergillus infection in this species was noted, and its relationship to spore counts from rotting vegetation, and stress.
Is further follow up action needed or recommended? By whom?	Consider options which could include treating or isolating potentially affected animals, closer monitoring, changes to routine husbandry, techniques or experimental procedures, termination, or suspension of a study. I have reviewed the previous necropsy reports for this species. There have been deaths from aspergillus in tūturuatu– most recently during the 2023/24 breeding season where (3) adult females died following laying their first clutch of the season, suggesting stress related immunosuppression from the efforts of breeding and/or exposure to overwhelming spore counts during the nesting process. They appear to be a species which is prone to aspergillus infection in captivity - 15% (32/217) of tuturuatu necropsied at Massey over the past 15 years have died aspergillosis. However this case may be related to concurrent stressful events e.g. the cold snap of weather 1 week prior to death, being held in a flock where social interactions might cause stress and being captured and handled for the vaccination trial. The sudden cold snap one week prior could also be a significant factor in causing environmental stress. Aspergillus can sit relatively dormant in the air sacs of a

	bird until stress causes immune suppression and allows the infection to take off. Because tuturuatu are prone to aspergillus infection, and it can be induced by a wide range of stressors and/or exposure to overwhelming spore counts, it is difficult to determine if there are actions we can take to avoid/prevent this occurring in the future. I do not think it is solely or directly a response to the vaccine trial. However, we will continue to constantly reassess the programme to minimise any capture/handling stress.
What recommendations could <u>you</u> make to the AEC about how this manipulation could be improved/modified?	Minimising handling events will minimise the risk that the trial work contributes to the stress on these birds. Timing handling events to avoid periods of stress will also reduce risk. This is already incorporated into the programme by avoiding the breeding period. Birds will not be handled from September to February. Maximising the time between handling events will also help reduce stress. Where there is leeway within the sampling time to extend the "rest" period, this will be undertaken.
Any other comments or observations of thoughts?	This has been an important finding to inform conservation managers of the risks associated with repeat handling of wildlife, and that these factors need to be taken into account for any future use of vaccinations in tuturuatu and other species.

Approval holder name: Kate (Catherine) McInnes

Signed: 9(2)(a) Date: 04/06/2024

Animal Ethics Committee Use

Follow up actions:

#	Actions /Comments	Follow Up By /when

Recommendations:

Adverse Event Report

Animal Ethics Committee

Animal Ethics Committee

V5 prepared 15/09/23 DOCDM-871369

An adverse incident is any unanticipated, unfavourable, or atypical event occurring to an animal during or as a result of routine husbandry, experimental manipulation, or disease.

The Adverse Incident does not necessarily result from a non-compliance with the AEC Approval.

Purpose

Reporting adverse events is a quality assurance and improvement tool. It is not undertaken as a punitive process.

By understanding what led to the event, we can collectively work towards improving the way that we manipulate animals for research, testing and teaching.

Unanticipated outcomes or events can be an injury to the animal or handler, broken equipment, adverse reactions to medications or the extreme; it can result in the serious injury or death of an animal.

The AEC are keen to discuss this process with staff, or to gather feedback on the process. Any comments can be sent to Emma Williams, Chair at aec@doc.govt.nz or emwilliams@doc.govt.nz

Information for Applicants - Process

Please complete this form and submit it electronically to the Chair DOC Animal Ethics Committee aec@doc.govt.nz or emwilliams@doc.govt.nz

SAVE YOUR REPORT INTO DOCCM

Name electronic file as AECXXX ADVERSE species key words e.g., AEC999 ADVERSE Tui mortality mist nets. Give full permissions to Emma Williams-Christchurch Office (AEC Chair).

Application/Approval number	AEC 447
Title	Avian Influenza vaccination safety and efficacy trial Kakariki
Approval holder	Kate McInnes (Rachel Stanyer – vet conducting the work that day)
Date of incident	17/04/2024
Time/ Weather Other environmental conditions	10am/ Fine and cool day
Location	Natureland Wildlife Trust, Houndsell Circle, Tahunanui, Nelson
Describe what happened	We were catching 4 female kakariki in their aviary for a physical examination, blood sample and second vaccination for Avian Influenza. The birds are closed into their feeding station once they have entered it and then caught up into a catch bag by hand. All of the others had been caught and were in their catch bags. This bird was the last to enter the feeding station and had been flying around for longer than usual. Capture was undertaken by Natureland staff listed on the AEC approval who are experienced in kakariki capture. They did not indicate that this capture event was unusual. The bird was examined and then blood collected by wing stab/capillary tube method according to the DOC SOP. Blood flowed freely and it was difficult to control bleeding when the sample had been obtained.
What action did you take?	It took longer to control the bleeding than normal. I used pressure with a swab, ice packs and then the animal care manager went to get a silver nitrate stick and eventually it stopped using this combination of techniques. Usually, pressure +/- an ice pack is sufficient. We released the bird back into the feeding station and kept her in there for monitoring. She was initially visibly stressed and wasn't moving or eating but after an hour or so she returned to normal behaviour and was released back into the aviary
What samples, photos or materials were taken?	None

What advice did you seek? From whom, and what was the advice?	I discussed the follow up care with the Animal care manager at Natureland. We decided to use the silver nitrate stick as an extra method of haemostasis.
Is further follow up action needed or recommended? By whom?	We decided to keep the bird in the feeding station immediately afterwards for monitoring and were in contact about her health after Rachel had left to make sure she didn't need any follow up care. She went on to recover well.
What recommendations could <u>you</u> make to the AEC about how this manipulation could be improved/modified?	1. Have silver nitrate sticks in the kit in preparation 2. If birds take longer to catch or are caught up last and have been flying around a lot, we should get them into a catch bag and then leave their procedure until last to allow them to calm down and blood pressure will drop 3. Use smaller needles – currently using 25g but we may try 26g next time 4. Allow the maximum period of time between blood sampling procedures so as not to be causing capture stress too often 5. Use more high value food to try and get them into the feed area more quickly 6. Vet to hide out of the way (already was doing this on this trip) as the presence of the vet in the aviary is stressful
Any other comments or observations of thoughts?	Repeated capture is stressful for these birds and they are becoming more reluctant to come into the feeders. Giving them as much of a break between captures will be important going forward. Having a quick thinking, experienced team on hand is key and being more prepared.

