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

November 2026

Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 224

Introduction

The Gene Technology Regulator (the Regulator) has decided to issue a licence 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. A Risk Assessment and Risk Management Plan (RARMP) for this application has been prepared by the Regulator in accordance with the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concluded that the proposed release poses negligible risk to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

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 application

Project title	Commercial supply of a genetically modified (GM) multivalent vaccine (Innovax®-ND-ILT) for chickens[1,2]
Parent organism	Turkey herpesvirus (*Mardivirus meleagridalpha1*) strain FC-126
Genetic modifications[3]	**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
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.

[1] The original title for the licence application submitted by Intervet Australia Pty Ltd was "Innovax ND ILT".
[2] The title has been updated from the title used during consultation to provide a distinction from other applications.
[3] 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.

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 consultation 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 does not 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.

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 licence requires the Regulator to be notified of the APVMA registration of the product and any amendments to the registration.

General licence conditions are imposed to ensure that there is ongoing oversight of the GM vaccine. Conditions are 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. The 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.