



Australian Government

Department of Health

Office of the Gene Technology Regulator

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

Licence No.: DIR 154

Licence holder: Bioproperties Pty Ltd

Title: Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT

Issued: 1 August 2017

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the [Office of the Gene Technology Regulator website](#) or by telephoning the Office on 1800 181 030.

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) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling activities involving genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* (the Act) and, as applicable, Corresponding State Law.

The Gene Technology 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 in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and the Department of Agriculture and Water Resources. 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.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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

Note about where dealings with GMOs are being undertaken pursuant to this licence

Information about where the dealings with the GMOs are being undertaken pursuant to this licence can be accessed on the [OGTR website](#).

Section 1 Interpretations and definitions

1. In this licence:

- (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001 (the Regulations);
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (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 any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions prevail over standard 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.

'APVMA' means the Australian Pesticides and Veterinary Medicines Authority.

'Broiler chickens' means chickens (*Gallus gallus domesticus*) raised or grown for meat.

'Decontaminate', (or **'Decontamination'**) means, as the case requires, kill the **GMO** by one or more of the following methods:

- a) chemical treatment;
- b) autoclaving;
- c) high-temperature incineration;
- d) composting;
- e) rendering;
- f) burial; and
- g) a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

'Equipment' includes, but is not limited to, droppers, swabs, vials, clothing, gloves, storage equipment, transport equipment (e.g. bags, containers, wheelbarrows, trucks, vehicles, crates), water tanks and lines, feed containers, composting equipment and tools.

'Flock' means all chickens housed in a single Shed, or contained in a single Range, at the same time.

'Free-range chicken farm' means a chicken farm that provides chickens with access to an outdoor area or range.

'GM' means genetically modified.

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

'GMO-naïve Flock' means a Flock that is not inoculated, nor intended to be inoculated, with the GMO.

'GMO stock' means the GMO as supplied in vials.

'ILTV' means infectious laryngotracheitis virus.

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

‘**Participating farm**’ means a poultry farm on which a Trial area exists.

‘**Personal information**’ means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information is true or not; and
- (b) whether the information is recorded in a material form or not.

‘**Processing facility**’ means the facility where chickens are slaughtered, processed or rendered.

‘**Range**’ means a fenced outdoor area intended to be accessed by free-range chickens.

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

‘**Sample**’ means any biological material collected from GMO-inoculated chickens or Sentinel chickens for subsequent analysis.

‘**Sentinel chicken**’ means a broiler chicken housed or contained with GMO-inoculated chickens but which is not itself vaccinated with the GMO or other vaccine against ILTV.

‘**Shed**’ means a roofed building used for securely housing poultry.

‘**Trial area**’ means an area within a Participating farm where the GMO is prepared or used as part of the trial. This includes, but is not limited to, the following:

- (a) Shed(s) where chickens are inoculated with the GMO and subsequently housed;
- (b) Ranges, enclosures and any housing structures used by GMO-inoculated chickens;
- (c) areas where Samples are taken from, or autopsies conducted on, GMO-inoculated chickens;
- (d) areas housing water tanks containing the GMO;
- (e) areas used to prepare the GMO for inoculation; and
- (f) storage areas for the GMO stock, litter, carcasses and waste that may potentially be contaminated with the GMO.

‘**Waterways**’ means all permanent natural waterways and man-made waterways that flow into natural waterways.

Section 2 General conditions and obligations

3. The holder of this licence ('the licence holder') is Bioproperties Pty Ltd.

4. The GMO covered by this licence is GM live attenuated *Infectious laryngotracheitis virus* (ILTV), as described in **Attachment A** of the licence.

5. The dealings authorised by this licence are to:

- a) conduct experiments with 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.

6. This licence does not authorise dealings with the GMO that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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

8. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence as part of the field trial, and (to the extent that the GMO may be present at the time) persons who subsequently transport or handle GMO-inoculated chickens or waste containing GMO.

Note: No particular conditions of this licence apply to persons transporting or handling GMO-inoculated chickens or waste once they have left a participating farm for transport to a Processing facility or waste disposal site.

9. The licence holder must keep a record of all persons covered by this licence who are engaged in the field trial on a Participating farm (including for transport to or from a Participating farm), and must keep a record of the contact details of the project supervisor(s) for the licence.

Note: Where contractors are used to conduct transport or decontamination/disposal, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.

Obligations of the Licence Holder

10. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the contact person(s) for the licence and project supervisor(s) change from that notified in the licence application or subsequently.

