Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence number: DIR 224

Licence holder: Intervet Australia Pty Ltd

Commercial supply of a genetically modified (GM) multivalent vaccine (Innovax®-ND-ILT) for chickens

Issued: 12 November 2026

Office of the Gene Technology Regulator

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) (the Act) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling activities involving genetically modified organisms.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the Act and, as applicable, corresponding State law.

In assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment, the Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment.

Other agencies that also regulate genetically modified organisms or genetically modified products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism listed in **Attachment A** of the licence.

Further Information on Licence DIR 224

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence. This document can be obtained from the Office of the Gene Technology Regulator (OGTR) website or by telephoning the Office on 1800 181

Section 1 Interpretations and Definitions

1. In this licence:

    (a) unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

    (b) words importing a gender include every other gender;

    (c) words in the singular number include the plural and words in the plural number include the singular;

    (d) expressions used to denote persons generally (such as “person”, “party”, “someone”, “anyone”, “no-one”, “one”, “another” and “whoever”), include a body politic or corporate as well as an individual;

    (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

    (f) where a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;

    (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

‘**Act**’ means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

‘**Annual Report**’ means a written report provided to the Regulator by the end of September each year containing all the information required by this licence to be provided in the Annual Report.

‘**GM**’ means genetically modified.

‘**GMO**’ means the genetically modified organism that is the subject of the dealings authorised by this licence.

‘**OGTR**’ means the Office of the Gene Technology Regulator.

‘Regulations’ means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

‘**Regulator**’ means the Gene Technology Regulator.

Section 2 General conditions and obligations

3. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension.

4. The licence holder is Intervet Australia Pty Ltd.

5. Any person, including the licence holder, may conduct any authorised dealing(s) with the GMO.

6. The dealings authorised by this licence are:

    (a) import the GMO;

    (b) transport of the GMO;

    (c) disposal of the GMO;

and the possession (including storage) and supply of the GMO for the purposes of, or in the course, of any of these dealings.

Note: Use of the GMO for veterinary purposes is not covered by the Gene Technology Act 2000 and therefore this licence is not required to authorise such use. The GMO is also subject to regulation by other federal and state departments and agencies, including the Australian Pesticides and Veterinary Medicines Authority and the Department of Agriculture, Fisheries and Forestry. These other departments and agencies may impose further requirements for, or limitations on, the use of the GMO or these dealings.

7. Dealings with the GMO may be conducted in all areas of Australia.

8. Dealings described in Condition 6 must not occur unless authorised by registration with the Australian Pesticides and Veterinary Medicines Authority (APVMA).

9. The licence authorises dealings with the GMO described in **Attachment A**.

2.1 Obligations of the Licence Holder

10. The licence holder must immediately notify the Regulator if any of its contact details change.

Note: Please address correspondence to OGTR.Applications@health.gov.au

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.

11. The licence holder must:

(a) inform the Regulator immediately in writing, of:

i. any relevant conviction of the licence holder; and

ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and

iii. any event or circumstances that would affect the capacity of the holder of this licence to meet the conditions in it; and

(b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the timeframe stipulated by the Regulator.

12. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

(a) the particular condition, including any variations of it; and

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

2.2 Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.

13. The licence holder must inform the Regulator if the licence holder becomes aware of:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

(b) any contraventions of the licence by a person covered by the licence; or

(c) any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition, that:

(a) the licence holder will be taken to have become aware of additional information of a kind mentioned in condition 13 if he or she was reckless as to whether such information existed; and

(b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in condition 13, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note: Contraventions of the licence may occur through the action or inaction of a person.

14. If the licence holder is required to inform the Regulator under condition 13, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030 or email to OGTR.M&C@health.gov.au.

15. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(a);

(b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(b);

(c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 13(c);

(d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;

(e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period;

(f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

Note: The Regulator may invite the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant to the progress of the dealings with the GMO.

2.3 Obligations of persons covered by the licence

16. If a person is authorised by this licence to deal with the GMO and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Section 3 Reporting and Documentation

3.1 Notification of authorisations by the Australian Pesticides and Veterinary Medicines Authority

17. If the GMO is included on the Public Chemical Registration Information System (PubCRIS), the licence holder must notify the Regulator in writing within 14 days of registration.

18. The licence holder must notify the Regulator in writing of any subsequent amendments to the conditions of the PubCRIS registration involving the pattern of usage, handling, storage, transport or disposal of the GMO, within 14 days of the change occurring.

3.2 Annual Report

19. The licence holder must provide an Annual Report to the Regulator by the end of September each year covering the previous financial year. An Annual Report must include:

(a) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMO or material from the GMO;

(b) information about the numbers of vaccine doses distributed to each State and Territory.

Note: Please address correspondence to OGTR.M&C@health.gov.au

ATTACHMENT A

DIR No: 224

Full Title: Commercial supply of a genetically modified (GM) multivalent vaccine (Innovax®-ND-ILT) for chickens

Licence Holder Intervet Australia Pty Ltd

GMO Description

GMO covered by this licence

A turkey herpesvirus genetically modified to express the fusion (F) protein from Newcastle disease virus and glycoproteins D and I from Infectious laryngotracheitis virus.

Parent Organism

Common Name: Turkey herpesvirus (HVT; strain FC-126)

Scientific Name: *Mardivirus meleagridalpha1*

Modified traits

Category: Vaccine – non-pathogenic

Description: The GMO has been genetically modified to express the F protein from NDV and gD and gI glycoproteins from ILTV, which together induce immunity against ND and ILT.