Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

July 2026

Risk Assessment and Risk Management Plan (Consultation version) for

DIR 224

Commercial supply of a genetically modified (GM) multivalent vaccine for chickens

Applicant: Intervet Australia Pty Ltd

This RARMP is open for consultation until 25 September 2026.

Written comments on the risks to human health and safety and the environment posed by this proposed supply of the GM multivalent vaccine for chickens are invited. You may make your submission.

via mail to: The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848, Canberra ACT 2601

or

via email to: ogtr@health.gov.au.

Please note that issues regarding the GM vaccine safety and labelling, benefits, and marketing and trade implications **do not** fall within the scope of these evaluations as they are the responsibilities of other agencies and authorities.

Summary of the Risk Assessment and Risk Management Plan (Consultation version) for Licence Application DIR 224

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application (DIR 224) for import, transport, storage, supply and disposal a genetically modified (GM) multivalent vaccine, known as Innovax®-ND-ILT, for the commercial supply of vaccine for chickens. These activities are classified as Dealings involving the Intentional Release (DIR) of genetically modified organisms into the Australian environment under the *Gene Technology Act 2000*.

The GM vaccine is based on a non-pathogenic strain of turkey herpesvirus, which prevents Marek's disease. It has been modified to express the fusion protein from Newcastle disease virus and 2 glycoproteins from infectious laryngotracheitis virus, which together induce immunity against ND and ILT.

Before the GM vaccine can be used, Intervet Australia Pty Ltd must also obtain regulatory approval from the Australian Pesticide and Veterinary Medicines Authority (APVMA). The APVMA administers the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) to regulate agricultural and veterinary chemical products, including veterinary vaccines. For commercial products, the standard form of approval is through registration. The APVMA can impose conditions on the use of veterinary products via registrations and permits.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed supply of the GM vaccine poses negligible risks to human health and safety and negligible risks to the environment. Licence conditions have been drafted for the proposed supply. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application number	DIR-224
Applicant	Intervet Australia Pty Ltd
Project title	Commercial supply of a genetically modified (GM) multivalent vaccine for chickens[1]
Parent organism	Turkey herpesvirus (*Mardivirus meleagridalpha1*) strain FC-126
Genetic modifications[2]	**Introduced genes**: - fusion (F) protein gene from Newcastle disease virus (NDV) – Expression of the F protein - glycoprotein D (gD) and glycoprotein I (gI) genes from infectious laryngotracheitis virus (ILTV) – Expression of the gD and gI glycoproteins

[1] The original title for the licence application submitted by Intervet Australia Pty Ltd was "Innovax ND ILT".

[2] Confidential Commercial Information (CCI): Some details of the genetic modification in the GM vaccine have been declared as CCI under section 185 of the Act. This information will be made available to the prescribed experts and agencies that are consulted on this application. CCI is not available to the public.

Previous releases	The GM vaccine has not been previously approved for release in Australia
Current approvals	The GM vaccine has been approved by the United States Department of Agriculture, the European Medicines Agency and the Veterinary Medicines Directorate in the United Kingdom.
Proposed locations	Australia-wide
Primary purpose	Commercial supply of a GM multivalent vaccine to prevent Newcastle disease (ND), infectious laryngotracheitis (ILT) and Marek's disease in chickens.

Risk assessment

The risk assessment process considers how the genetic modification and activities conducted with the GM vaccine, in the context of import, transport, storage and disposal for the purpose of supply, might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short- and long-term risks were considered.

Credible pathways to potential harm that were considered include the potential exposure of people to the GMO, the potential exposure of animals to the GMO, and the potential for the GMO to recombine with other similar viruses. The potential for the GMO to be released into the environment and its effects were also considered.

The risk assessment concludes that risks to the health and safety of people are negligible and the risks to the environment from the proposed supply of this vaccine are negligible. No specific risk treatment measures are required to manage these negligible risks.

The principal reasons for the conclusion of negligible risks associated with import, transport, storage and disposal of the GMO are:

- The parental organism, turkey herpesvirus (HVT), has narrow host range limited to avian species and it is non-pathogenic, and this is not expected to be altered by the inserted genes;
- HVT is not known to infect non-avian species, including humans, and the introduced genes and their products are not expected to cause harm to humans;
- The likelihood of accidental exposure to the GMO by people and the environment would be minimised due to well-established transport, storage and disposal procedures that are regulated by each State and Territory, and by local councils;
- The GMO would be imported under a DAFF import permit that requires specific import conditions to manage biosecurity risks;
- The GMO would need to be registered with the APVMA, who would impose conditions on the use, transport, storage and disposal of the vaccine; and
- Recombination between the GMO and other alphaherpesviruses is unlikely to result in emergence of a novel more transmissible or virulent alphaherpesvirus strain.

Risk management

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. The risk management plan is given effect through licence conditions. Draft licence conditions are detailed in Chapter 4 of the RARMP.

The risk management plan concludes the negligible risks can be managed to protect the health and safety of people and the environment. The product is not currently registered by the APVMA and registration with the APVMA is required prior to commercial use. The draft licence requires the Regulator to be notified of the APVMA registration of the product and any amendments to the registration (see Chapter 4).

General conditions were also included in the draft licence to ensure that there is ongoing oversight of the GM vaccine. Conditions were included requiring the applicant to report any new information obtained after release of the GMO to allow the collection of information to verify the findings of the RARMP. Post-market surveillance of veterinary vaccines is carried out in an ongoing capacity by State and Territories. The draft licence also contains several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and other reporting requirements, which includes an obligation to report any unintended effects.

Table of contents

Abbreviations

AgVet Code	*Agricultural and Veterinary Chemicals Code Act 1994*
AHA	Animal Health Australia
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential Commercial Information
CEF	Chicken embryo fibroblast
DAFF	Department of Agriculture, Fisheries and Forestry
DIR	Dealings involving Intentional Release
DNA	Deoxyribonucleic acid
EPA	Environment Protection Authority
F	Fusion
FFE	Feather-follicle epithelium
gD	Glycoprotein D
gI	Glycoprotein I
gE	Glycoprotein E
GM	Genetically modified
GMP	Good Manufacturing Practice
GMO	Genetically modified organism
GTTAC	Gene Technology Technical Advisory Committee
HGT	Horizontal gene transfer
HVT	Turkey herpesvirus
ILT	Infectious laryngotracheitis
ILTV	Infectious laryngotracheitis virus
IR	internal repeat
kb	Kilobase pair of DNA
LGA	Local government area
MD	Marek's disease
MDV	Marek's disease virus
mL	Milli litre
ND	Newcastle disease
NDV	Newcastle disease virus
NH	Haemagglutinin-neuraminidase
NSW	New South Wales
NT	Northern Territory
OGTR	Office of the Gene Technology Regulator
PBL	Peripheral blood lymphocytes
PCR	Polymerase chain reaction
QLD	Queensland
RARMP	Risk Assessment and Risk Management Plan

RNA	Ribonucleic acid
SA	South Australia
TAS	Tasmania
the Act	The *Gene Technology Act 2000*
the Regulations	The Gene Technology Regulations 2001
the Regulator	The Gene Technology Regulator
UL	Unique long region
US	Unique short region
USA	United States of America
UV	Ultraviolet light
VIC	Victoria
WA	Western Australia

Chapter 1 Risk assessment context

Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

2. The Act and the Gene Technology Regulations 2001 (the Regulations), together with corresponding State and Territory legislation, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

3. Section 50 of the Act requires that the Gene Technology Regulator (the Regulator) must prepare a Risk Assessment and Risk Management Plan (RARMP) in response to an application for release of GMOs into the Australian environment. Sections 50, 50A and 51 of the Act and sections 9 and 10 of the Regulations outline the matters which the Regulator must take into account and who must be consulted when preparing the RARMP.

4. The *Risk Analysis Framework* (RAF) (OGTR, 2013) explains the Regulator's approach to the preparation of RARMPs in accordance with the Act and the Regulations. The Regulator has also developed operational policies and guidelines that are relevant to DIR licences. These documents are available from the Office of the Gene Technology Regulator (OGTR website).

5. Figure 1 shows the information that is considered, within the regulatory framework above, in establishing the risk assessment context. This information is specific for each application. Risks to the health and safety of people or the environment posed by the proposed supply are assessed within this context. Chapter 1 describes the risk assessment context for this application.

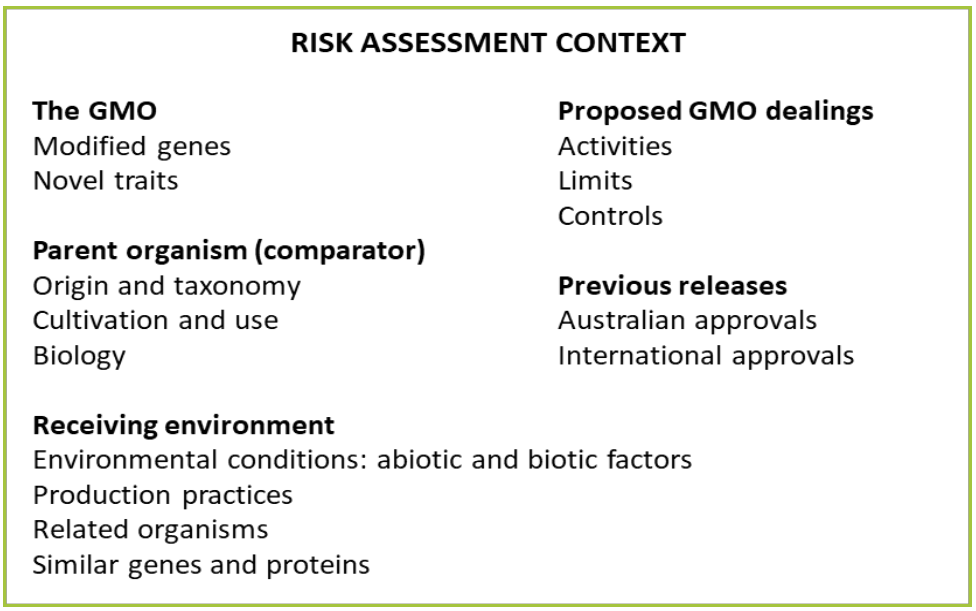

Figure 1. Summary of parameters used to establish the risk assessment context, within the legislative requirements, operational policies and guidelines of the OGTR and the RAF.

6. Since this application is for commercial purposes, it does not meet the criteria for a limited and controlled release application under section 50A of the Act. Therefore, under section 50(3) of the Act, the Regulator was required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of the RARMP. This first round of consultation included the Gene Technology Technical Advisory Committee (GTTAC), State and Territory Governments, Australian Government

authorities and agencies prescribed in the Regulations and the Minister for the Environment. A summary of issues contained in submissions received is provided in Appendix A.

7. Section 52 of the Act requires the Regulator to seek comment on the RARMP from the experts, agencies and authorities outlined above, as well as the public, through a second round of consultation.

1.1 Interface with other regulatory schemes

8. Gene technology legislation operates in conjunction with other regulatory schemes in Australia. The GMO and any proposed dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Department of Agriculture, Fisheries and Forestry (DAFF). These dealings may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

9. The APVMA provides a national registration and permit scheme for agricultural and veterinary chemical products. It administers the provisions of the *Agricultural and Veterinary Chemicals Code Act 1994* (AgVet Code). For registration, the APVMA assesses whether a new veterinary vaccine meets the criteria set out in the AgVet Code before it is registered in the Register of Agricultural and Veterinary Chemical Products. A new veterinary vaccine that is not registered may be legally used for animal trials by obtaining a permit from the APVMA.

10. As part of the registration process, the APVMA must first approve the new active constituent and then assess the quality, safety and efficacy of the vaccine. Quality aspects could include batch-to-batch consistency in vaccine composition, purity and potency. The product must also be manufactured in premises that comply with Good Manufacturing Practice (GMP), which is also audited by the APVMA. Safety aspects include the toxicological profile of the vaccine and its residues, including metabolites and degradation products. The APVMA approves the label, which includes instructions for the handling and storage, and directions for supply of veterinary vaccines, to ensure safe use. The APVMA would also carry out an environmental risk assessment to minimise environmental risks. The States and Territories are responsible for the enforcement of the conditions associated with an APVMA registration and carry out post-market surveillance.

11. FSANZ develops the food standards in the Food Standards Code with advice from other government agencies and input from stakeholders. The Standards in the Food Standards Code are legislative instruments and cover the composition of some foods, such as dairy, meat and beverages. FSANZ is also responsible for labelling of packaged and unpackaged food, including specific mandatory warnings or advisory labels.

12. Food standards are enforced by the states and territories (usually their health or human services departments) or, in some cases, by local government. These authorities regularly check food products for compliance with the Food Standards Code.

13. FSANZ has developed the Primary Production and Processing (PPP) Standard for Poultry Meat (Standard 4.2.2) (Food Standards Australia New Zealand, 2023) and PPP Standard for eggs and egg products (Standard 4.2.5) (Food Standards Australia New Zealand, 2018). PPP Standards (which only apply in Australia) aim to strengthen food safety and traceability throughout the food supply chain from paddock to plate. The standard introduces new legal safeguards for growing live poultry and requires poultry growers to identify and control food safety hazards associated with poultry farming. Poultry processors are also required to identify and control food safety hazards associated with poultry processing (which includes the slaughtering process) and verify the effectiveness of the control measures.

14. The applicant has proposed importing the vaccines into Australia. These imports would be subject to permits obtained from DAFF. DAFF administers Australian biosecurity conditions for the importation of biological products under the *Biosecurity Act 2015*. Biological products include those derived from

animals or microbes such as food, therapeutics, laboratory materials and vaccines (including GM treatments).

15. To avoid duplication of regulatory oversight, risks that have been considered by other regulatory agencies would not be re-assessed by the Regulator.

16. For the commercial supply of a GM veterinary vaccine, dealings regulated under the Act include the import, transport, storage and disposal of GMOs. The Regulator assesses risks to people as a consequence of conducting these activities and risks from persistence of the GMO in the environment.

1.2 Background on target diseases

1.2.1 Marek's disease (MD)

17. MD is a common disease of domestic chickens and causes significant economic losses in the poultry industry (Xu et al., 2025). It is caused by *Gallid alphaherpesvirus 2,* commonly known as Marek's disease virus (MDV). The virus is strictly cell-associated, carries an oncogene in its genome, and has a molecular structure and genome organisation similar to those of herpes simplex viruses (Gimeno, 2008). MDV infection can lead to T-cell lymphomas (immune cells forming tumour cells), immunosuppression (weakened immune system), and high mortality in infected flocks (Gimeno, 2008; Gimeno et al., 2001; Okura et al., 2021).

18. *Gallid alphaherpesvirus 2* belongs to the *Mardivirus* genus, within the *Alphaherpesvirinae* subfamily of the *Orthoherpesviridae* family (previously known as *Herpesviridae* family). The *Mardivirus* genus included 3 closely related species, previously designated as serotypes of MDVs.

19. Serotype 1 (MDV1), corresponding to *Gallid alphaherpesvirus 2,* includes all the virulent strains and is the only serotype capable of causing MD. Therefore, it is commonly referred to as MDV. This species is further divided into mild (m), virulent (v), very virulent (vv), and very virulent plus (vv+) strains.

20. Serotype 2 (MDV2), corresponding to *Gallid alphaherpesvirus 3*, and serotype 3 (MDV3), corresponding to *Meleagrid alphaherpesvirus 1*, were originally isolated from chickens and turkeys, respectively. These species are considered non-pathogenic (Gimeno, 2008; Purchase et al., 1971b; Xu et al., 2025).

21. MDV3 is also known as turkey herpesvirus (HVT). It is the parent organism of the GM vaccine proposed in this application. Details of HVT are discussed in Section 3 of this chapter.

1.2.2 Newcastle disease (ND)

22. ND, caused by Newcastle disease virus (NDV), is highly contagious and one of the most economically significant avian diseases affecting the poultry industry. NDV, also known as avian paramyxovirus 1 *or Orthoavulavirus orthoavulavirus 1,* belongs to the genus *Orthoavulavirus* within the family *Paramyxoviridae*. NDV contains a single-stranded, negative-sense RNA genome that encodes 6 structural proteins and 2 non-structural proteins (Ma et al., 2025).