Note: please address correspondence to ogtr.applications@health.gov.au

11. The licence holder must notify the Regulator in writing of any amendments to the permit PER81178 from the APVMA, including dosage, administration route, usage, handling, storage, transport or disposal of the GMO, within 14 days of the change occurring.

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.

12. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.

13. The licence holder must:

- (a) inform the Regulator immediately in writing, of:
 - i) any relevant conviction of the licence holder occurring after the issue of this licence; 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 occurring after the issue of this licence 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 stipulated timeframe.

14. The licence holder must be able to access and control all Trial Areas to the extent necessary to ensure compliance with conditions of this licence for the duration of the life of the licence.

The following conditions seek to ensure that persons conducting the dealings covered by licence conditions are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.

15. Prior to conducting any dealings with the GMO, the licence holder must provide to the Regulator (for each Participating farm, where relevant) the following information:

- (a) names of all organisations and persons or functions or positions of the persons who will be engaged in the field trial covered by the licence, with a description of their responsibilities;

Note: Examples of functions or positions are 'project supervisor', 'farm manager', 'farm labourer' etc.

- (b) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them;

Note: This may include a description of any contracts, training, labelling, contractual agreements with other organisations or persons such as a poultry company, poultry farm owner(s), commercial waste providers or courier companies.

- (c) written methodology to reliably detect the GMO, or the presence of the genetic modification in a recipient organism; and

- (d) written procedure for monitoring of clinical signs and symptoms of infectious laryngotracheitis and testing for the GMO in a GMO-naïve Flock as required by Conditions 68 and 69.

16. At least 14 days prior to inoculating chickens with the GMO at each Participating farm, the licence holder must provide to the Regulator a Compliance Management Plan for that Participating farm, detailing:

- (a) procedures to be implemented to achieve compliance with:

- i) conditions in Section 3 of this licence;
- ii) APVMA permit number PER81178;
- iii) routine biosecurity procedures of the National Farm Biosecurity Manual for Poultry Production (Department of Agriculture and Water Resources, 2009); and
- iv) local council and/or State requirements relevant to biosecurity for the Participating farm, including in relation to waste disposal on- or off-farm and transport of chickens; and

- (b) how the licence holder will access and control Trial Areas of the participating farm to the extent necessary to ensure compliance with conditions of this licence for the duration of the licence.

Note: This may include a description of any contracts, agreements, or other enforceable arrangements.

Note: The Compliance Management Plan must include the following information as it applies to the Participating farm and activity, to the reasonable satisfaction of the Regulator:

- (a) *training of authorised persons conducting dealings;*
- (b) *storage, preparation and handling of the GMO prior to and during administration, and disposal of any remaining unused GMO;*
- (c) *procedures to be used for monitoring and identification of clinical signs and symptoms of infectious laryngotracheitis in chickens;*
- (d) *Participating farm, Shed and Range biosecurity measures, including entry, exit and cleaning procedures;*
- (e) *maintenance of Sheds and fencing to ensure chickens are securely enclosed;*
- (f) *segregation of the GMO-inoculated chickens from other poultry on the Participating farm, so as to minimise the spread of ILTV;*

- (g) *procedures for farm personnel, veterinarians, visitors, contractors and pick-up crews entering and exiting the Trial area(s);*
- (h) *measures to be taken to ensure farm personnel, veterinarians, visitors, contractors and pick-up crews do not have contact with birds outside the Participating farm unless appropriate decontamination has occurred;*
- (i) *cleaning of equipment;*
- (j) *pest, predators and wild bird management;*
- (k) *management of livestock other than poultry;*
- (l) *temporary storage, transport and disposal of used litter;*
- (m) *temporary storage, transport and disposal of carcasses;*
- (n) *decontamination of litter and carcasses on- or off-farm;*
- (o) *measures to be taken to minimise persistence of the GMO in the Trial area(s), following removal of GMO-inoculated chickens;*
- (p) *handling, collection and transport of live GMO-inoculated chickens to Processing facilities and facilities certified by the Regulator to PC2, including transport routes;*
- (q) *contingency plan as specified in Condition 70; and*
- (r) *record keeping as required by Conditions 9, 10, 15, 68, 69, 72-75.*

17. Any changes to the information provided under Condition 16 must be communicated in writing to the Regulator within 14 days of the changes occurring.

18. If the Regulator requires changes or additions to a provided Compliance Management Plan in order to satisfy Condition 16, the licence holder must make the changes or additions within the time period specified by the Regulator.

19. 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.