Approval holder name:

Signed: 9(2)(a) Date: 04/06/2024

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Application/Approval number	AEC 447
Title	Avian Influenza vaccination safety and efficacy trial Kakariki
Approval holder	Kate McInnes (Rachel Stanyer – Vet conducting the work that day)
Date of incident	29/05/24
Time/ Weather Other environmental conditions	9.45am -Cold but Fine day
Location	Natureland Wildlife Trust, Houndsell Circle, Tahunanui, Nelson
Describe what happened	The keepers were starting to catch up 4 male Kakariki in their aviary which involves putting food into the feed station and then once they go in, shutting the door so they can be caught by hand into catch bags. They caught up one male and got him into the catch bag. The keeper realised within moments he wasn't fighting in her hand so she looked into the bag and he was on his back, not moving. He had died instantly. Rachel was called into the aviary but he had already died.
What action did you take?	Rachel checked the bird to see if anything could be done but he was already dead. Rachel packaged him and sent him for post mortem examination at Wildbase, Massey immediately.
What samples, photos or materials were taken?	Rachel tried to get a post mortem blood sample – intracardiac but failed. We think his blood had already clotted. The whole body sent chilled to Wildbase, Massey.
What advice did you seek? From whom, and what was the advice?	Rachel discussed with the keepers what had happened and what we should do next. They had already caught up a female bird – and decided to carry on and blood sample that bird only. We decided that the male birds were all now very stressed so did not continue with further catching up. Rachel called Kate McInnes straight away to discuss and we decided that we should leave any further catching up to another day as capture stress was a concern.

Is further follow up action needed or recommended? By whom?	Yes- as discussed with Kate McInnes we need to review capture procedure and review if there was anything different about this catch up to previous times. Other birds were monitored throughout the day to make sure they recovered from the stress even though they weren't caught The bird was sent for a necropsy to Massey University and the result is attached. The cause of death was trauma. There was a fatal injury to the bird's head. It is likely that the bird struck its head on the side of the wooden feeder/door during the capture process. We will attempt further captures during June to obtain the post vaccination blood samples. However these will be done with an abundance of caution and if birds are reluctant to be caught, we will abandon the attempt. At the next capture event we will carefully monitor how the birds behave and determine where the risk points are in the capture process to help design further mitigation measures. The decision to abandon capture attempts will be at the discretion of the experienced staff. We have reiterated that the risk of injury needs to be managed without any pressure to obtain the bloods i.e for animal welfare purposes, DOC is totally accepting that we may not be able to recapture these birds in the short term, so the staff should not feel pressure to undertake capture if they are at all uneasy about the birds' behaviour on the day.
What recommendations could <u>you</u> make to the AEC about how this manipulation could be improved/modified?	The problems we have are that : - The birds are becoming more stressed each time we catch them and they are more reluctant to come into the feeding station even though this process is part of their normal daily routine. They seem to know what is happening because the keeper is staying around the feeder - We also have the added problem that the Kea in the female kakariki aviary are now alarm calling very loudly when Rachel appears on site. This is an issue as it is alerting all the birds to the catch up . - Rachel is already hiding away from the birds until they are caught - The capture technique we are using is low stress compared to other options like hand nets, mist nets etc and has not been associated with any issues in the past at this site. Recommendations:

	- Give the birds the biggest break from capture we can between samples, - Give them high value foods to make capture more streamlined - Habituate them to having a keeper staying around the feeders as per capture day, but make this a routine daily event on non-capture days too. - Only target the birds that we can catch easily i.e. be prepared to fail in captures and don't try to force the issue. Accept that not all birds will be recaught at each attempt, and ultimately some birds may not be resampled. The necropsy result has been further discussed with the capture team at Natureland. Given the change in behaviour of these birds as a result of repeated capture, we will continuously re-evaluate all aspects of the capture/handling process and equipment. This necropsy result shows an added risk due to the hard wooden structure of the capture/feeding box. We will review if any actions/equipment could be managed to reduce the risk of a repeat of this event. Any further capture will require additional mitigation of this risk, now it has been identified. Any additional padding may affect the habituation of the birds to the capture box/feeder and will need to be slowly introduced. Additionally they will need to be "parrot proof" to avoid the birds chewing on the material. Adjustment to the amount of light in the box to reduce stress/panic response could be made. Additional recommendations will be made after these further discussions.
Any other comments or observations of thoughts?	Parrots are challenging to work with as they are so smart and have long memories. These birds are captive and habituated to humans and they are finding this very stressful so there are lessons to be learned about vaccinating other species that are stressy and small – it may not be a straightforward option for some species, especially in wild or sanctuary settings where they aren't as used to people.

Approval holder name:

Signed: 9(2)(a) Date: 06/06/2024

Animal Ethics Committee Use

Follow up actions:

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Recommendations: