



Summary of Licence Application DIR 233

Intervet Australia Pty Ltd (Intervet) has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Project Title	Commercial supply of Innovax-ND-H5, a genetically modified (GM) multivalent chicken vaccine ¹
Parent organism	Turkey herpesvirus (<i>Mardivirus meleagridalpha1</i>) strain FC 126
Genetic modifications	
Genetic modifications²	Introduced genes: • fusion (F) protein gene from Newcastle disease virus – Expression of the F protein • haemagglutinin H5 gene from avian influenza virus – Expression of the H5 protein
Principal purpose	Commercial supply of a GM multivalent vaccine to prevent highly pathogenic avian influenza (HPAI), Newcastle disease, and Marek's disease in chickens.
Previous approvals	The vaccine has not been previously supplied in Australia. It is authorised for use in the European Union.
Proposed limits and controls	
Proposed location	Australia-wide
Proposed period of release	Ongoing from issue of licence

The application

Intervet is seeking approval for the import, transport, storage, supply and disposal of a live GM multivalent vaccine, known as Innovax-ND-H5, as part of the commercial supply of the vaccine for chickens.

Other regulatory approvals

A separate approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA) is also required before the GM vaccine can be used as a vaccine for poultry. The APVMA can impose conditions on the use of veterinary products in registrations and permits. A permit from the Department of Agriculture, Fisheries and Forestry (DAFF) will also be required for import of the GM vaccine into Australia.

Next steps

The Gene Technology legislation sets out what the 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 original title for the licence application submitted by Intervet is "Innovax ND H5 live vaccine".

² 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.

After seeking advice from 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. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed supply.

At this stage, the consultation RARMP is expected to be released for comment in **January 2027**.

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 233.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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