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

August 2024

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 202

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. 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 commercial supply 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.

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)
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 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.

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

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 Department of Agriculture, Fisheries and Forestry (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. To maintain critical aspects of the risk context, a condition requiring the licence holder to advise end users of the vaccine to only vaccinate healthy dogs, and to follow recommended vaccination schedule is included in the licence.

General conditions were also included in the 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 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.