23. NDV is transmitted via direct contact, aerosols and contaminated materials. It has a broad avian host range, with infections reported in more than 250 species. (USDA-APHIS, 2017). The virus can also infect non-avian species, including humans, where infection typically results in mild self-limiting disease, most commonly conjunctivitis, with occasional mild respiratory or flu-like symptoms restricted to the respiratory and neurological systems (Ul-Rahman et al., 2022). In very rare cases, severe neurological disease, including fatal outcomes, has been reported in immunocompromised individuals (Goebel et al., 2007; Kuiken et al., 2018; Winter et al., 2021). Transmissions of NDV from birds to humans have been reported; however, there is no evidence to support human to human transmission (Ul-Rahman et al., 2022; USDA-APHIS, 2017). NDV is predominantly transmitted horizontally, with only rare and unconfirmed reports of possible vertical transmission (Capua et al., 1993).

1.2.3 Infectious laryngotracheitis (ILT)

24. Infectious laryngotracheitis, caused by ILT virus (ILTV), is another important highly contagious respiratory disease affecting the poultry industry. ILTV, also known as Gallid herpesvirus 1, is a member of the Ortho*herpesviridae* family, *Alphaherpesviridae* subfamily. (Gowthaman et al., 2020; Ou and Giambrone, 2012). Similar to HVT, ILTV contains a linear double-stranded DNA genome approximately 150-155 kilobase pairs (kb) in length. The genome comprises unique long (UL) and unique short (US) regions, with the US region flanked by inverted repeats (IR) sequences. ILTV virions consist of 4 distinct structural elements; the envelope, tegument, nucleocapsid and core (Gowthaman et al., 2020). The envelope contains multiple immunogenic glycoproteins that are required for virus entry, membrane fusion and virus egress (Kumar et al., 2019).

25. ILTV has a highly selective host range limited to avian species, primarily affecting galliform birds, with chickens serving as the primary host and reservoir (Mo and Mo, 2025). It is not known to be transmitted to eggs or eggshells (Gowthaman et al., 2020) and there is no evidence to indicate infection in humans or other non-avian species.

Section 2 The proposed dealings

26. Intervet Australia Pty Ltd (Intervet) is seeking authorisation for the commercial supply of a live genetically modified (GM) multivalent vaccine, known as Innovax®-ND-ILT, for chickens Australia-wide.

27. The GM vaccine is based on a non-pathogenic strain of turkey herpesvirus, which naturally provides protection against MD. It has been modified to express the fusion (F) protein from NDV and glycoprotein D (gD) and glycoprotein I (gI) from ILTV. The GM vaccine is expected to induce immunity against MD, ND and ILT in chickens. The vaccinated chickens would enter general commerce, including human food.

28. As part of the ongoing commercial supply of the GM vaccine, the dealings assessed by the Regulator are to:

(a) import the GMO;

(b) transport the GMO;

(c) dispose of the GMO;

and possession (including storage), supply or use of the GMO for the purposes of, or in the course of, any of the above.

2.1 Details of the proposed dealings

29. The GM vaccine would be manufactured overseas in GMP licensed sites and imported into Australia under an import permit from DAFF. The product would need to be registered through the APVMA before commercial use. As mentioned in Section 1.1, the APVMA would also approve the labels for the GM vaccine, which would contain instructions for the handling and storage, and directions for supply to ensure safe use.

30. The GM vaccine would be supplied in 2 components: i) the GMO concentrate, supplied in 2 mL glass ampoules packaged in canes and transported and stored in liquid nitrogen containers (-196 °C), and ii) the solvent, supplied in multilayer plastic bags and stored below 30 °C. Each individual ampoule would be labelled with an APVMA approved label indicating the contents of the ampoule and an accompanying leaflet with instructions for use, storage, and disposal. During transport, the outer most container would include the name, address, and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected.

31. The GM vaccine would be used on commercial poultry farms as per an approved APVMA registration. The liquid nitrogen container would be stored securely in an upright position in a room separated from the hatching/chicken room in the hatchery.

32. The GM vaccine would be prepared for administration by mixing the contents of the GMO ampoule with the solvent. The GM vaccine would be administered to 18- or 19-day-old embryonated chicken eggs by *in-ovo* injection (0.05 mL), or to day-old chickens in the commercial poultry farms as a single subcutaneous dose (0.2 mL) administered in the neck. The applicant proposes to register these methods of administration with the APVMA.

33. All residual vials and associated waste which has come into contact with the GM vaccine (such as syringes and ampoules) would be discarded in accordance with State/Territory, local council and Environmental Protection Agency (EPA) requirements, the poultry industry biosecurity standards (Animal Health Australia, 2020; Australian Chicken Meat Federation, 2020; Department of Agriculture Fisheries and Forestry, 2009a, b), and conditions imposed by the APVMA registration of the GM vaccine. These requirements and guidelines all aim to limit the exposure of other people or animals to the waste.

Section 3 Parent organism

34. The GMO is derived from the FC-126 strain of turkey herpesvirus (HVT), which was originally isolated from turkeys in 1970 (Witter et al., 1970). The characteristics of the parent organism provide a baseline for comparing the potential for harm from dealings with the GMO. As such, the relevant biological properties of HVT will be discussed here.

3.1 Taxonomy and biology

As described in Section 1.2, HVT is classified within the *Mardivirus* genus, which belongs to the *Alphaherpesvirinae* subfamily of the *Orthoherpesviridae* family (Atasoy, 2021; Xu et al., 2025). It is a non-pathogenic alphaherpesvirus that naturally infects turkeys and chickens without causing disease (Witter et al., 1970; Xu et al., 2025). Despite its lack of pathogenicity, HVT induces protective immunity in chickens against MD caused by virulent MDV1 (Atasoy, 2021; Witter et al., 1970; Xu et al., 2025) and this property has led to its widespread use as a live vaccine, either alone or in combination with other MDV serotypes, to protect against MD (Purchase et al., 1971b; Xu et al., 2025).

3.2 Structure and genomic organisation

35. Herpesviruses share a broadly similar virion structure and life cycle (Dotto-Maurel et al., 2025). Similar to other herpesviruses, the HVT virion is comprised of 4 distinct structural elements: envelope, tegument, capsid and core. The outer lipid envelope, which contains glycoproteins, surrounds the tegument – a protein-rich region between the envelope and capsid. The capsid encloses the core, which contains the viral double-stranded DNA (dsDNA). Herpesviruses vary in size between 120 and 260 nm mainly due to variable amounts of tegument proteins (Dotto-Maurel et al., 2025).

36. HVT has a dsDNA genome approximately 159 kb pairs (Figure 2), with genomic organisation and gene content similar to MDV1 and MDV2. The genome contains a UL and a US, as well IR, that flank each unique region (Figure 2).

Figure 2. Schematic view of genomic structure of HVT. **U_L/U_S**: unique long/short, **TR_L/TR_S**: terminal repeat long/short, **IR_L/IR_S**: internal repeat long/short (Afonso et al., 2001; Dotto-Maurel et al., 2025).

37. The HVT genome is predicted to encode 99 functional proteins (Afonso et al., 2001). These proteins share 34 to 82% similarity with MDV1 and MDV2, indicating that these viruses are closely related. HVT shares 76 conserved genes with MDV1, mostly located in the UL and US regions; however, significant differences are present within and surrounding the IR regions.

38. Compared with MDV1, HVT contains 13 additional genes and is missing 16 genes present in MDV1, including the *pp38* and *meq* genes that are implicated in the host T-cell lymphoma development (Afonso et al., 2001; Kingham et al., 2001). These differences may account for the non-pathogenic nature of HVT and its host range.

3.3 Viral infection and replication

39. Following infection, HVT replicates within the respiratory tract, spreads to lymphoid organs, and then undergoes semi-productive lytic replication in T and B cells. HVT spreads horizontally via direct cell-to-cell contact (Okura et al., 2021); however, it is not known to spread vertically (Paul et al., 1972; Witter and Solomon, 1972). As mentioned previously, HVT lacks key virulence and oncogenicity-associated genes present in MDV1, including those involved in virulence, oncogenicity and immune evasion, which likely account for its non-pathogenic nature and limited host range (Afonso et al., 2001).

40. Herpesviruses, including HVT, share conserved life cycle phases (Dotto-Maurel et al., 2025). Herpesviruses bind to host-cell surface proteins through viral envelope glycoproteins, followed by entry and transport of the capsid to the host-cell nucleus. Viral DNA replication and nucleocapsid assembly occur within the nucleus, after which nucleocapsids migrate through the nuclear membrane into the cytoplasm, and associate with tegument proteins. The nucleocapsids are then re-enveloped in cytoplasmic organelles and mature particles are then released by exocytosis (Dotto-Maurel et al., 2025).

41. Cell-free infectious HVT virions are released from feather-follicle epithelium (FFE) and spread through the feather from the infected host (Okura et al., 2021).

42. The HVT viral DNA integrates into the host genome, which enables the establishment of HVT latency in T cells, reactivation, transport to the skin and shedding into the environment (Denesvre et al., 2024).

3.4 Integration, mutation and recombination

43. HVT integrates into the host chromosomes at the telomeric regions (Denesvre et al., 2024). This is enabled by telomeric repeat arrays (TMRs) located at both ends of its genome, which are identical to the host telomeres (Denesvre et al., 2024).

44. Alphaherpesviruses evolve through both recombination and point mutations. However, as their DNA polymerases have highly efficient proofreading activity, recombination plays a key role in driving their evolution and genetic diversity (Loncoman et al., 2017). The rate of natural recombination varies across different alphaherpesvirus species, and most studies have focused primarily on human alphaherpesviruses. Recombination has been assessed in some poultry viruses, including ILTV and MDV1. For example, genome sequencing studies of ILTV have revealed that the virulent Class 8 and 9 strains resulted from natural recombination between vaccine strains used in Australia. In addition, comparative analysis of genome sequences indicate that recombination occurs in MDV1, as evidenced by unusually high synonymous divergence in some genes or by high similarity in specific virulence-associated genes, despite strains being clustered separately in phylogenetic analyses (Loncoman et al., 2017). Based on these studies, recombination could occur in HVT although it has not been reported to date.

45. Recombination requires a host cell to be simultaneously co-infected by 2 viruses that have significant homologous nucleic acid sequences to allow the exchange of genetic information. As mentioned above, the HVT genome resembles the genomic organisation and gene content of other alphaherpesviruses and shows high similarity to other MDV serotypes.

46. Vaccination with HVT strains prevents the clinical manifestations of the MD, but does not prevent MDV infection and shedding (Rémy et al., 2020). Hence, chickens vaccinated with HVT commonly become co-infected with virulent MDV (Ding et al., 2024). In addition, HVT is often administered in combination with MDV serotype 2 and/or serotype 1 strains as multivalent vaccines and no recombination between these vaccine strains has been reported. A literature search found no evidence that HVT undergoes natural recombination with other viruses, including MDV1.

3.5 Epidemiology

3.5.1 Host range and transmissibility

47. Members of the *Mardivirus* genus, including HVT, have been identified only in avian species, and the production of cell-free infectious viruses observed only in FFE (International Committee on Taxonomy of Viruses). The host range of HVT is narrow and primarily limited to gallinaceous birds, in which infection, replication and transmission have been documented (Kobayashi et al., 1986; Okura et al., 2021; Purchase et al., 1971a; Witter and Solomon, 1972).

48. HVT transmits efficiently between turkeys because they are its natural, fully permissive host capable of supporting complete viral replication and producing high levels of cell-free infectious virus (Witter and Solomon, 1972; Xu et al., 2025). In contrast, chickens are a semi-permissive host for HVT. Although HVT can replicate in chickens, viral maturation in the FFE is delayed and inefficient (Okura et al., 2021). As a result, infected chickens show poor or no shedding of infectious virus and limited or no horizontal transmission to other chickens (Cho, 1975; Okura et al., 2021; Xu et al., 2025). However, turkey to chicken and chicken to turkey transmission can occur under controlled conditions (Cho, 1975; Witter and Solomon, 1972).

49. Vaccination of Japanese quail with HVT suggests that the virus can infect this species, as shown by the isolation of the virus from some vaccinated quails, and detection of HVT-specific antibodies in more than one-quarter of the vaccinated birds. This immune response was associated with reduced incidence of Marek's disease (Kobayashi et al., 1986).

50. Cell cultures from various avian species have been shown to be susceptible to HVT infection, including embryo fibroblast and kidney cells from chicken, duck, quail, pheasant, turkey, pigeon and goose (Purchase et al., 1971a). Human HeLa cells used as a control were not susceptible to HVT infection (Purchase et al., 1971a). To date, there are no reports of HVT infection in mammals, including humans.

3.5.2 Bio-distribution

51. Despite being the natural host, studies on the biodistribution of HVT in turkeys are limited. HVT was first isolated from kidneys of infected turkeys (Witter et al., 1970) and subsequently detected in blood, where infectious virus appeared to be associated with the buffy coat – the layer of white blood cells and platelets (Witter and Solomon, 1972). Another study utilising ultrastructural (electron microscopy) examination of turkeys naturally infected with HVT showed a broad tissue distribution, with viral particles detected in the heart, spleen, lung, brain, intestine, kidney, cecal tonsil, proventriculus, bone marrow, white blood cells, pancreas and gonadal tissues (Barrett Hein and Mora, 1980). The liver, gizzard and muscle did not show the presence of virions although nuclear changes were observed in hepatic tissue (Barrett Hein and Mora, 1980). Overall, HVT shows widespread distribution across neural, visceral and lymphatic tissues, indicating systemic dissemination.

52. In chickens, HVT is first detected in the lungs shortly after infection, followed by rapid dissemination to lymphoid organs including the thymus, spleen, and lung-associated lymphocytes within 2 days post-infection (dpi), and to the bursa of Fabricius by 4 dpi (Okura et al., 2021). Viral maturation into cell-free infectious virions occurs in the FFE beginning at 6 dpi, which is the only tissue shown to produce extracellular infectious HVT (Okura et al., 2021).

3.5.3 Latency

53. The ability to establish latency to evade the host immune system is a key biological survival mechanism of herpesviruses. Like other herpesviruses, HVT is known to establish latent infections in its host (Denesvre et al., 2024; Holland et al., 1998). Latency is characterised by the suppression of viral replicative functions and the absence of detectable infectious virus (Wilson and Mohr, 2012).

54. HVT establishes latency in T cells, allowing lifelong persistence in the host (Denesvre et al., 2024). As mentioned previously, this is enabled by integration of the HVT genome into telomeres of the host cell chromosome (Denesvre et al., 2024). During latency, herpesviruses modulate both their viral genes

and host genes to evade detection and elimination of the infected cell by host immune system (Dotto-Maurel et al., 2025).

55. Viral reactivation and shedding can occur spontaneously but are more likely when the host is under biotic or abiotic stress. For example, hypoxia, apoptosis, or temperature changes can trigger MDV reactivation in cell culture (Mallet et al., 2022; Tien et al., 2023). For HVT and other herpesviruses integrated within host telomeres, viral reactivation may also be induced by natural telomere shortening. This could either reduce suppression of viral gene transcription or trigger telomeres to recombine, which can result in the release of the viral genome from the integration site (Kheimar et al., 2017).

3.5.4 Prevalence

56. HVT was first isolated in Australia from turkeys in 1971. Locally isolated strains were subsequently used as vaccine for prevention of MD due to quarantine regulations in Australia requiring the use of endemic virus strains (Mustaffa-Babjee, 1971; Mustaffa-Babjee and Spradbrow, 1973; Prasad and Spradbrow, 1977).

57. HVT FC-126 strain has been used in live vaccines worldwide for several decades for the control of Marek's disease (Islam et al., 2002; Mustaffa-Babjee and Spradbrow, 1973; Walkden-Brown. and Groves., 2013). In Australia, vaccines containing the HVT FC-126 strain have been approved under APVMA registration and used in Australia for more than 25 years. (APVMA PubCRIS database).