20. The licence holder must not permit a person covered by this licence to conduct any dealing unless:

- (a) the person has been informed of any particular licence conditions that apply to them, including any variation of them; and
- (b) the licence holder has obtained from the person a signed and dated statement that the person:
 - i) has been informed of the particular licence condition(s) including any variation of them; and
 - ii) has understood and agreed to be bound by the licence conditions, or variation.

21. The licence holder must ensure that only persons with the capacity to comply with the applicable biosecurity procedures, as documented in the relevant Compliance Management Plan, are engaged to transport live GMO-inoculated chickens from a Participating farm to a Processing facility, or to transport and treat waste potentially contaminated with the GMO from a Participating farm.

Note: Condition 21 does not impose licence conditions on persons engaged to conduct the described activities, but the licence holder is responsible for ensuring only people that have the capacity to follow appropriate procedures, in accordance with the Compliance Management Plan, are permitted to conduct

the activities. This may involve, for example, contractual arrangements, including record keeping obligations and auditing of practices.

22. The licence holder must:

- (a) inform the persons covered by this licence to whom a particular condition applies that any personal information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in Condition 20.

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 and risk management plan is communicated to the Regulator.

23. 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 paragraph 23(a) 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 paragraph 23(b) or 23(c), 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.

24. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made within a day of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.

25. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, such information must be provided in a manner, and within the time period, stipulated by the Regulator.

Obligations of persons covered by the licence

26. Persons covered by this licence engaged in the field trial must not deal with the GMO except as expressly permitted by this licence.

27. 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 Limits and control measures

Note: This licence does not expressly authorise or prohibit any dealings or storage in facilities certified by the Regulator. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licenced or if it is a notifiable low risk dealing (NLRD) or an exempt dealing and complies with all relevant statutory requirements.

Limits on the release

The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMO may be released, and on other activities that can be undertaken.

28. Participating farms must be located within the following local government areas:

NSW	Victoria
Lake Macquarie	Yarra Ranges
Central Coast	Mornington Peninsula
Hawkesbury	South Gippsland
Penrith	Cardinia
Liverpool	Casey
Camden	Geelong
Wollondilly	Colac Otway
	Golden Plains
	Surf Coast
	Buloke
	Gannawarra
	Loddon
	Campaspe
	Central Goldfields
	Mount Alexander
	Macedon Ranges
	City of Greater Bendigo
	Hindmarsh
	West Wimmera
	Yarriambiack

29. A cumulative maximum of 2,000,000 Broiler chickens over the life of the licence may be inoculated with the GMO.

30. Sentinel chickens must be treated as though they are chickens inoculated with the GMO for the purposes of this licence.

31. The experiments with the GMO may be undertaken at a maximum of 40 Participating farms over the life of this licence.

32. Inoculation and housing of GMO-inoculated chickens at Participating farms and storage of GMO stock must be completed by 1 August 2022.

Note: Live GMO-inoculated chickens must be either transferred to Processing facilities or facilities certified by the Regulator to PC2 before 1 August 2022. GMOs not required for further experimentation must be Decontaminated on or before 1 August 2022.

33. If experimentation and analysis with the GMOs, GMO-inoculated chickens or Samples, is not conducted in accordance with NLRD requirements, or as exempt dealings, such activities may only be undertaken within a Trial Area.

34. The licence holder must ensure that a copy of the licence and the Compliance Management Plan is available and readily accessible at each Participating farm.

Controls on the release

The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMO, and apply to dealings on Participating farms and transport to and from these farms.

Participating Farms

35. The boundary of a Trial area on a Participating farm must be at least 1000 metres from poultry located on other poultry farms that are not included in the field trials permitted by this licence.

36. The Trial area must be at least 50 metres from any Waterway.

37. Sheds and fencing for Ranges or Participating farms must be maintained so as to prevent GMO-inoculated chickens escaping.

38. Access to Trial Areas must be restricted to only persons authorised by the Licence holder.

39. Signs indicating the presence of the GMO must be displayed at all entrances to Trial Areas.

40. Measures to manage pests, predators and wild birds must be in place at Trials areas and/or Participating farms.

Inoculation with the GMO

41. Measures must be in place to minimise the likelihood of spillage of the reconstituted GMO outside the broiler sheds.

42. Measures must be in place to ensure that any spills or leaks of the GMO outside the shed before or during administration of the GMO are decontaminated immediately as per the Contingency Plan.

43. Administration of the GMO to Broiler chickens must occur inside a shed.

44. Only healthy Broiler chickens may be inoculated with the GMO.

45. Broiler chickens inoculated with the GMO must not be given any other vaccine against ILTV during their lifetime.

46. Persons preparing the GMO for administration must be, or must be supervised by, a registered veterinarian or a person appropriately trained to prepare and administer the GMO.

