



Summary of the Risk Assessment and Risk Management Plan (Consultation version) for Licence Application DIR 220

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application (DIR 220) for the import, transport, storage and disposal of a multivalent vaccine containing a genetically modified (GM) Venezuelan Equine Encephalitis Virus (VEEV) that produces the glycoprotein from Feline leukemia virus (FeLV), as part of its commercial supply to vaccinate cats. These activities are classified as Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment under the *Gene Technology Act 2000*.

Before vaccines containing the GMO 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

Project title	Commercial supply of multivalent cat vaccines containing a genetically modified component for the prevention of feline leukemia virus infection ¹
Parent organism	Venezuelan Equine Encephalitis Virus (VEEV) vaccine strain TC-83
Genetic modifications	Deleted genes: <ul style="list-style-type: none">- Viral structural genes - to render the GMO unable to produce new viral particles Introduced gene: <ul style="list-style-type: none">- Feline leukemia virus glycoprotein gene – trigger an immune response against the feline leukemia virus and protect animals against later infection
Previous releases	The GMO in the vaccine has not been previously approved for release in Australia

¹ The title for the licence application submitted by Intervet Australia Pty Ltd is “Commercial DIR application for Nobivac NXT HCPChFeLV Live Vaccine for cats, plus fall out vaccine product Nobivac NXT HCPFeLV Live Vaccine for cats”.

Current approvals	The GMO and the vaccine are currently approved for use by the United States Department of Agriculture and are under review by the European Medicines Agency.
Proposed locations	Australia-wide
Primary purpose	Commercial supply of the multivalent vaccines to protect against infectious diseases in cats.

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 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 included 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. Specific measures are included in the licence to maintain the risk context.

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

- The GMO is unable to produce new viral particles and is unlikely to cause disease in cats, horses or other susceptible mammalian species;
- 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 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 of the GMO with other alphaviruses is highly unlikely due to superinfection exclusion mechanisms.

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 a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and other reporting requirements, which include an obligation to report any unintended effects.