58. Therefore, HVT is expected to be present in local turkey and chicken populations and may also be present in other poultry species in Australia that are susceptible to HVT. A literature search found no reports that indicate the presence of HVT in Australian wild birds.

3.5.5 Controls and vaccines currently available

59. Control measures and vaccination against HVT are not required as HVT is non-pathogenic virus in birds and is not known to infect non-avian species (Afonso et al., 2001; Atasoy, 2021; Xu et al., 2025).

3.5.6 Stability and decontamination methods

60. HVT is a cell-associated virus and relies in viable host cell for efficient infectivity (Witter et al., 1970). As an enveloped virus, its persistence outside the host is limited and strongly influenced by viral properties and environmental conditions such as temperature, humidity, ultraviolet radiation and presence of organic material (Zeng et al., 2023).

61. Stability studies showed that cell-free HVT vaccine rapidly loses activity within hours following reconstitution with diluent and storage at 4-6°C. The vaccine retained approximately 90%, 80% and 60% of its original titre at 1, 2 and 4 hours post-dilution, respectively, indicating a time-dependent loss of potency after preparation (Zanella et al., 1974).

62. Under favourable conditions such as low temperatures and presence of protective organic matter, herpesviruses can persist in the environment for extended periods (Zeng et al., 2023). In particular, MD viruses have been shown to remain infectious in dried feather material and poultry dust for up to a year (Jurajda and Klimes, 1970). The applicant has stated that stability of HVT or the GM vaccine in dust particles has not been determined under field conditions.

63. Similar to other enveloped viruses, HVT is sensitive to heat, UV, organic solvents (e.g. ether, chloroform, 70% ethanol, isopropanol or other lipolytic solvents) and oxidising agents (e.g. 0.2% bleach) (Croughan and Behbehani, 1988; Gowthaman et al., 2020; Lytle and Sagripanti, 2005; Tyler and Ayliffe, 1987).

Section 4 The GMO - nature and effect of the genetic modification

4.1 The genetic modifications

64. The GMO is a live HVT FC-126 strain modified by the insertion of an expression cassette, containing the F protein gene from NDV, the gD and gI genes from ILT, and requlatory sequences. It was propogated in chicken embryo fibroblast (CEF) cells, plaque purified and confirmed by sequencing to verify correct insertion of the expression cassette.

65. Some details about the construction and testing of the GMO have been declared Confidential Commercial Information (CCI) under Section 185 of the Act. Under Section 187 of the Act, this information must not be disclosed except where it is made available to the Commonwealth or a Commonwealth Authority, a State agency or the Gene Technology Technical Advisory Committee in the course of carrying out their duties or functions under the Act or under corresponding State law.

4.1.1 NDV F protein

66. Glycoprotein F is one of the structural proteins expressed by NDV. The native protein is localised on the surface of the virus and is required for efficient cellular infection by mediating fusion between the viral envelope and the host cell plasma membrane during viral entry (Lamb and Jardetzky, 2007; Swanson et al., 2010). In addition to the F protein, membrane fusion by NDV also requires a second surface glycoprotein, known as haemagglutinin-neuraminidase (HN), which functions as the viral attachment protein and possesses both receptor binding and neuraminidase activities (Morrison et al., 1991).

67. Studies in chicken embryo cells using retroviral expression systems showed that the F protein does not mediate cell fusion unless the cell also expresses the HN protein (Morrison et al., 1991). Subsequent studies demonstrated that the HN protein triggers conformational changes in the F protein that drive the membrane fusion process (Stone-Hulslander and Morrison, 1997; Swanson et al., 2010). These results indicate that both F and HN proteins are required to be co-expressed on the same viral particle for fusion to occur. Other viral attachment proteins such as influenza virus hemagglutinin cannot substitute for HN to complement the NDV F protein during fusion (Morrison et al., 1991; Stone-Hulslander and Morrison, 1997).

68. It is expected that the NDV F protein inserted in the GMO will not affect viral infection, as NDV fusion activity is mediated by the F protein and requires a specific interaction with the HN protein that is not present in the GMO.

4.1.2 ILTV glycoproteins D and I

69. Glycoprotein D (gD) and glycoprotein I (gI) are conserved among alphaherpesviruses. In ILTV, gD is an envelope glycoprotein that interacts with host cell receptors and plays an essential role in ILTV infection (Kumar et al., 2019; Xu et al., 2025). It shares structural homology with gD of herpes simplex virus, a well-characterised receptor-binding protein that initiates viral membrane fusion with host cells (Zhang et al., 2011).

70. Glycoprotein I (gI) is another envelope protein expressed by ILTV. During ILTV infection, it binds to another glycoprotein E (gE), forming the gE/gI protein complex. This complex is essential for efficient cell-to-cell spread of ILTV (Armat et al., 2022), facilitating direct transmission between neighbouring cells without relying on release of cell-free virions. Deletion of both gI and gE genes results in reduced or no viral spread between cells despite retaining replication competence (Armat et al., 2022).

4.2 Characterisation of the GMO

4.2.1 Phenotypic and genomic stability

71. As previously described, the GMO is derived from a non-pathogenic HVT, which is modified by the insertion of an expression cassette, containing genes from NDV and ILT. The GM vaccine is not produced throught attenuation.

72. The GMO was sequenced after multiple passages in CEF cells. The sequencing results showed a 100% match for the inserted expression cassette and the corresponding HVT flanking regions, confirming the stable integration of the expression cassette into the HVT genome. The results also confirmed that no unintended vector-derived DNA was inserted during the development of the GM vaccine.

73. The GM vaccine shows a phenotype comparable to that of the parent HVT strain (see Section 4.2.2 below).

4.2.2 Biodistribution, shedding and transmission in target and non-target animals

74. One day old specific pathogen free (SPF) chickens were inoculated with the GMO or the parent HVT FC-126 strain and biodistribution assessed by polymerase chain reaction (PCR) and immunofluorescence assay using antibodies specific to HVT or the GMO. Samples from the spleen, lung, bursa, trachea, peripheral blood lymphocytes (PBL) and FFE were collected and analysed at several time points over a 5-week period post-inoculation. Both the GMO and the parental virus were detected in all samples, except trachea. The GMO and the parental strain showed similar tissue tropism in PBL, spleen and lung. However, the GMO was not detected in bursa and FFE samples collected at later time points, unlike the parental strain, suggesting reduced replication of the GM vaccine. The applicant has stated that the GM vaccine and the parental strain showed comparable chronology of viral appearance *in vivo*. Overall, these data indicate that the biodistribution of the GMO is comparable to that of the parent strain in chickens.

75. The applicant performed studies to evaluate the spread of the GMO from vaccinated to unvaccinated animals. The first study evaluated the shedding and transmission by housing vaccinated chickens in contact with unvaccinated chickens and turkeys for up to 8 weeks. The GMO was not detected in unvaccinated chickens or turkeys at any time point, suggesting that no transmission of the GMO to unvaccinated animals occurred. However, HVT was detected in unvaccinated chickens at the later time points. It was concluded that this HVT infection originated from the test turkeys, which were HVT-positive and had been kept together with the chickens prior to vaccination. However, it is uncertain whether the HVT infection in unvaccinated animals prevented the transmission of the GM vaccine.

76. The spread of the GMO between non-target animals was evaluated in turkeys and quails. Birds were vaccinated subcutaneously with an overdose of either the GMO or the parental HVT FC-126 strain. Each vaccinated group was housed with unvaccinated birds of the same species for up to 4 weeks. The results showed that both the GMO and its parental strain were able to replicate in turkeys and quails without causing any clinical signs. No transmission of the GMO to unvaccinated turkeys or quails was observed. In contrast, the parental HVT FC-126 strain was transmitted to unvaccinated turkeys but not to unvaccinated quails.

77. Another study assessed whether Innovax®-ILT, a vaccine based on the same parent organism but expressing only the gD and gI genes from ILT, and the HVT FC-126 strain, were able to infect and spread in mice. Mice were vaccinated subcutaneously with an overdose of Innovax®-ILT or HVT FC-126 and were housed with unvaccinated mice for up to 2 weeks. The animals were examined for the presence of virus. The results showed that no virus was detected in either vaccinated mice or unvaccinated mice. No clinical signs or macroscopic lesions were observed in any of the mice.

78. Overall, the GMO showed comparable tissue distribution, shedding and transmission to that of the parental HVT strain.

4.2.3 Safety and efficacy

79. The efficacy of the GM vaccine in preventing 3 diseases in chickens was evaluated using challenge strains of MDV, NDV and ILTV. For these assessments, 2-3 groups of 18-day-old embryonated eggs were inoculated *in ovo*, or one-day-old chickens were inoculated subcutaneously with the GM vaccine. Each group received a different dose for each virus challenge and a control group inoculated with a diluent placebo was included in each administration route and each virus stain. The percentage of the test chickens showing clinical symptoms caused by the relevant virus strain was calculated and compared to the placebo control group.

80. The GM vaccine showed high levels of protection against MDV, NDV, and ILTV, with 97%, 97%, and 94% disease prevention rates following *in ovo* inoculation, and 88%, 100%, and 100% disease prevention rates following subcutaneous inoculation, respectively. In contrast, placebo treated control groups showed 0-20% protection.

81. A study investigating the co-administration of the GM vaccine with Nobilis Rismavac (also known as Rispens (CVI988); a live attenuated strain of MDV1) has been provided. Administration of the maximum doses of both vaccines via *in ovo* or subcutaneous route did not result in any safety concerns in chickens observed over 123 days. The applicant has stated that no adverse reactions were observed in laboratory studies and field trials with the GMO. Literature searches have found no reports of adverse effects associated with the GMO either in chickens or in the environment to date.

4.2.4 Decontamination of the GMO

82. Methods to decontaminate herpesviruses, including HVT, which have been described in Section 3.5.6, would also be effective against the GMO.

4.3 Approvals of the GMO

83. The GM vaccine has been approved by the United States Department of Agriculture since 2019, and by the European Medicines Agency and the Veterinary Medicines Directorate in the United Kingdom since 2020.

84. The GM vaccine has not been previously authorised for commercial supply in Australia.

Section 5 The receiving environment

85. The receiving environment forms part of the context for assessing risks associated with dealings with GM vaccine (OGTR, 2013). It informs the consideration of potential exposure pathways, including the likelihood of the GMO spreading or persisting outside the site of release. Relevant information about the receiving environment includes state and local council requirements relevant to poultry farming; commercial farming and processing practices; biosecurity standards for poultry farms; waste management practices; related viral species in the environment; and potential hosts in the environment.

5.1 Site of vaccination

86. The intended primary receiving environment for the GMO would be chickens, administered by either *in ovo* to 18- or 19-day-old embryonated chicken eggs or subcutaneously to one-day-old chickens using needle-based equipment. The GMO would be administered by trained professionals who have experience with both the equipment and with vaccination of chickens. The applicant will need to seek a registration from the APVMA to authorise these modes of administration.

87. The secondary receiving environment would be the poultry farms where the chickens would be vaccinated.

88. The principal route by which the GMO may enter the wider environment following vaccination is via shedding. Further, GMO may also enter the environment via accidental spills of the vaccine or in eggs (*in ovo* inoculation).

5.2 Corporate structures

89. The chicken meat industry is predominantly vertically integrated, where generally, individual companies own almost all aspects of production (breeding farms, multiplication farms, hatcheries, feed mills, some broiler farms, and processing plants). Two large integrated national companies supply approximately 70% of Australia's broiler (meat) chickens - Baiada and Inghams Enterprises. Inghams and Baiada are privately owned, with farming and processing operations in most states. The rest are medium-sized, privately owned companies, and several smaller processors.

90. Growing broiler chickens, from one day old chicks to the day of processing, is generally contracted out by processing companies to contract growers. Approximately 800 growers produce about 80% of Australia's broiler chickens under these contracts. Other broiler chickens are produced on large company farms, or on farms owned and managed by 'intermediary' companies which own several farms, each managed by a farm manager, and who enter into contracts with processing companies to grow out chickens on a larger scale.

91. Contract growers own the farm and provide the management, infrastructure, equipment, labour, bedding and other inputs to rear chickens. The processing company provides (and owns) the chickens and provides feed, medication and technical advice (Australian Chicken Meat Federation, 2020).

92. Limited publicly available information is available on the corporate structure of the egg production industry, but the information available suggests a similar structure to the chicken meat industry (Australian Eggs, 2026a).

5.3 Poultry farm management

93. Poultry farms need to comply with a range of state and territory requirements designed to protect people and the environment (see Table 1). Farms should also adhere to quality management systems incorporating standards such as GMP and the Hazard Analysis of Critical Control Points (HACCP) and manage the farms in accordance with strict state environmental codes.

Table 1 Links to state and territory requirements in Australia.

State	Website
ACT	https://www.accesscanberra.act.gov.au/city-services/environment-protection-authority/environment-protection-policies-and-guidelines#Guidelines
NSW	https://www.dpi.nsw.gov.au/animals-and-livestock/poultry-and-birds
NT	https://nt.gov.au/industry/agriculture/livestock/keeping-poultry-and-pigeons*
QLD	https://www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/livestock/poultry/poultry-farming-queensland/starting-poultry-farm/legal-requirements
SA	https://www.pir.sa.gov.au/biosecurity/animal_health/poultry
TAS	https://nre.tas.gov.au/biosecurity-tasmania/product-integrity/food-safety/meat-and-poultry
VIC	https://agriculture.vic.gov.au/livestock-and-animals/poultry-and-eggs/compliance/laws-regulations-and-standards-for-poultry-owners
WA	https://www.dpird.wa.gov.au/businesses/livestock-farming/chickens-and-poultry/

*No large commercial poultry farms are currently present in NT

94. Local councils and/or state government agencies such as Environment Protection Authorities (EPA) are responsible for the approval of intensive agriculture developments including free range poultry farms. Local councils are generally the responsible authority for the administration or enforcement of planning schemes. This means that councils would assess and determine farm planning permit applications. Councils are also responsible for monitoring and enforcing the compliance of poultry farm operators with their planning permit conditions. In addition, the poultry company may require minimum distances between the poultry farm and other poultry farms, or livestock farms owned or managed by them or by others.

95. Boundary setbacks may be required by councils and are defined as the distance between the nearest external edge of any new chicken shed, litter stockpile or compost pile and the farm boundary. Boundary setbacks mitigate visual amenity issues and the immediate impact of odours, dust, aerosols and noise emissions from sheds, litter, or compost piles on the amenity of adjacent land and the surrounding area.

96. Separation distances are used to reduce the effects of odour, dust, aerosols and noise of a chicken farm. The separation distance is the distance from the nearest external edge of a broiler shed to the nearest external edge of a sensitive use (e.g. house or public building) on land beyond the broiler farm property. It excludes sensitive uses directly associated with the broiler farm operations – e.g. residential dwellings on the broiler farm property. Separation distances usually extend across adjoining properties that are not owned by the farm owner. Where separation distances are not specified by state and local government departments and agencies, the following separation distance are suggested: 500 m separation between farm and land zone that is not compatible with development (e.g. residential/rural residential areas) and 250 m separation between farms and any sensitive land use (e.g. neighbouring houses) located on land that is compatible with development (e.g. on land designated rural, farming or similar) (McGahan, 2026). A guideline published by AgriFutures also included a separation distance formula, which considers number of birds, location, terrain and climate (McGahan, 2026). The greater the separation distance and the boundary setback, the lower the likelihood of offensive odour and dust adversely impacting the surrounding community.

5.3.1 Broiler chicken farms

97. When commercial chickens are grown for meat, they are commonly referred to as broilers and can be grown in conventional, free-range, and organic production systems. Australian broilers are not kept in cages, regardless of the production system used (Poultry Hub Australia, 2026d).

98. Commercial chickens used as broilers are transported from hatcheries to broiler farms in ventilated chick boxes in air-conditioned trucks prior to going through the following phases:

- brooding phase, where chicks are placed on the floor of the sheds and given supplementary heating;
- growing phase (around 42-56 days of age); and
- harvesting phase (when chickens are transported to a factory for processing).

