Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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Summary of the Risk Assessment and Risk Management Plan

(Consultation Version) for

Licence Application DIR 202

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application (DIR 202) for import, transport, storage and disposal for the commercial supply of a live attenuated vaccine containing canine distemper virus (CDV) and a genetically modified (GM) canine parvovirus (CPV) (Nobivac Puppy DP Plus) for dogs. 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*.

Before the vaccine containing a GM component 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-202
Applicant	Intervet Australia Pty Ltd
Project title	Commercial supply of a live attenuated vaccine containing canine distemper virus and a genetically modified canine parvovirus (Nobivac Puppy DP Plus) for dogs[1]
Parent organism	Canine parvovirus type 2 (CPV-2)

[1] The title for the licence application submitted by Intervet Australia Pty Ltd is “Nobivac Puppy DP Plus Live Vaccine”.

Introduced gene and modified trait	Introduction of a wild type CPV-2c capsid into the attenuated CPV 154 strain, resulting in an attenuated live vaccine that does not cause severe disease in dogs.
Previous releases	The GM vaccine has not been previously approved for release in Australia
Current approvals	The GM vaccine is currently approved for use in 36 countries by the European Medicines Agency and the Philippines Federal Drug Administration.
Proposed locations	Australia-wide
Primary purpose	Commercial supply of the GM vaccine against CDV and CPV-2 in dogs.

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 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. Specific risk treatment 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 has a limited host range, is attenuated and unlikely to cause disease in dogs or other susceptible mammalian species;
- Canine parvovirus does not cause disease in humans or animals other than dogs, except for some susceptible mammalian carnivore species including big cats;
- 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 another parvoviruses is possible but since the vaccine contains genetic material from CPV-2 similar to that circulating in Australia, similar genetic material would already be present in the environment.

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 risk of recombination leading to novel CPV-2 strains was assessed as negligible given the risk context in which the dealings would be conducted which includes APVMA registration. As the product is not currently registered by the APVMA and to maintain critical aspects of the risk context, specific risk treatment measures, such as vaccination of only healthy dogs, a time window between live vaccine administrations and restriction to not vaccinate a dog with two compatible live vaccines concurrently were included in the draft licence (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 effect.