Australian Government
Department of Health
Office of the Gene Technology Regulator

29 June 2022

Summary of Licence Application DIR 193

Bioproperties Pty Ltd has made an application under the *Gene Technology Act 2000* (the Act) for commercial supply of a genetically modified (GM) vaccine for chickens, Vaxsafe® ILT.

Project Title	Commercial supply of a genetically modified infectious laryngotracheitis vaccine for chickens[1]
Parent organism	Infectious laryngotracheitis (ILT) virus
Genetic modifications	
Introduced genes	The gene encoding glycoprotein G protein has been deleted from the CSW-1 strain of the ILT virus genome. Removal of this gene is intended to attenuate the virus, such that it does not cause severe disease in vaccinated chickens but is still able to stimulate an immune response which can protect against later infection by ILT virus.
Principal purpose	Commercial supply of an attenuated GM ILT vaccine
Previous releases	The GM vaccine has been previously approved for a trial to vaccinate broiler chickens against ILT virus in selected chicken farms in rural Victoria and New South Wales (DIR-154)
Proposed locations	Australia-wide
Proposed period of release	Ongoing from date of issue of licence

The application

Bioproperties Pty Ltd is seeking approval for transport, storage, supply to poultry farms and disposal of a live attenuated GM infectious laryngotracheitis (ILT) vaccine (known as Vaxsafe® ILT) as part of its commercial supply of a vaccine for chickens. The activities associated with the commercial supply of the Vaxsafe® ILT vaccine are classified as Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Other regulatory approvals

The Australian Pesticides and Veterinary Medicines Authority (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 normal form of approval is through registration. The APVMA can impose conditions on the use of veterinary products in registrations and permits.

Next steps

The gene technology legislation sets out what the Gene Technology Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

[1] The title for the licence application submitted by Bioproperties Pty Ltd is “Commercial supply of Vaxsafe ILT”.

After consultation with the prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. These stakeholders will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **October 2022**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- 'Questions and Answers' document for this application
- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR 193.
- have any questions about the application or the legislated evaluation process.

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