99. During transport for processing, chickens are placed in crates in an open truck and transported in accordance with the relevant state legislation. Crates, trucks, equipment and other materials used to transport the chickens from the shed to the processing plants are decontaminated with disinfectant after delivery of chickens. The Standard for Poultry Meat (Standard 4.2.2) requires that transportation vehicles and equipment be effectively cleaned, sanitised and in good working order to ensure poultry is not made unsafe or unsuitable for human consumption (Food Standards Australia New Zealand, 2023).

100. The sheds are cleaned out once all the birds are harvested (approximately 60 days) and prepared for a new batch of chicks. This involves removing bedding, brushing floors, scrubbing feed pans, cleaning

out water lines, scrubbing fan blades and other equipment, and checking rodent bait stations. High-pressure hoses are used to thoroughly clean the whole shed. The floor is usually rammed earth and because low water volumes are used, there is little water runoff. Once cleaned, the sheds are sanitised with disinfectant or insecticides that have been approved by the APVMA. After a full clean-out, company veterinarians or servicemen test the shed to confirm that it has been adequately cleaned (Poultry Hub Australia, 2026e).

101. Free range broiler chickens are produced using similar management, housing, rearing and feeding practices as conventional broiler chickens. Free range broiler chickens are harvested within the same timeframe as shed-housed chickens. The major differences are that free range broiler chickens are allowed access to an outside run for part of each day (at least after the brooding period) and often have lower target stocking densities.

102. Only free-range chickens can be used to produce certified organic meat and must be grown without the use of artificial colours and synthetic chemicals; be fed predominantly certified organic ingredients; and cannot be treated with routine vaccination unless it is required by law or if the disease cannot be controlled with organic management practices (Poultry Hub Australia, 2026a). NDV vaccine has been compulsory for commercial poultry under National ND Management Plans since 2002, particularly for flocks over 1000 birds and long-lived birds. HVT and ILT vaccinations are not compulsory; however, owners are being encouraged to consider vaccinating as MD and ILT are common diseases in poultry (AgricultureVictoria, 2026).

5.3.2 Layer chicken farms

103. When commercial chickens are grown to produce eggs, they are commonly referred to as layers and can be grown in caged, barn laid, free range and organic production systems. Production can range from extensive (small scale), semi-intensive (few hundred to thousands of hens) and intensive (100,000 – 500,000 hens) (Poultry Hub Australia, 2026b).

104. Commercial chickens used as layers typically go through the following phases (Poultry Hub Australia, 2026c):

- The brooding phase (day old-6 weeks), where they need additional heat to control their body temperature.
- The growing phase (6-20 weeks), where they can regulate their body temperatures but still need to be protected from climate extremes.
- The moving phase (16-18 weeks), when the hens are moved to their laying quarters.
- The adult layer phase (20 up to 78 weeks), where they are producing eggs. They need to be fed carefully and housed at 21-28°C.

105. Caged farming relies on the layers being kept in cages within sheds that include automated feeding, watering and climate control, ventilation and lighting. The Model Code of Practice for the Welfare of Animals stipulates the minimum space between hens is 550 cm^2 (Australian Eggs, 2026c).

106. Layers that produce barn laid eggs are allowed to roam the sheds without being in kept in cages (Australian Eggs, 2026b).

107. Free range layers are allowed meaningful and regular access to an outdoor range during daylight hours (Australian Eggs, 2026d).

108. Similar to broilers, organic eggs can only be produced by free range layers that must be raised without the use of artificial colours and synthetic chemicals; be fed predominantly certified organic ingredients; and cannot be treated with routine vaccination unless it is required by law or if the disease cannot be controlled with organic management practices (Poultry Hub Australia, 2026a).

5.4 Biosecurity

109. Each state and territory has its own biosecurity regulations and legislation. The following departments are responsible for the biosecurity:

- Environment, Planning and Sustainable Development Directorate – Environment (ACT);
- Department of Primary Industries (NSW);
- Northern Territory government (NT);
- Department of Agriculture and Fisheries (QLD);
- Department of Primary Industries and Regions (SA);
- Department of Natural Resources and Environment Tasmania (Tas);
- Agriculture Victoria (Vic); and
- Department of Primary Industries and Regional Development (WA).

110. Biosecurity considerations include the following: import of animals for domestic or commercial purposes, management of animal diseases (including vaccination and risk of transmission), and animal welfare. Australia also has a national *Biosecurity Act 2015* and a website for managing and reporting national pest and disease outbreaks, which is managed by DAFF.

5.5 Poultry farm biosecurity standards

111. There are also various guidelines published by Animal Health Australia (AHA) and DAFF in conjunction with various poultry industry groups and state and territory departments. This includes the *National Farm Biosecurity Manual Poultry Production*, *National Water Biosecurity Manual Poultry Production* and *National Farm Biosecurity Technical Manual for Egg Production* (Animal Health Australia, 2023; Department of Agriculture Fisheries and Forestry, 2009a, b). These guidelines include documentation and training; facility standards; personal protection equipment and procedures; operational standards and high-risk biosecurity procedures. These standards are applicable to all poultry producers including free range farms. There are 2 levels of biosecurity, Level 1 (routine biosecurity that should be implemented and followed daily) and Level 2 (high risk biosecurity that should be implemented in the event of an outbreak of an emergency or serious endemic disease) (Department of Agriculture Fisheries and Forestry, 2009a).

5.5.1 Documentation and training

112. Under these guidelines, each production facility must keep a copy of the National Farm Biosecurity Manual Poultry Production and/or the National Farm Biosecurity Technical Manual for Egg Production depending on the type of facility or a more detailed document encompassing either manual, that is easily accessible to staff. The manual also states that staff need to be trained in relevant parts of the manual and evidence of this training kept.

5.5.2 Facility standards – conventional and free range

113. The guidelines also states that the production area (sheds or free-range area, feed storage and handling area, and area immediately surrounding the sheds including pick-up areas) must have a perimeter fence or otherwise well-defined boundary (e.g. creek, vegetation) establishing a clearly defined biosecurity zone. Trees and shrubs should be selected to minimise wild bird attraction. The area around sheds must be kept free from debris and vegetation should be mown regularly. Vegetation buffers for environmental compliance should not be compromised.

114. The production area must have a stock proof fence if livestock graze on the property. Grazing near sheds (i.e. on part of the production area) is only permitted where the grazing area is separated by a stock proof barrier from the area used by poultry. Drainage from livestock pastures must not enter

poultry enclosures or areas that can be accessed by poultry. These standards are in place to prevent transmission of contaminants from livestock to poultry.

115. The main entrance to the production area must be capable of being closed to vehicle traffic (e.g. lockable gate always kept locked) and must display appropriate signage including 'Biosecure Area No Entry Unless Authorised' or similar wording. In addition, signage including contact numbers must direct visitors to contact the producer before proceeding. Facilities should be available for the cleaning and disinfection of equipment before entry.

116. There must be a change area away from sheds with clean protective clothing and boots provided. Entry to sheds must only be made through entrances with a footbath containing a suitable disinfectant. There must be provision for scraping the soles of boots before dipping to ensure the disinfectant contacts the soles of the boots. An alternative system using separate production area- and shed-footwear may be used. Facilities for hand sanitation must also be placed at the entry to each shed.

117. Feeding systems must, wherever possible, be closed to ensure that feed in silos and feed delivery systems is protected from access and contamination by wild birds and rodents. Feed spills should be cleaned up without delay to prevent the congregation of wild birds.

118. Drinking water should be accessed inside the shed; or, if watering stations are required outside, they should be of a type that cannot be easily accessed by wild birds (e.g. a nipple system). The watering system should be maintained, to prevent leakage and the creation of wet patches within or outside the shed. Water tanks should be checked regularly to ensure that they remain bird-proof.

119. Drinking water for poultry, as well as cooling water used in poultry sheds, must meet appropriate water standards. Water that does not meet the standard must be treated (e.g. chlorination, ultraviolet, iodine) to ensure that the standard is met. All surface water (dam, river etc.) must be treated before being used as drinking water for poultry. Treated water supply must be kept in a closed system from the point of treatment to the drinker.

120. All poultry housing must be designed and maintained to prevent the entry of wild birds and limit the access of vermin as far as is practical.

121. The production area should be adequately drained to prevent accumulation and stagnation of water likely to attract waterfowl, especially in the areas around sheds.

122. An appropriate vermin control plan must be developed and implemented, including rodents, foxes, wild dogs and cats. A baiting program for rodents must be implemented where a risk assessment deems this necessary (e.g. live rodents, droppings, nests). Beetle populations within shed litter should be controlled via an integrated pest management approach by using pesticides, composting and total shed and litter clean-out.

123. Only commercially produced avian species are to be kept in the production area and no other avian species (including aviary birds and pet birds) or pigs are to be kept on the property.

124. If more than one commercially produced avian species is kept in the production area, the species should be housed and managed separately, with suitable biosecurity arrangements for each species. Shared equipment should be cleaned and disinfected between uses.

125. Used litter and manure must not be stockpiled in the production area. Used litter and manure must be stored in an appropriately designed storage area away from the production area.

126. Dead chickens must be collected regularly and stored in freezers if the number of dead birds is likely to cause environmental impacts or increased biosecurity risks. Containers and freezers used for collecting dead birds must be cleaned and sanitised between batches. Dead bird disposal methods must conform with applicable environmental compliance requirements.

5.5.3 Additional standards for free-range farms

127. The following biosecurity measures are specific for free-range farms in addition to the conventional farming described above.

128. Good fencing is required to prevent the entry of animals such as dogs, foxes and cats. In many situations, however, fencing alone is insufficient to stop such intrusions; therefore, some free-range enterprises keep specially trained dogs with the chickens, as protection against other animals and against unauthorised human entry. Dogs must not enter sheds unless as part of the flock security strategy. Guard dogs such as these are not regarded as a biosecurity risk but rather as a biosecurity tool.

129. Where footbaths are not appropriate for a free-range paddock, a system should be documented and implemented to monitor and prevent any potential hazardous organic material or litter entering free range paddocks.

130. In free range farms, chickens may have some exposure to wild birds. Therefore, documented measures must be taken to minimise the congregation of waterfowl and the impact of wild birds. The attraction of wild birds can be minimised by placing feeders and water inside the shed, rather than in the open range where wild birds would have easier access. Placement of bird netting in critical feeding areas may also reduce the risk.

131. In free-range farms with sheds or other housing, manure deposits outside the hatch openings must be removed after each batch, and ramps used by chickens must be scraped and cleaned after each batch.

132. Grass on and around the farm must be kept cut to reduce rodent attraction.

5.5.4 Farm personnel and visitor standards – conventional and free range

133. Production area personnel or any person residing on the property must not have contact with any other poultry, avian species or pigs unless they have a complete head-to-toe shower and change into new protective footwear and clothing prior to entering the production area.

134. Personnel must wear laundered clean clothes each day to work and ensure that they do not become contaminated by contact with avian species or pigs on their way to work. It is critical that boots worn in sheds are not worn or taken outside the production area.

135. Company service personnel visiting the production area must wear protective clothing and footwear, as approved by the production facility manager. Hands must be sanitised before entering sheds.

136. Contractors who have had contact with poultry or other birds that day or keep birds at their home must not enter sheds and/or ranges populated or ready to be populated with birds unless it is an emergency, and they have showered from head-to-toe, changed clothes and boots and wear hair covering. Tools taken into the production area must be cleaned before entry into sheds and must be free of dust and organic matter.

137. All persons must agree to comply with the entry conditions by signing the visitors' log and such visits must be approved by the manager before visitors may enter sheds and ranges. This requirement also applies to vaccination crews.

138. During processing of chickens, pick-up crews work from youngest to oldest or all young birds or all old birds on a shift basis in accordance with the processing company's pick-up biosecurity procedures. Pick-up crews must not keep birds at their homes. Drivers must sanitise their hands and boots before and after each pick-up or delivery to a production area. Trucks carrying unused or used litter must be cleaned and disinfected between production areas.

139. A system for tracing movements of delivery personnel (e.g. through delivery dockets and feed company records) must be implemented.

5.5.5 High level biosecurity

140. In the event of an outbreak of disease, the *National Farm Biosecurity Manual for Poultry Production* recommends the following measures (Department of Agriculture Fisheries and Forestry, 2009a):

- limiting visitors from entering the production area unless essential;
- visitors must have a head-to-toe shower before and after visit;
- used clothing and personal protective equipment must remain on property;
- any vehicle entering the property must be washed and disinfected before and after going onto the property;
- poultry and litter must not be moved on or off property until disease status is clarified.

141. Farms require a contingency plan to cope with occurrences of high mortalities. An investigation must be conducted to ascertain the cause of death and the best option for the disposal of the dead birds. Where normal disposal methods are not feasible, the relevant regulatory authorities (e.g. the local council, the state EPA) may need to be contacted to help identify alternative options.

142. If the cause of the death is an Emergency Animal Disease, then the relevant Australian Veterinary Emergency Plan (Ausvetplan) would be activated, and the appropriate authorities would be notified. In this situation, the entire flock may be euthanised. The disposal of carcasses, used litter and feed, and the decontamination of equipment would be under the direct control of the state's Chief Veterinary Officer.

143. The Biosecurity Incident Management System provides guidance for the management of biosecurity incident response in Australia and can be applied to all biosecurity sectors. Typically, the states and territories have primary responsibility for preparing and responding to biosecurity incidents within their borders. DAFF has a role in providing national leadership and coordination in preparing for and responding to biosecurity incidents.

5.6 Transport of live chickens

144. In Australia, transport of animals including poultry is regulated by state and territories in accordance with the *Australian Animal Welfare Standards and Guidelines – Land Transport of Livestock* (Animal Health Australia, 2012). The standards cover responsibilities and competency of personnel; transport vehicles and facilities (e.g. temperature, ventilation and containers, including cleaning processes); loading, transporting, and unloading procedures; and the humane destruction of livestock.

145. The standards apply to all those responsible for the care and management of livestock that are transported, including drivers, transport companies, owners, agents and livestock handlers at farming enterprises, depots, saleyards, feedlots and livestock-processing plants. The chain of responsibility begins with the owner or their agent and extends to the final receiver of the livestock (Animal Health Australia, 2012).

146. Prior to transport, poultry stocks are assessed to determine if they are suitable for transport by the grower. Any birds that are found to be unsuitable for transport are managed on farm or humanely destroyed before the day of pick up (Animal Health Australia, 2012).

147. The implementation dates for the standards by the states and territories can be found here. In addition, each state and territory are also responsible for the regulation of animal welfare. A list of the state and territory animal welfare legislation can be found here.

5.7 Waste management

148. The management of waste (litter and carcasses) from poultry farms must meet the requirements of the Environment Protection Authority (EPA) from the different states and territories in addition to

local councils. This management strategies include composting, burial on the farm/landfill and transport to rendering farms, which have been described in detail in the RARMP for DIR-154.

149. In brief, litter/waste must:

- be removed immediately and transported in covered vehicles;
- be managed to avoid contamination of surface waters, stormwater drains, waterways, catchment and ground waters, and avoid excessive fly breeding;
- not be buried near houses and water sources; and
- be kept free of rodents, cats, dogs, feral animals, scavenging birds and flies.

150. Chicken carcasses could be sent to rendering farms where they are processed with high heat and pressure. The rendering facilities are regulated by state/territory or local council requirements. They are highly automated, minimising any direct contact of workers or the external environment with microbiological contaminants. The high heat and pressure used in the rendering process would destroy any GMO that are potentially still present in the carcasses.

5.8 Presence of related viral species in the receiving environment

151. The presence of related viruses may offer an opportunity for introduced genetic material to transfer between the GMO and other organisms or for genetic recombination in the receiving environment.

152. As mentioned previously, live HVT vaccines are registered for use in chicken farms to prevent Marek's disease in Australia.

153. As mentioned in Section 3.2 and 4.1 of this Chapter, the HVT genome possesses high similarity to other MDV serotypes, including MDV1. Marek's disease affects both commercial and backyard poultry and is endemic in Australia (Biosecurity Tasmania). Although HVT vaccination prevents the clinical signs of the Marek's disease, it does not stop MDV infection or shedding; therefore, HVT-vaccinated chickens could be co-infected with MDV1 (Section 3.4).

154. Another important avian herpesvirus is *Gallid herpesvirus 1* (ILTV), which belongs to the subfamily *Alphaherpesvirinae* and commonly infects poultry, including chickens. ILTV is considered endemic in Australia and outbreaks have predominantly recurred in chicken farms in Victoria and NSW (Blacker et al., 2011). Similarly, *Psittacid herpesvirus 1* (PsHV-1) belongs to the *Iltovirus* genus in the subfamily *Alphaherpesvirinae* and causes Pacheco's disease, an acute and potentially lethal respiratory infection in psittacine birds such as macaws, parrots and cockatoos. Sequence analyses suggest PsHV-1 and ILTV are phylogenetically closely related but are distinct from the Marek's disease virus (Thureen and Keeler, 2006). PsHV-1 and ILTV do not share the same host species. PsHV-1 has been reported in very rare cases in birds imported from overseas and was first reported recently in wild bird species, including psittachine and non-psittacine birds in Australia (Department of Agriculture Fisheries and Forestry, 2020; Wildlife Health Australia, 2023).

155. Other avian alphaherperviruses have been detected in wild native Australian birds (Wildlife Health Australia, 2024). These include *Columbid alphaherpesvirus 1* (CoAHV-1) which is endemic in feral pigeons (Phalen et al., 2017), as well as *Podargid alphaherpesvirus 1*, *Cacatuid alphaherpesvirus 1* and *Cacatuid alphaherpesvirus 2*. These alphaherperviruses are not known to infect chickens as herpesviruses tend to be host specific.

5.9 Presence of similar genetic material in the environment

156. The balance of an ecosystem could be perturbed by the introduction of new genetic material through horizontal gene transfer or through release of GMO into the environment. However, the effect of perturbation would be relatively small if the genetic material was already present in the system and did not confer any selective advantage to an organism that gained this genetic material.

157. The GMO is derived from HVT FC-126 vaccine, which is regularly administered in Australian commercial poultry. The GMO is modified to express the fusion protein from NDV and 2 glycoproteins from ILTV. Live NDV and ILTV vaccines are commonly administered in Australian poultry and these viruses – excluding virulent NDV strains – are present in Australia (Agriculture Victoria). Hence, the same or similar genetic material from the GMO would already be present in the environment.

5.10 Potential hosts in the environment

158. The intended host for the GM vaccine is chickens. The GMO has been demonstrated to also infect turkeys and quails without causing any clinical symptoms (Chapter 1, Section 4.2.1).

159. As described in in Chapter 1, Section 3.5.1, the host range of the parental organism HVT is limited to gallinaceous birds. In Australia, feral chickens, turkeys, pheasants and peafowls, from the family *Phasianidae*, are present. A search in the Australian Bird & Bat Banding Scheme (ABBBS) database showed that there are 3 native species belonging to *Phasianidae* family (*Coturnix chinensis* - king quail, *Coturnix pectoralis* – stubble quail, and *Coturnix ypsilohora* – brown quail) and 2 introduced species (*Pavo cristatus* – Indian peafowl and *Phasianus Colchicus* - common pheasant). Indian peafowl and common pheasant are introduced species and not commonly found and are listed as feral pests in Australia (West, 2011). A literature search found no reports indicating that HVT cause disease in these birds.

Section 6 Previous authorisations

160. This GM vaccine has not been previously authorised for commercial supply in Australia.

161. The GM vaccine has been approved by the United States Department of Agriculture since 2019, and by the European Medicines Agency and the Veterinary Medicines Directorate in the United Kingdom since 2020.

Chapter 2 Risk assessment

Section 1 Introduction

162. The risk assessment identifies and characterises risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of gene technology (Figure 4). Risks are identified within the established risk assessment context (Chapter 1), taking into account current scientific and technical knowledge. A consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

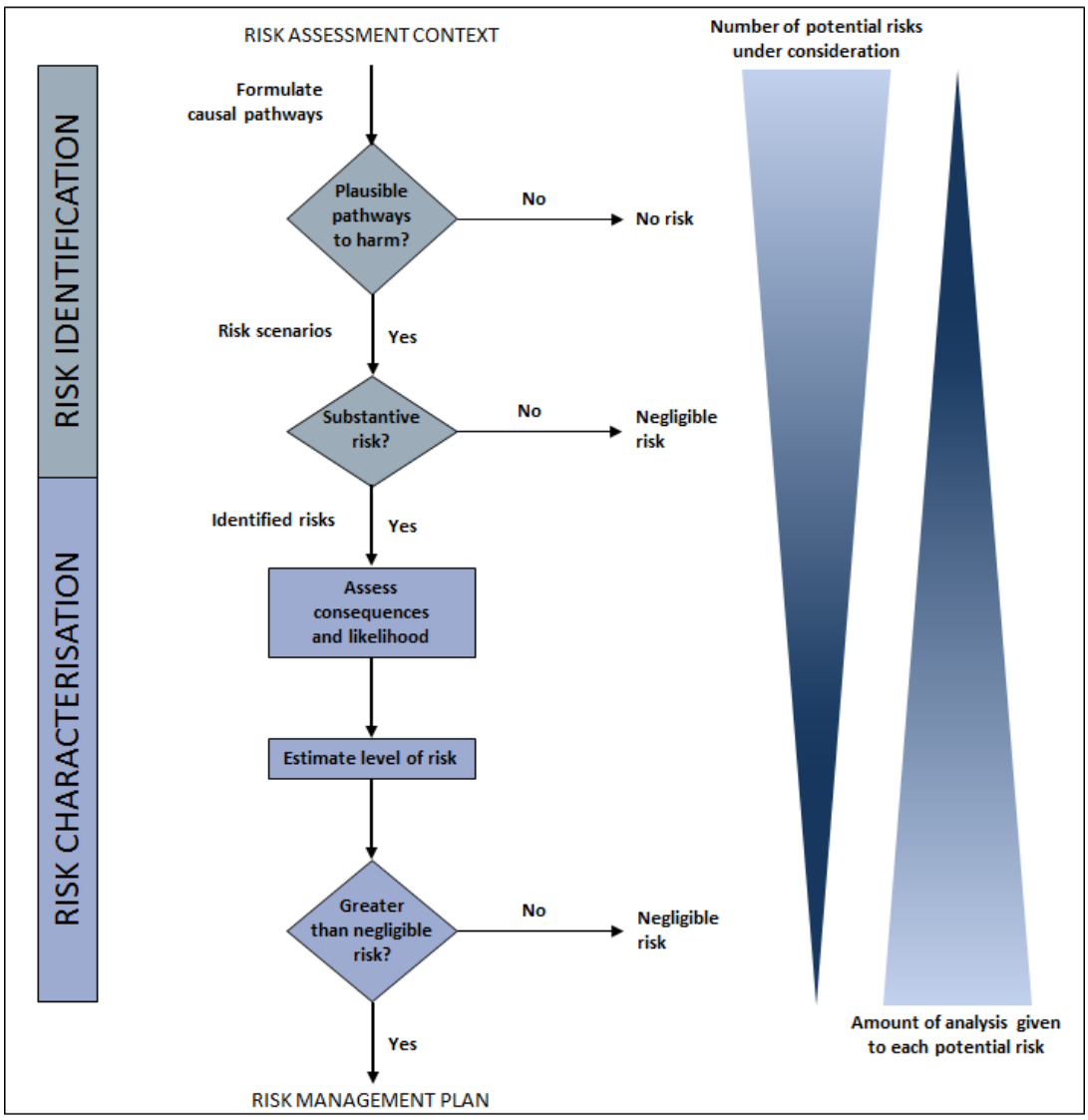

Figure 4: The risk assessment process

163. The Regulator uses a number of techniques to identify risks, including checklists, brainstorming, previous agency experience, reported international experience and consultation (OGTR, 2013).

164. Risk identification first considers a wide range of circumstances in which the GMO, or the introduced genetic material, could come into contact with people or the environment. This leads to postulating causal pathways that may give rise to harm for people or the environment from dealings with a GMO. These are called risk scenarios.

165. Risk scenarios are screened to identify substantive risks, which are risk scenarios that are considered to have some reasonable chance of causing harm. Risk scenarios that could not plausibly occur, or do not lead to harm in the short and long term, do not advance in the risk assessment process (Figure 4), i.e. the risk is considered no greater than negligible.

166. Risk scenarios identified as substantive risks are further characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). The consequence and likelihood assessments are combined to estimate the level of risk and determine whether risk treatment measures are required. The potential for interactions between risks is also considered.

Section 2 Risk identification

167. Postulated risk scenarios are comprised of three components (Figure 5):

i. The source of potential harm (risk source)

ii. A plausible causal linkage to potential harm (causal pathway), and

iii. Potential harm to people or the environment.

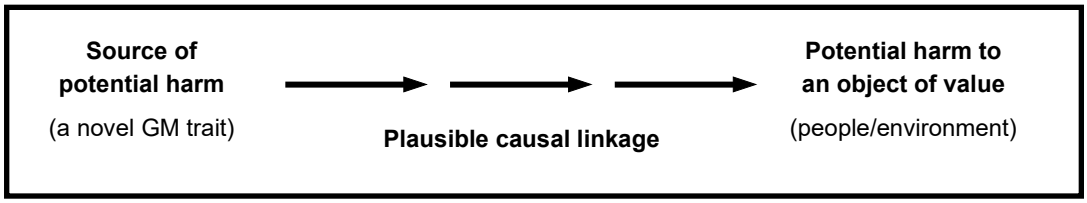

Figure 5: Components of a risk scenario

168. When postulating relevant risk scenarios, the risk context is taken into account, including the following factors detailed in Chapter 1:

- the proposed dealings
- the proposed limits including the extent and scale of the proposed dealings
- the proposed controls to limit the spread and persistence of the GMO and
- the characteristics of the parent organism(s).

2.1 Risk source

169. The parent organism of the GMO is the HVT FC-126 strain. Details of the biology and transmissibility of HVT are discussed in Chapter 1, Sections 3.1 and 3.5.1. HVT transmission primarily occurs through inhalation of virus-containing dust or dander derived from the feather follicles of infected birds. It is plausible that chickens vaccinated with the GMO could transmit the virus to uninfected chickens or other susceptible avian species (e.g. turkey, quail and other galliform birds).

170. The sources of potential harms can be intended novel GM traits associated with the genetic modification, or unintended effects arising from the use of gene technology.

171. As discussed in Chapter 1, Section 4.1, the GMO has been modified by the introduction of an expression cassette containing the F protein gene from NDV and the *gD* and *gI* genes from ILT. This modification is considered further as a potential source of risk.

172. Unintended effects can arise through horizontal gene transfer (HGT) which is the stable transfer of genetic material from one organism to another without sexual reproduction. As discussed in Chapter 1, Section 3.4, chickens vaccinated may be exposed to other vaccines or become co-infected with virulent MDV strains and the HVT genome contains sequences that could provide the homology required for recombination. The novel trait may result in negative or positive effects on the fitness of the recipient organism. This pathway is further considered as a potential source of risk.

173. HVT is known to be non-pathogenic, has a very limited host range and is not known to infect non-avian species. A similar host range is expected for the GMO. In the event of exposure of non-avian species to the GMO, it is highly unlikely that it would result in harm to those animals. Therefore, this pathway will not be further discussed.

174. The current assessment focuses on risks posed to people and to the environment, including long term persistence of the GMO, which may arise from the transport, storage or disposal of the GMO.

2.2 Causal pathway

175. The following factors are taken into account when postulating plausible causal pathways to potential harm:

- the proposed dealings, which are transport or disposal of the GMO and possession (including storage) in the course of any of these dealings,
- regulations in placed for the transport or disposal of the GMO by other regulatory agencies, the States and Territories,
- characteristics of the parent organism,
- routes of exposure to the GMOs,
- potential for transmission,
- potential effects of the genetic modification on the properties of the organism,
- potential exposure of other organisms to the GMOs in the environment,
- the release environment,
- spread and persistence of the GMOs (e.g. dispersal pathways and establishment potential),
- environmental stability of the organism (e.g. tolerance to temperature, UV irradiation and humidity),
- potential risk of revertant/novel strains due to HGT,
- practices before and after administration of the GMO including veterinary practices.

176. Although these factors are taken into account, some are not included in the risk scenarios because they are regulated by other agencies, have been considered in previous RARMPs or are not expected to give rise to substantive risks (see Sections 2.4.1 to 2.4.2 below).

177. The APVMA regulates the quality, safety and efficacy, and trade risks associated with the GM vaccine under the AgVet Code, as mentioned in Chapter 1, Section 1.1. This includes safety and efficacy of the vaccine; environmental risks; and recommended practices for the use, transport, storage and disposal of the GM vaccine. Therefore, risk scenarios in the current assessment focus primarily on risks posed to people and to the environment from the GMO, and not the intended vaccine recipients (chickens).

178. The Act provides for substantial penalties for unauthorised dealings with GMOs or non-compliance with licence conditions and also requires the Regulator to have regard to the suitability of an applicant to hold a licence prior to the issuing of the licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities. Therefore, unauthorised activities will not be considered further.

2.3 Potential harms

179. Potential harms from the GM vaccine include:

- harm to the health of people or desirable organisms, including disease in humans or in avian species other than chickens

- the potential for establishment of a novel virus that could cause harm to people or the environment.

2.4 Postulated risk scenarios

180. Four risk scenarios were postulated and screened to identify substantive risks. These hypothetical scenarios are summarised in Table 2.

181. In the context of the activities proposed by the applicant and considering both the short and long term, none of the risk scenarios give rise to any substantive risks that could be greater than negligible (discussed in depth in sections 2.4.1-2.4.2; this chapter).

Table 2 Summary of hypothetical risk scenarios from dealings with GM vaccine

Risk scenario	Risk source	Possible causal pathway	Potential harm	Substantive risk	Reason
1	GMO	Exposure of people undertaking dealings to the GMO: During: (a) Preparation and administration of the GMO; (b) Handling and transport of chickens vaccinated with the GMO; (c) Unintentional spills; or (d) Transport, storage or disposal of the GMO and waste associated with GMO ⬇ Infection of people with the GMO	Local inflammation/ adverse immune response	No	• Vaccination would be conducted by trained workers or qualified persons who are trained in the appropriate use of sharps. • Commercial poultry industries follow strict biosecurity procedures. • Transport of live chickens are regulated by the state and territories in accordance with national standards and guidelines. • Storage and disposal of carcasses and other contaminated farm waste should follow local council and state requirements. • HVT vaccines have a history of safe use with no adverse effects in people from direct exposure. • HVT is non-pathogenic and has very narrow host range limited to avian species and is not known to infect humans. The introduced gene has not been associated with toxicity or allergenicity in people.

Risk scenario	Risk source	Possible causal pathway	Potential harm	Substantive risk	Reason
2	GMO	Exposure of people to the GMO via: (a) Consumption of meat, eggs or egg products; or (b) Contact with live vaccinated chickens outside the poultry farm ⬇ Infection of people with the GMO	Adverse immune response	No	• As per RS 1, HVT vaccines have a history of safe use. In addition, HVT is non-pathogenic and has very narrow host range. • Cooking will destroy the GMO. • Food products must adhere to the Food Standards Code. • Other HVT vaccines have a history of safe use with no reports of adverse effects in people indirectly (via consumption of meat/eggs).
3	GMO	Exposure of other susceptible birds to the GMO via contact with: (a) Chickens or contaminated material within the chicken farms; (b) Chicken or eggs during transport; or (c) Chickens or contaminated material outside the chicken farms ⬇ Exposed birds become infected ⬇ Disease in susceptible birds; or vaccination of feral/pest birds	Decreased numbers of susceptible birds or Increased numbers of feral/pest birds	No	• Exposure is minimised due to strict biosecurity procedures in poultry farms. • Measures are in place to minimise wild birds accessing sheds, farms and water tanks in commercial poultry farms. • Local council and state requirements impose conditions to prevent contamination of water sources. • GMO is unable to maintain a stable presence in the environment for long periods. • Transmission of GMO from vaccinated chickens to other birds is unlikely. • GMO is non-pathogenic and unlikely to cause disease in native birds, including wild quails.

Risk scenario	Risk source	Possible causal pathway	Potential harm	Substantive risk	Reason
4	GMO	Vaccination of poultry farm chickens with the GMO ⬇ Infection of cells by GMO ⬇ Transduced cells are co-infected with other alphaherpesviruses ⬇ Homologous recombination with other alphaherpesviruses (field, vaccine or WT strains) ⬇ Generation of novel recombinant alphaherpesvirus strains ⬇ Infection of chickens and/or other susceptible avian species	Disease in chickens and/or other susceptible species	No	• HVT vaccines have been used for several decades with no reports of recombination with other alphaherpesviruses. • Commercial poultry industries follow strict biosecurity procedures that will minimise exposure to MDV1 and other alphaherpesviruses. • The inserted genes are not expected to alter host range or replication capability of the recipient MDV1 or other alphaherpesviruses.

2.4.1 Risk scenario 1

Risk source	GMO
Causal pathway	Exposure of people undertaking dealings to the GMO: During: a) preparation and administration of the GMO; b) handling and transport of chickens vaccinated with the GMO; c) unintentional spills; or d) transport, storage or disposal of the GMO and waste associated with GMO ⬇ Infection of people with the GMO
Potential harm	Local inflammation/adverse immune response

Risk source

182. The source of potential harm for this postulated risk scenario is the GMO.

Causal Pathway

183. People conducting the dealings could be exposed to the GMO in several ways. The GMO could be transmitted indirectly by contaminating clothes and hands during an unintentional spill of the GMO or during the preparation and administration of the GMO. Transmission could also occur through a needle stick injury during *in ovo* or subcutaneous injection of the GMO. People handling waste containing the GMO could be exposed to the GMO via contact (e.g. hands, clothing, trucks and containers used for transport). This exposure could potentially result in infection with the GMO that could lead to local inflammation/adverse immune response.

Exposure during preparation and administration of the GMO

184. As discussed in Chapter 1, Section 2.1, the GMO would be supplied as a freeze-dried vaccine in ampoules, which would need to be reconstituted prior to use. There is the potential for exposure of people involved in the administration of the GMO by aerosol formation during preparation and administration; from breakage/spillage of GMO onto surfaces during preparation and administration; or via needle stick injury.

185. The GM vaccine would be prepared and administered by trained professionals who have experience with both the equipment including needles and vaccine administration.

186. Based on other registered vaccines, the APVMA registration of veterinary vaccines would include a label indicating the dosage; method of administration; precautions; personal protective equipment (PPE) requirements; and instructions relating to first aid, storage, and disposal of the GMO. Compliance with these behavioural practices by personnel administering the GMO would reduce the likelihood of unintended exposure of people to the GMO.

187. The existing work practices mentioned above would minimise the potential exposure of people to the GMOs during preparation and administration of the vaccine.

Exposure during handling and transport of the chickens inoculated with the GMO

188. As mentioned in Chapter 1, Section 3.5.2, parent organism HVT is mainly transmitted by inhalation of feather follicles dust from infected chickens. The same mode of transmission is expected for the GM vaccine (Chapter 1, Section 4.2.2). Therefore, personnel in poultry farms may also be exposed to the GMO when handling chickens that have been vaccinated with the GMO or via materials or surfaces contaminated with the GMO during transport of vaccinated chickens. As mentioned above, poultry personnel must adhere to strict biosecurity procedures (Chapter 1, Section 5.5) which includes proper protective clothing and footwear; sanitising hands; and exclusion for the day if they had contact with poultry or other birds (unless it is an emergency and they have a shower and change of clothes). This would limit the exposure of people to the GMO.

189. As described in Chapter 1, Section 4.2.2, the GMO and the parental HVT virus were detected in all samples collected from vaccinated chickens, except trachea; however, the GMO was not detected in bursa and FFE at later time points compared to the parental strain, indicating reduced replication of the GMO. This is supported by the absence of detectable transmission of the GMO from vaccinated to unvaccinated birds.

190. The transport of chickens to harvesting farms or layer farms are regulated by the state and territories in accordance with the *Australian Animal Welfare Standards and Guidelines – Land Transport of Livestock*. This would include the proper handling of the livestock and cleaning procedures for the vehicles transporting chickens.

191. Adherence to the biosecurity procedures and the Australian Animal Welfare Standards and Guidelines – Land Transport of Livestock would limit the exposure of the GMO to people handling the GMO.

Exposure via unintentional spill

192. If the GMO was unintentionally/accidentally spilled or lost during transport or storage, this could result in exposure to people transporting or storing the GMO via the generation of aerosols or contamination of surfaces.

193. As described in Chapter 1, Section 2.1, the GMO would be packaged in sealed ampoules (primary container) subsequently packaged into a cane (secondary container) and stored and transported in a vessel containing liquid nitrogen. This would lower the likelihood of unintended dispersal of the GMOs.

194. The GM vaccine is expected to be not scheduled under the Poisons Standard as it is a poultry vaccine. The vaccine will be stored securely in a warehouse and transported to poultry farms in accordance with state legislation. APVMA registered vaccines would include storage instructions.

195. The transport and storage procedures discussed above would meet the containment requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, which ensures that the GM vaccine would be properly contained for transport and storage. This would mitigate exposure due to spills of the GMO during these dealings.

Exposure during disposal of the GMO and waste contaminated with the GMO

196. Individuals may be inadvertently exposed to GMOs while disposing of used, expired, or unused ampoules of the GM vaccine. In addition, people could also possibly be exposed to the GMO during the disposal of waste contaminated with the GMO (e.g. poultry litter or dead chicken carcasses or feathers).

197. As mentioned in Chapter 1, Section 2.1, the applicant has stated that all residual vaccine and associated waste that has come into contact with the GMO (such as syringes and ampoules) would be discarded in accordance with State/Territory, local council and Environmental Protection Agency (EPA) requirements; the poultry industry biosecurity standards; and conditions imposed by the APVMA registration of the GM vaccine. APVMA registered veterinary vaccines would have disposal instructions on their label to dispose the container appropriately. Based on similar registered

vaccines, this is likely to involve decontamination using chemical disinfectants prior to disposal (Vaxsafe® HVT).

198. The disposal of carcasses and litter generated from poultry farming would need to meet the requirements of the EPA from the various state and territories (Chapter 1, Section 5.5), which would take into account the possibility of transmission to other people and the environmental impact. In addition, all waste and litter would also need to follow industry biosecurity standards, which all aim to minimise the impact of the waste on the environment.

199. The disposal and decontamination procedures discussed above would minimise the likelihood of exposure of people that could be associated with conducting these dealings with the GMOs.

Potential harm

200. As mentioned in Chapter 1, Section 3.5.1, HVT is non-pathogenic and has a very narrow host range. It is not known to infect, or cause disease or adverse immune responses in humans. The introduced genes are not expected to alter the host range of the GM vaccine. ILTV, from which the gD and gI genes are derived, is also not known to infect humans. Although NDV, from which the F protein gene is derived, has been reported to infect humans in rare cases, the F protein function requires a highly specific interaction with the NDV HN protein on the same viral particle and this cannot be complemented by HN proteins from other viruses (Chapter 1, Section 4.1).

201. As described in Chapter 1, Section 4.2.2, no GMO was detected in either the vaccinated mice (a model for mammalian species) or in-contact mice housed with them. No clinical signs or macroscopic lesions were observed in any of the mice.

202. Live HVT vaccines and live attenuated NDV and ILTV vaccines are widely used in poultry. As a result, HVT, NDV (F protein) and ILTV (gD and gI glycoproteins) are present in the poultry production environment. It is likely that people are routinely exposed to HVT vaccines and the transgenes with no reports of infection (clinical or subclinical), toxicity or allergic reactions.

Conclusion

203. The exposure of people to the GMO resulting in local inflammation/adverse immune response is not identified as a risk that could be greater than negligible. Therefore, it does not warrant further detailed assessment.

2.4.2 Risk scenario 2

Risk source	GM vaccine
Causal pathway	Exposure of people to the GMO via: (a) Consumption of meat, eggs or egg products; or (b) Contact with live vaccinated chickens outside the poultry farm ⬇ Infection of people with the GMO
Potential harm	Adverse immune response

Risk Source

204. The source of potential harm for this postulated risk scenario is the GMO.

Causal Pathway

Exposure via consumption of meat, eggs or egg products

205. It is proposed that chickens or eggs from chickens vaccinated with the GMO would enter the human food supply. Other people not involved with the dealings could potentially exposed to the GMO via the consumption of meat, eggs or egg products.

206. Most chicken meat sold for human consumption lacks the internal organs, gastrointestinal tract and the head where the GMO may be present. As described in Chapter 1, Section 3.5.2, muscle tissue did not show the presence of virus following HVT infection in turkey; instead HVT was detected across neural, visceral and lymphatic tissues. This biodistribution is expected to be similar in chickens and the biodistribution of the GMO was comparable to that of HVT, based on the provided data in Chapter 1, Section 3.5.2 and 4.2.2. If the GMO is present in trace amounts in processed chickens, it is unlikely to survive the cooking process. In addition, any poultry would need to adhere to the Primary Production and Processing (PPP) Standard for Poultry Meat (Standard 4.2.2) and PPP Standard for Eggs and Egg Products (Standard 4.2.5). These standards require poultry growers to identify and control food safety standards associated with poultry growing, processing, egg safety hazards and traceability of eggs to ensure a reduction in foodborne illnesses.

207. *In ovo* vaccination would only occur in eggs destined to hatch to produce layer or broiler chicken and not for eggs entering the food chain. The main reason for *in ovo* vaccination is to protect chicken from viral diseases before they even hatch. Therefore, it is very unlikely that eggs that have been vaccinated with the GM vaccine will enter the food supply chain.

208. HVT and ILTV are not known to be transmitted vertically from chickens to eggs. NDV is predominantly transmitted horizontally, with only rare and unconfirmed cases of vertical transmission (Capua et al., 1993; Ul-Rahman et al., 2022). However, as discussed in Risk Scenario 1, the introduced NDV F protein is not functional in the absence of the NDV HN protein. It is highly unlikely the introduced transgenes would alter the transmission of HVT. Therefore, it is highly unlikely the GMO would be transmitted from chickens to eggs.

209. As discussed in Risk Scenario 1, the GMO was not detected in bursa and FFE at later period of the infection compared to HVT, likely due to reduced replication of the GMO. In addition, as described in Chapter 1 Section 4.2.2, no GMO was detected in either the vaccinated mice (a model for mammalian species) or unvaccinated mice housed with them. No clinical signs or macroscopic lesions were observed in any of the mice.

Exposure via contact with live vaccinated chickens outside the poultry farm

210. It is plausible that live vaccinated chickens could be sold to the public (Poultry Australia). It would likely involve day-old chicks, point-of-lay birds or mature hens. As described in Chapter 1, Section 4.2.2, transmission studies indicate minimal shedding of the GMO following vaccination as demonstrated by the absence of transmission between vaccinated birds. In addition, as discussed previously, the GMO is not expected to infect mammals, including humans.

211. Based on the reasons above, it is very unlikely that people consuming meat or eggs will be exposed to the GMO.

Potential harm

212. As discussed in Risk Scenario 1 and in Chapter 1, Section 3.5.1, HVT has a very narrow host range and is not known to infect or cause an immune response in humans. There are several registered live HVT vaccines that are currently used in poultry farms in Australia, with no reports of adverse effects resulting from exposure to HVT in people consuming meat or eggs. In addition, NDV and ILTV strains are naturally occurring in the environment or widely used in live vaccines so exposure to these viruses and their proteins is highly likely, with no reports of infection, toxicity or adverse immune responses.

213. As described in Chapter 1, Section 4.2.2, the GM vaccine was not shown to infect mice and cause clinical signs and macroscopic lesions in them.

Conclusion

214. The potential for exposure to the GMO from the consumption of meat, eggs or egg products or from contact with live vaccinated chickens outside the poultry farm, resulting in harm to people is not identified as a risk that is greater than negligible. Therefore, it does not warrant further assessment.

2.4.3 Risk scenario 3

Risk source	GM vaccine
Causal pathway	Exposure of other susceptible birds to the GMO via contact with: (a) Chickens or contaminated material within the chicken farms; (b) Chicken or eggs during transport; or (c) Chickens or contaminated material outside the chicken farms ⬇ Exposed birds become infected (e.g. other commercial poultry species or wild, feral, pest, native or pet/household birds) ↙ Disease in susceptible birds ↘ vaccination of feral/pest birds
Potential harm	Decreased numbers of susceptible birds Or Increased numbers of susceptible feral/pest birds

Risk Source

215. The source of potential harm for this postulated risk scenario is the GMO.

Causal Pathway

216. Other susceptible birds (e.g. other commercial poultry species or wild, feral, pest, native or pet/household birds) may be exposed to the GMO via transmission from chicken farms, during the transportation of chickens and eggs, from the disposal of waste, from unintentional spills, or via insect vectors.

Exposure to other susceptible birds through transmission from farms, waste and unintentional spills

217. There is a likelihood that free range chickens could encounter other susceptible birds if they are allowed outside the sheds. However, as mentioned in Chapter 1, Section 5.5.3, measures must be in place to discourage wild birds accessing the farm, and the number of susceptible wild birds near poultry farms would be expected to be low. Compliance with these biosecurity guidelines, as discussed in Risk Scenario 1, would minimise the exposure of other susceptible birds to the chickens vaccinated with the GMO. HVT is known to establish latency in vaccinated chickens and is shed from the FFE and released in feather dust particles of vaccinated chickens. Similarly, it should be assumed that vaccinated chickens may shed the GMO until slaughter. However, transmission studies indicate minimal shedding of the GMO following vaccination, which may reflect reduced replication of the GMO compared to HVT (Chapter 1, Section 4.2.2).

218. Other commercial poultry farms are present in Australia (e.g. turkey, pheasant and Japanese quail). Although unlikely, there is a potential that production of more than one commercially produced avian species be carried out in the same farm. Therefore, there is a possibility that the GMO could be transmitted to other sheds within the farm from workers or shared equipment. However, all commercial poultry farms follow strict biosecurity arrangements. As mentioned in Chapter 1, Section 5.5.2, if more than one commercially produced avian species is kept in the production area, they are to be managed separately with suitable biosecurity arrangements and shared equipment should be cleaned and disinfected between uses. Adherence to these biosecurity guidelines would limit the potential spread of the GMO between different sheds and farms.

219. Other susceptible birds could be exposed to the GMO via contact with waste (e.g. carcasses, litter, PPE used to enter sheds and water run offs) from poultry farms. However, as mentioned in Chapter 1, Section 5.7, poultry farms have measures in place to minimise the gathering of wild animals accessing the waste areas; and avoid the contamination of surface waters, stormwater drains, waterways, catchment and ground waters. In addition, as mentioned in Risk Scenario 1, the disposal or carcasses and waste generated would need to meet the EPA requirements from various state and territories. These management procedures would limit the exposure of other susceptible birds to the waste generated in poultry farms.

220. HVT is predominantly transmitted via inhalation of feather dust/dander, which would be same for the GMO as the introduced genes would not affect the transmission as described in Risk Scenario 1 and 2. No transmission of the GMO from vaccinated to unvaccinated birds was observed as demonstrated in laboratory studies of chickens, turkeys and quails (Chapter 1, Section 4.2.2); however, it cannot be excluded as HVT is known to be transmitted from chicken to turkey. Transmission to other susceptible birds could potentially occur during the transport of vaccinated chickens from the farm. As mentioned above, it should be assumed that vaccinated chickens may shed the GMO until slaughter.

221. The GMO could be released into the environment through a spill during transport, storage or disposal where susceptible birds could be exposed to the GMO. This could result in exposure of these birds to the GMO. As discussed in Risk Scenario 1, there are a range of measures in place that would reduce the chances of GMO being released into the environment. In addition, as an enveloped virus, the GMO persistence outside the host is limited as described in Chapter 1, Section 3.5.6 minimising the persistence of the virus in the environment.

222. In the unlikely event that the GMO is released into sewage water, it will be markedly diluted due to the small quantity of GMO present in a large volume of liquid waste or water. In addition, as described in Chapter 1, Section 3.5.6, a HVT vaccine, from which the GM vaccine was derived, was shown to rapidly lose its activity within hours following reconstitution with diluent. Therefore, it is highly unlikely that infection of birds could occur following exposure to an environmental source.

Exposure via transport of chickens or eggs

223. Transmission of the GMO could also occur if susceptible birds encounter trucks carrying vaccinated chickens/eggs. As mentioned above, transmission studies suggest minimal shedding of the GMO following vaccination. Also, HVT is not known to transmit to eggs. As discussed in Chapter 1, Section 3.3, HVT establishes a latent infection and that reactivation could occur when birds are stressed, potentially during transport. The *Australian Animal Welfare Standards and Guidelines – Land Transport of Livestock*, includes various requirements to ensure that welfare of poultry and minimise stress on the livestock during transport. It would also be unlikely that other susceptible birds would be close enough to trucks carrying vaccinated chickens to be exposed to the GMO.

224. Other susceptible birds could also be exposed to the GMO via indirect contact with trucks contaminated with the GMO during transport. Proper cleaning procedures of transport crates/containers and transport trucks between journeys are included in the *Australian Animal*

Welfare Standards and Guidelines – Land Transport of Livestock. This would minimise the contact of susceptible birds with surfaces that could have been potentially contaminated with the GMO during transport of livestock.

225. Overall, the exposure of other susceptible birds to the GMO via the transport of vaccinated chickens/eggs is highly unlikely.

Exposure via contact with live vaccinated chickens outside the poultry farm

226. Other susceptible birds outside the poultry farms could be exposed to the GMO indirectly from contact with someone who has been in contact with the GMO while working in the poultry farm. As mentioned in Chapter 1, Section 5.5, poultry farms personnel would need to comply with biosecurity procedures to minimise any transmission outside the poultry farms or between sheds. This includes having change areas away from shed with clean protective clothing and boots; footbaths containing disinfectants at entry/exit points. These measures should minimise the potential for exposure of personnel to the GMO and subsequent transmission to other susceptible birds outside the poultry farm.

227. As discussed in Risk Scenario 2, it is plausible that live vaccinated chickens could be sold to the public, including as day-old chicks, point-of-lay birds or mature hens. As discussed in Risk Scenario 1, HVT, from which the GMO derived, has a host range limited to specific avian species, which is not expected to be altered by the introduced genes. As described in Chapter 1, Section 4.2.2, transmission studies indicate minimal shedding of the GMO following vaccination as demonstrated by the absence of transmission between vaccinated and unvaccinated birds. Therefore, it is highly unlikely that infection of birds could occur following exposure to vaccinated chickens outside the poultry farm.

Potential harm

228. If susceptible birds are exposed to the GMO, they could potentially be infected. As described in Chapter 1, Section 3.5.1, HVT could potentially infect other birds in the *Phasianidae* family (e.g. commercial poultry species such as pheasants; or wild/feral species such as pheasants and peafowls). In addition, the GMO has been shown to infect bird species within this family including chickens, turkeys and quails, indicating these birds could also be susceptible to the GMO (Chapter 1, Section 4.2.2).

229. However, the parent HVT strain is non-pathogenic (Chapter 1, Section 3.1) and has been used as live vaccines worldwide, including Australia, for decades against Marek's disease with no reports of adverse events (Chapter 1, Section 3.5.4). Similarly, no clinical signs or disease was observed in the birds vaccinated with GMO (Chapter 1, Section 4.2.2). As described in Risk Scenario 1 and 2, HVT has a very narrow host range, which is not expected to be altered by the introduced genes.

230. As the GMO is expected to prevent MDV1, NDV and ILTV infections in vaccinated chickens, exposure of wild/feral birds (e.g. pheasant and peafowl) could also potentially result in immunity towards these viruses. This could inadvertently result in increased numbers of wild pheasant and peafowl. However, for this scenario to lead to harm to the environment, a large number of wild pheasant and peafowl birds would have to become infected with the GMO, and these viruses would need to be an important factor limiting the populations. As mentioned in Chapter 1, Section 5.10, peafowls and pheasants are introduced species, not commonly found. The likelihood that these species of birds will be found in large numbers near commercial poultry farms is very low. Reported outbreaks of MDV1, NDV and ILTV are also not common, therefore the likelihood that these 3 viruses are an important limiting factor of pheasant and peafowl populations is very unlikely.

231. As mentioned in Chapter 1, Section 5.10, there are native quail species in Australia that belong to the *Phasianidae* family. The GMO has been shown to infect quail species following vaccination without causing disease and no GMO transmission was observed in unvaccinated quails housed with

vaccinated ones. In the unlikely event that the native quail species are exposed to the GMO, it is highly unlikely that the GMO cause disease and/or spread in these species.

232. In the unlikely event that other types of commercial poultry (e.g. turkey, pheasant) are exposed to the GMO, it is likely that exposed flocks would be indirectly vaccinated against MDV1, NDV and ILTV as the GMO is non-pathogenic vaccine. As described in Chapter 1, Section 5.9, HVT, NDV and ILT vaccines are commonly administered in Australian poultry, and these viruses are present in the Australian environment. Therefore, bird species in Australia are likely already exposed to the same or similar genetic material as that present in the GMO, with no reports of adverse effects or selective advantages to birds.

Conclusion

233. The potential of indirect exposure of the GMO via transmission from chicken farms; during the transportation of chickens and eggs, resulting in decreased numbers of other commercial poultry flocks or other susceptible bird species due to disease causing death, or increased number of feral/pest birds that have an adverse impact on other species is not identified as a risk that could be greater than negligible. Therefore, it does not warrant further assessment.

2.4.4 Risk Scenario 4

Risk source	GM vaccine
Causal pathway	Vaccination of poultry farm chickens with the GMO ⬇ Infection of cells by GMO ⬇ Transduced cells co-infected with other alphaherperviruses ⬇ Homologous recombination with other alphaherperviruses (field, vaccine or WT strains) ⬇ Generation of novel recombinant alphaherpervirus strains ⬇ Infection of chickens and/or other susceptible avian species
Potential harm	Disease in chickens and/or other susceptible species

Risk source

234. The source of potential harm for this postulated risk scenario is the GMO.

Causal Pathway

235. The likelihood of recombination occurring in viruses is dependent on co-circulation of different viruses in the same geographical area, genetic similarity between the viruses, rate of co-infection of a host with both viruses, and viral population size within the infected host. For recombination between another alphaherpesvirus and the GMO to occur, both viruses would need to be present and

replicating in the same cell at the same time. This could occur if chickens are exposed to another HVT or other MDV serotypes either before or after vaccination, or if multiple vaccines are administered to the same bird at the same time.

236. The GMO could also form a latent infection (Chapter 1, Section 4.3.1) in vaccinated chickens, whereby the GMO could be reactivated when the birds are stressed. Chickens with reactivated GMO could potentially be exposed to another alphaherpesvirus, or to a second vaccine strain resulting in two strains being present at the same time. However, there are animal welfare guidelines and legislation in place that are regulated by states and territories to ensure that the stress on chickens is minimised during poultry farming or during transport. In addition, as mentioned in Risk Scenarios 1 and 3, strict biosecurity procedures are in place to ensure that any disease is not transmitted into and out of the shed/poultry farm.

237. In addition to factors in Risk Scenarios 1 and 3, sheds are also decontaminated and tested after birds are harvested to ensure that potential disease agents are removed. This would prevent the presence of diseases in the shed when a new flock is introduced minimising the likelihood of a new flock being exposed to infectious avian viruses.

238. As discussed in Chapter 1, Section 3.1 and 3.2, the parent organism is closely related to other MDV serotypes. If recombination were to occur, it would more likely involve another HVT strain or other MDV serotypes.

239. If recombination does occur, it could result in loss of the inserted genes from the GMO. However, the resulting virus would revert to the non-pathogenic parental HVT and would not pose any additional risk beyond that of HVT itself. Alternatively, transfer of the inserted genes to another HVT or MDV2 (another non-pathogenic MDV serotype) could also occur. However, the resulting recombinant virus would not have increased host range or replication capability and as such would not pose any harm other than those that have already been considered for the GMO. As discussed in previous risk scenarios, the inserted genes are not expected to increase host range or replication capability.

240. As described in Chapter 1, Section 3.4, HVT vaccination prevents the clinical signs of the Marek's disease but does not prevent MDV1 (pathogenic MDV1 serotype) infection or shedding. As a result, chickens vaccinated with HVT commonly become co-infected with MDV1. If recombination results in transfer of the inserted genes to circulating MDV1 strains, it could generate novel recombinants of MDV strain(s). This is unlikely to increase their host range and disease-causing capabilities in chickens or other susceptible avian species. This is because co-administration of the parent HVT vaccine with MDV1 strains or other virus vaccine strains has not been reported any recombination events, and the GMO, which shares the same backbone as HVT, has been shown to have a comparable phenotype with HVT. Based on data provided by the applicant (Chapter 1, Section 4.2.1), the GMO and attenuated MDV1 strain co-administration did not raise safety concerns over 4 months observation period.

241. As discussed in previous risk scenarios, the inserted genes are not expected to increase host range or replication capability in the GMO compared to HVT. Instead, the GMO showed reduced replication in some tissues, including FFE, compared to HVT. Given the high similarity between HVT and MDV1, the inserted genes would be expected to have similar limited effects in MDV1. Therefore, recombination between the GMO and other MDV strains leading to a more transmissible or virulent MDV1 strain is considered unlikely. In the unlikely event that a novel recombinant arises, it would need to be transmitted to other chickens or birds to establish and maintain its presence. It is not known how long a novel MDV1 strain would need to recombine, infect hosts, and establish itself as a new strain. If recombination occurs and results in a novel MDV strain, broiler chickens are only kept for about 7-8 weeks before harvesting, limiting the potential of transmission of the new recombinant strain. Layer chickens on the other hand are kept for longer (20 - 78 weeks) but have shown to have a

better targeted immune response, which probably contributes to their longer lifespan (Koenen et al., 2002).

242. In the event of an outbreak caused by a novel MDV1 strain, biosecurity measures as described in Chapter 1, Section 5.5.5, would be in place to manage the potential spread of the disease (e.g. proper PPE, decontamination of facilities, euthanising the entire flock and disposal of potentially contaminated materials). This would be under direct control of the state's Chief Veterinary Officer and would be the responsibility of state and territories.

243. APVMA registered vaccines would include precautions on their labels to only vaccinate healthy birds. Strict biosecurity procedures are also in place to limit the interaction of chickens in commercial poultry with other avian species that may harbour MDV1 infection.

244. Therefore, based on the data available, historical precedence and adherence to biosecurity guidelines, the likelihood that recombination between the GMO and MDV1 would lead to an established novel pathogenic MDV1 strain is considered highly unlikely.

245. As mentioned in Chapter 1, Section 3.2, the HVT genome shares overall genomic organisation and gene content with other alphaherpesviruses, indicating a degree of similarity. As discussed above, homologous recombination between HVT and the more closely related MDV1 is considered unlikely. Therefore, the likelihood of recombination between HVT and more distantly related alphaherpesviruses would be expected to be even lower. In addition, there has not been any reports showing that HVT can recombine with other viruses, including other alphaherpesviruses.

246. In the highly unlikely event of recombination with ILTV, the transfer of ILTV gD and gI to the ILTV genome could result in additional copies and increased expression of these genes. As described previously (Chapter 1, Section 4.1), glycoprotein D and I are involved in cell entry and cell to cell spread, respectively. Increased expression of these proteins may enhance the efficiency of infection at the cellular level; however, this is unlikely to substantially impact on overall virulence in the absence of changes in other determinants, including immune evasion mechanism and replication capacity. Also, this is not expected to alter the host range beyond that of wild type ILTV.

247. Overall, it is highly unlikely that recombination between the GMO and other alphaherpesviruses, including ILTV, would result in emergence of a more transmissible or virulent strain.

Potential harm

248. The potential harm from this scenario is increased disease in chickens and other susceptible species.

249. In the unlikely event that recombination between HVT and MDV1 or other alphaherpesviruses were to occur, it could result in the generation of a novel strain of MDV1 or another alphaherpesvirus. If this occurred within a farm, the opportunity for it to spread to other susceptible birds would be restricted by high level of biosecurity measures and notification requirements for the relevant disease. This would limit its ability to spread to other chickens and to establish and maintain its presence.

250. In the event of an outbreak caused by the novel recombinant strain, biosecurity measures as described in Chapter 1, Section 5.5.5, would be in place to manage the potential spread of the disease (e.g. proper PPE, decontamination of facilities, euthanising the entire flock and disposal of potentially contaminated materials).

Conclusion

251. The potential for the GMO and MDV1 strains or other alphaherpesviruses to produce novel strains due to recombination is not identified as a risk that could be greater than negligible. Therefore, it does not warrant further detailed assessment.

Section 3 Uncertainty

252. Uncertainty is an intrinsic property of risk analysis and is present in all aspects of risk analysis. This is discussed in detail in the Regulator's Risk Analysis Framework document.

253. Uncertainty is addressed by approaches such as balance of evidence, conservative assumptions, and applying risk management measures that reduce the potential for risk scenarios involving uncertainty to lead to harm. If there is residual uncertainty that is important to estimate the level of risk, the Regulator will take this uncertainty into account when making decisions.

254. Uncertainty can arise from a lack of experience with the GMO. There is uncertainty regarding the potential for the GMO infecting susceptible Australian wild birds. The parent HVT strain is non-pathogenic and has been used as live vaccines worldwide, including Australia, for decades against Marek's disease with no reports of adverse events. In addition, no clinical signs or disease was observed in the birds vaccinated with the GMO. There is also uncertainty regarding recombination of the GMO with circulating alphaherpesviruses in the Australian environment. The GMO has been approved for use in the USA since 2019 and in Europe and the UK since 2020, and there have been no recorded recombination events to date. Additional information regarding the potential for recombination between the GMO and other alphaherpesviruses is considered in Chapter 2, Risk Scenario 4 and the overall risk has been assessed as posing negligible risk.

255. Post release review (PRR) will also be used to address uncertainty regarding future changes to knowledge about the GMO or the receiving environment. PRR is typically required for commercial GMO releases, which generally do not have limited durations.

Section 4 Risk evaluation

256. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

257. Factors used to determine which risks need treatment may include:

- risk criteria,
- level of risk,
- uncertainty associated with risk characterisation, and
- interactions between substantive risks.

258. Four risk scenarios were identified whereby the proposed dealings might give rise to harm to people or the environment The level of risk for each risk scenario was considered negligible, considering both the short and long term. The principal reasons for these conclusions are summarised in Table 2.

259. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GMO into the environment are considered to be negligible. The Risk Analysis Framework (OGTR, 2013), which guides the risk assessment and risk management process, defines negligible risks as risks of no discernible concern with no present need to invoke actions for mitigation[3].

[3] As none of the proposed dealings are considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the Act mandates a minimum period of 30 days for consultation on the RARMP. However,

260. While no specific risk management measures are required, control measures are likely to be imposed by the APVMA during the registration process to manage any risks associated with the vaccine. Control measures for administration of other live attenuated vaccines are currently imposed under other APVMA registrations. These control measures are considered important for maintaining the risk context and discussed further in Chapter 3.

the Regulator has allowed up to eight weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

Chapter 3 Risk management plan

Section 1 Background

261. Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan addresses risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through proposed licence conditions.

262. Under section 56 of the Act, the Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

263. All licences are subject to three conditions prescribed in the Act. Section 63 of the Act requires that each licence holder inform relevant people of their obligations under the licence. The other statutory conditions allow the Regulator to maintain oversight of licensed dealings: Section 64 requires the licence holder to provide access to premises to OGTR inspectors and Section 65 requires the licence holder to report any information about risks or unintended effects of the dealing to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder are also required to be reported to the Regulator.

264. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in Section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under Section 152 of the Act.

Section 2 Risk treatment measures for substantive risks

265. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people and the environment from the proposed commercial release of the GMO. These risk scenarios were considered in the context of the scale of the proposed release and the receiving environment, considering both the short and long term. The risk evaluation concluded that no specific risk treatment measures are required to treat these negligible risks.

266. As there were no substantive risks identified, no specific conditions were included in the draft licence. However, it is noted that the commercial supply of the product containing the GMO will also require the registration of the product with the APVMA, which is likely to contain restrictions of only vaccinating healthy chickens.

Section 3 General risk management

267. All DIR licences issued by the Regulator contain a number of conditions that relate to general risk management. These include conditions relating to:

- applicant suitability
- testing methodology
- identification of the persons or classes of persons covered by the licence
- reporting structures
- access for the purpose of monitoring for compliance
- other modes of administration.

3.1 Applicant suitability

268. In making a decision whether or not to issue a licence, the Regulator must have regard to the suitability of the applicant to hold a licence. Under Section 58 of the Act, matters that the Regulator must take into account include:

- any relevant convictions of the applicant
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country
- the capacity of the applicant to meet the conditions of the licence.

269. If a licence were issued, the conditions would include a requirement for the licence holder to inform the Regulator of any circumstances that would affect their suitability.

3.2 Testing methodology

270. If a licence were issued, Intervet Australia Pty Ltd would be required to provide a method to the Regulator for the reliable detection of the GMO, and the presence of the introduced genetic materials in a recipient organism. As part of the application, the applicant supplied appropriate detection methods to detect the introduced genes in the GMO. Therefore, a requirement to provide detection methods is not included in the draft licence.

3.3 Identification of the persons or classes of persons covered by the licence

271. If a licence were issued, any person, including the licence holder, could conduct any permitted dealing with the GMO.

3.4 Modes of administration

272. The applicant has proposed 2 modes of administration (*in ovo* and subcutaneous injection). The risks associated with this method of administration have been included in the risk assessment for DIR 224, but the mode of administration is not conditioned in the licence. Any administration of the vaccine must adhere to the labelling requirements imposed by the APVMA.

3.5 Reporting requirements

273. If issued, the licence would oblige the licence holder to immediately report any of the following to the Regulator:

- any additional information regarding risks to the health and safety of people or the environment associated with the dealings;
- any contraventions of the licence by persons covered by the licence;
- any unintended effects of the release.

274. The licence holder is also obliged to submit an Annual Report containing any information required by the licence.

275. There are also provisions that enable the Regulator to obtain information from the licence holder relating to the progress of the commercial release (see Section 4, below).

276. If issued, the licence would also require the licence holder to notify the Regulator of the following authorisations by the APVMA:

- inclusion on the Public Chemicals Registration Information System (PubCRIS); and
- any amendments to the registration.

3.6 Monitoring for compliance

277. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow the Regulator, inspectors or other person authorised by the Regulator, to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing.

278. In cases of non-compliance with licence conditions, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. The Act provides for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the licence or directions from the Regulator, especially where significant damage to the health and safety of people or the environment could result.

Section 4 Post release review

279. Regulation 10 requires the Regulator to consider the short and the long term when assessing risks. The Regulator takes account of the likelihood and impact of an adverse outcome over the foreseeable future and does not disregard a risk on the basis that an adverse outcome might only occur in the longer term. However, as with any predictive process, accuracy is often greater in the shorter rather than longer term.

280. For the current application for a DIR licence, the Regulator is including conditions that require ongoing oversight to provide feedback on the findings of the RARMP and ensure the outcomes remain valid for future findings or changes in circumstances. If a licence was issued, this ongoing oversight would be achieved through PRR activities. The three components of PRR are:

- adverse effects reporting system (Section 4.1)
- requirement to monitor specific indicators of harm (Section 4.2)
- review of the RARMP (Section 4.3).

The outcomes of these PRR activities may result in no change to the licence or could result in the variation, cancellation or suspension of the licence.

4.1 Adverse effects reporting system

281. Any member of the public can report adverse experiences/effects resulting from a GMO to the OGTR through the Free-call number (1800 181 030), mail (MDP 54 – GPO Box 9848, Canberra ACT 2601) or via email to the OGTR inbox (ogtr@health.gov.au). Reports can be made at any time on any DIR licence. Credible information would form the basis of further investigation and may be used to inform a review of a RARMP (see Section 4.3 below) as well as the risk assessment of future applications involving similar GMOs.

4.2 Requirement to monitor specific indicators of harm

282. Collection of additional specific information on an intentional release provides a mechanism for ‘closing the loop’ in the risk analysis process and for verifying findings of the RARMP.

283. This may involve monitoring the specific indicators of harm that have been identified in the risk assessment. The term ‘specific indicators of harm’ does not mean that it is expected that harm would necessarily occur if a licence was issued. Instead, it refers to measurement endpoints which are expected to change should the authorised dealings result in harm. Should a licence be issued, the licence holder would be required to monitor these specific indicators of harm as mandated by the licence.

284. The triggers for this component of PRR may include risk estimates greater than negligible or significant uncertainty in the risk assessment.

285. The characterisation of the risk scenarios discussed in Chapter 2 did not identify risks greater than negligible. Therefore, they were not considered substantive risks that warranted further detailed assessment. No specific indicators of harm have been identified in this RARMP for application DIR 224. However, specific indicators of harm may also be identified during later stages, e.g. following the consideration of comments received on the consultation version of the RARMP, or if a licence were issued, through either of the other components of PRR.

286. Conditions have been included in the licence to allow the Regulator to request further information from the licence holder about any matter to do with the release, including research to verify predictions of the risk assessment.

4.3 Review of the RARMP

287. The third component of PRR is the review of RARMPs after a commercial/general release licence is issued. Such a review would take into account any relevant new information, including any changes in the context of the release, to determine if the findings of the RARMP remained current. The timing of the review would be determined on a case-by-case basis and may be triggered by findings from either of the other components of PRR, or by relevant new scientific information, or be undertaken after the authorised dealings have been conducted for some time. If the review findings justified either an increase or decrease in the initial risk estimate(s) or identified new risks to people or to the environment that require management, this could lead to changes to the risk management plan and licence conditions. In the case of a veterinary vaccine where the APVMA is the primary regulatory body overseeing the vaccine, any review of the RARMP or licence would likely only be initiated in consultation with APVMA.

Section 5 Conclusions of the consultation RARMP

288. The risk assessment concludes that the proposed commercial release of the GM vaccine poses negligible risks to the health and safety of people and a negligible risk to the environment as a result of gene technology.

289. The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, if a licence were to be issued, general conditions are proposed to ensure that there is ongoing oversight of the release.

Chapter 4 Draft licence conditions

Section 1 Interpretations and Definitions

1. In this licence:

    (a) unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

    (b) words importing a gender include every other gender;

    (c) words in the singular number include the plural and words in the plural number include the singular;

    (d) expressions used to denote persons generally (such as “person”, “party”, “someone”, “anyone”, “no-one”, “one”, “another” and “whoever”), include a body politic or corporate as well as an individual;

    (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

    (f) where a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;

    (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

‘**Act**’ means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

‘**Annual Report**’ means a written report provided to the Regulator by the end of September each year containing all the information required by this licence to be provided in the Annual Report.

‘**GM**’ means genetically modified.

‘**GMO**’ means the genetically modified organism that is the subject of the dealings authorised by this licence.

‘**OGTR**’ means the Office of the Gene Technology Regulator.

‘Regulations’ means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

‘**Regulator**’ means the Gene Technology Regulator.

Section 2 General conditions and obligations

3. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension.

4. The licence holder is Intervet Australia Pty Ltd.

5. Any person, including the licence holder, may conduct any authorised dealing(s) with the GMO.

6. The dealings authorised by this licence are:

    (a) import the GMO;

    (b) transport of the GMO;

(c) disposal of the GMO;

and the possession (including storage) and supply of the GMO for the purposes of, or in the course, of any of these dealings.

Note: Use of the GMO for veterinary purposes is not covered by the Gene Technology Act 2000 and therefore this licence is not required to authorise such use. The GMO is also subject to regulation by other federal and state departments and agencies, including the Australian Pesticides and Veterinary Medicines Authority and the Department of Agriculture, Fisheries and Forestry. These other departments and agencies may impose further requirements for, or limitations on, the use of the GMO or these dealings.

7. Dealings with the GMO may be conducted in all areas of Australia.

8. Dealings described in Condition 6 must not occur unless authorised by registration with the APVMA.

9. The licence authorises dealings with the GMO described in **Attachment A**.

2.1 Obligations of the Licence Holder

10. The licence holder must immediately notify the Regulator if any of its contact details change.

Note: Please address correspondence to OGTR.M&C@health.gov.au

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.

11. The licence holder must:

(a) inform the Regulator immediately in writing, of:

i. any relevant conviction of the licence holder; and

ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and

iii. any event or circumstances that would affect the capacity of the holder of this licence to meet the conditions in it; and

(b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

12. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

(a) the particular condition (including any variations of it); and

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

2.2 Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.

13. The licence holder must inform the Regulator if the licence holder becomes aware of:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

(b) any contraventions of the licence by a person covered by the licence; or

(c) any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition, that:

(a) the licence holder will be taken to have become aware of additional information of a kind mentioned in condition 13 if he or she was reckless as to whether such information existed; and

(b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in condition 13, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note: Contraventions of the licence may occur through the action or inaction of a person.

14. If the licence holder is required to inform the Regulator under condition 13, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030 or email to OGTR.M&C@health.gov.au.

15. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(a);

(b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(b);

(c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(c);

(d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;

(e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period;

(f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

Note: The Regulator may invite the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant to the progress of the dealings with the GMO.

2.3 Obligations of persons covered by the licence

16. If a person is authorised by this licence to deal with the GMO and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Section 3 Reporting and Documentation

3.1 Notification of authorisations by the Australian Pesticides and Veterinary Medicines Authority

17. If the GMO is included on the Public Chemical Registration Information System (PubCRIS), the licence holder must notify the Regulator in writing within 14 days of registration.

18. The licence holder must notify the Regulator in writing of any subsequent amendments to the conditions of the PubCRIS registration involving the pattern of usage, handling, storage, transport or disposal of the GMO, within 14 days of the change occurring.

3.2 Annual Report

19. The licence holder must provide an Annual Report to the Regulator by the end of September each year covering the previous financial year. An Annual Report must include:

(a) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMO or material from the GMO;

(b) information about the numbers of vaccine doses distributed to each State and Territory.

Note: Please address correspondence to OGTR.M&C@health.gov.au

ATTACHMENT A

DIR No: 224

Full Title: Commercial supply of a genetically modified (GM) multivalent vaccine for chickens

Licence Holder Intervet Australia Pty Ltd

GMO Description

GMO covered by this licence

A turkey herpesvirus genetically modified to express the fusion (F) protein from Newcastle disease virus and glycoproteins D and I from infectious laryngotracheitis virus.

Parent Organism

Common Name: Turkey herpesvirus (HVT; strain FC-126)

Scientific Name: *Mardivirus meleagridalpha1*

Modified traits

Category: Vaccine – non-pathogenic

Description: The GMO has been genetically modified to express the F protein from NDV and gD and gI glyproteins from ILTV, which together induce immunity against ND and ILT.

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Appendix A: Summary of submissions

The Regulator received several submissions from prescribed experts, agencies and authorities[4] on matters relevant to preparation of the RARMP. All issues raised in submissions relating to risks to the health and safety of people and the environment were considered. These issues, and where they are addressed in the consultation RARMP, are summarised below.

Submission	Summary of issues raised	Comment
1	Agrees that the following should be included in the RARMP: • Potential for accidental exposure of humans and animals to the GMO leading to harm; • Potential for recombination of the GMO with other alphaherpesviruses; and • Potential for the GMO to be harmful to the environment.	These issues have been considered in Chapters 1 and 2 of the Risk Assessment and Risk Management Plan (RARMP).
	Advises that the Regulator should consider including more detail on the context with Australian native birds.	Information on the potential hosts in the environment, including Australian native and wild bird species that may be susceptible has been provided in the RARMP (see Chapter 1, Section 3.5.4 and 5.8, and Chapter 2, Section 2.4.3).
2	Noted that the councils are not expected to provide specialist scientific advice in relation to this application. Recommends considering the following matters:	
	• Potential exposure of persons involved in transport, storage, handling, administration and disposal of the GM vaccine.	The potential risks regarding proposed GMO dealings have been addressed in the RARMP in Chapter 1, Section 2.1 and Chapter 2, Risk Scenarios 1 and 2.
	• Potential exposure pathways to the environment including unintended spills, incorrect disposal, release into waste streams, or exposure to non-target organisms including wild birds or other susceptible avian species.	The potential exposure to other susceptible birds through transmission from farms, waste and unintentional spills or through transport of chickens or eggs has been addressed in Chapter 2, Risk Scenario 3 of in the RARMP.
	• Whether the GM vaccine or material from the GM vaccine could persist spread or be released outside the intended vaccinated chicken population in a way that may result in harm to people or the environment.	The potential persistence, shedding, transmission, stability and potential for recombination of the parent organism have been discussed throughout Chapter 1 (Section 3.5 and Section 4.3) and Chapter 2 (Risk scenarios 1 to 4).

[4] Prescribed expects, agencies and authorities include GTTAC, State and Territory Governments, Australian government agencies and the Minister for the Environment.

Submission	Summary of issues raised	Comment
	• Potential for GM vaccine recombination or complementation with other poultry viruses, field strains or live vaccines and whether any restrictions are required regarding concurrent use with other live vaccines.	The potential for recombination of the GM vaccine has been discussed in Chapter 1 (Section 3.5 and Section 4.2.1) and Chapter 2 (Risk scenario 4).
	• Whether appropriate controls are required for storage, transport, cold chain management, handling, administration, spill response, and disposal of unused vaccine, empty containers, contaminated materials, and waste generated during vaccination.	These issues are outside of the scope of the Regulator's assessment and will be considered by APVMA in their registration process.
	• Whether appropriate information training, record keeping, incident reporting, and biosecurity measures should apply to persons covered by the licence and end users of the GM vaccine. • Whether record keeping requirements should apply to enable traceability of vaccine batches, locations of use, operators, numbers of birds vaccinated, and any observed adverse effects.	The RARMP concludes that the GMO poses negligible risk to human health and safety or the environment and therefore specific risk management conditions are not required. However, general risk management conditions, including reporting and documentation requirements have been included in the draft licence to ensure that there is ongoing oversight of the release. This also includes provision of any new information relating to risks to human health and safety or the environment caused by the GMO. In addition, the RARMP outlines post-release review activities that contribute to ongoing oversight of this commercial release (Chapter 3, Section 4).
	• Whether post release monitoring adverse event reporting or other ongoing oversight conditions should be included to identify adverse impacts, unintended effects or new information relating to risks to human health and safety or the environment.	The licence holder is required to inform the Regulator if the licence holder becomes aware of any additional information, contraventions and any unintended effects of the dealings authorised by the licence (Condition 13).
3	Noted they have no advice or comments on the preparation of the RARMP.	Noted.
4	Noted they have no comments on the application. Welcome the opportunity to comment on the consultation RARMP.	Noted.
5	Noted that: • it is unlikely that the vaccine would directly or inadvertently enter the food chain or transfer to other species. • vaccinated chickens would enter the food chain, however, it is unlikely to pose a risk.	The likelihood of harm from the GMO entering the food chain is addressed in Chapter 2 (Risk scenario 2).
	• the vaccine is currently used in the EU and the USA and expect that any issues	The RARMP concludes that the GMO poses negligible risk. General risk management conditions, particularly conditions 13, 15 and 19,

Submission	Summary of issues raised	Comment
	arising in those jurisdictions would be identified and taken into account.	are included in the draft licence to ensure that there is ongoing oversight of the release. In addition, the RARMP outlines post-release review activities that contribute to ongoing oversight of this commercial release (Chapter 3, Section 4).