47. Persons preparing the GMO for administration must wear personal protective equipment, including eye protection and gloves.

48. Persons must decontaminate hands after preparing the GMO or administering the GMO.

49. Broiler chickens may be inoculated with the GMO by eye drop or via drinking water.

50. GMO-inoculated chickens must be segregated from all other poultry kept at the Participating farm, other than Sentinel chickens.

51. GMO-inoculated chickens must be confined in the sheds for the first 14 days after administration of the GMO.

52. Any GMO-inoculated chicken displaying clinical signs or symptoms of infectious laryngotracheitis must be confined to a shed for the duration of the symptoms.

53. Measures must be implemented to minimise access of wild birds and other animals to sheds during administration of the GMO and while GMO-inoculated chickens display clinical signs or symptoms of infectious laryngotracheitis.

Work practices at the Participating farm

54. The Compliance Management Plan must be implemented at each Participating farm.
55. If any of the events described in Condition 70 occur, the appropriate procedure(s) from the Contingency Plan must be implemented.
56. The licence holder must ensure that all authorised persons undertaking dealings at the Participating farm (e.g. handling the GMO, GMO-inoculated chickens, or any Equipment or waste potentially contaminated with GMO) are trained in and employ standard biosecurity procedures as detailed in the Compliance Management Plan.
57. All persons exiting a Shed or Range containing GMO-inoculated chickens must decontaminate their hands and footwear.
58. All Equipment that may be contaminated with the GMO must be decontaminated according to the Compliance Management Plan prior to being used for any other purpose.

Transport and storage of GMO stock and Samples

59. Transport and storage of the GMO stock or Samples must be in accordance with PC2 GM Micro-organisms Requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* in force at the time of transport and storage.

Harvest and transport of live Broiler chickens

Note: Condition 21 requires the licence holder to ensure that only persons that have the capacity to adhere to relevant biosecurity procedures as documented in the Compliance Management Plan are engaged for transport of live GMO-inoculated chickens from a Participating farm.

60. The licence holder must not permit live GMO-inoculated chickens to be transported except to nominated Processing facilities or to facilities certified by the Regulator to PC2.
61. The licence holder must ensure that transport of live GMO-inoculated chickens occurs in accordance with the Compliance Management Plan.
62. For transport of live GMO-inoculated chickens to facilities certified by the Regulator to PC2, measures must be implemented to minimise dispersal of the GMO if live chickens are transported within 14 days of being inoculated with the GMO or if displaying clinical signs or symptoms of infectious laryngotracheitis.
63. Live GMO-inoculated chickens must not be harvested for the purposes of transport to Processing facilities:
 - (a) within 14 days of being inoculated with the GMO, or
 - (b) if displaying clinical signs or symptoms of infectious laryngotracheitis.
64. The licence holder must have accounting procedures to record delivery of GMO-inoculated chickens and Sentinel chickens at their intended destination.

Decontamination of the GMO

65. Any areas at a Participating farm which are used to temporarily store carcasses or litter which are potentially contaminated with the GMO, must be Decontaminated according to the Compliance Management Plan after removal of stored carcasses or litter.
66. After the removal of all GMO-inoculated chickens from a shed, used litter must be removed, and the entire shed including feed containers, water tanks and water lines must be Decontaminated according to the Compliance Management Plan, before the next batch of birds is introduced.
67. The licence holder must ensure that waste potentially contaminated with the GMO (including litter, chicken carcasses and manure) is Decontaminated according to the Compliance Management Plan before it can be used for any other purpose.

Note: If waste is to be transported from a Participating farm for decontamination, Condition 21 requires the licence holder to ensure that only persons that have the capacity to adhere to relevant biosecurity procedures as documented in the Compliance Management Plan are engaged for transport and decontamination.

Testing for the GMO post-decontamination

68. Following decontamination of a shed that housed GMO-inoculated chickens, and if the subsequent Flock is GMO-naïve, the GMO-naïve Flock must be monitored for clinical signs or symptoms of infectious laryngotracheitis.

69. If clinical signs or symptoms of infectious laryngotracheitis are detected in chickens under Condition 68, the chickens must be tested for the unintended presence of the GMO. Any positive finding must be reported to the Regulator as soon as practical.

Contingency plans

70. At least 14 days prior to inoculating chickens with the GMO at each Participating farm, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of:

- (a) the unintentional release of the GMO, such as a spill;
- (b) the loss of the GMO stock;
- (c) severe weather conditions such as flooding occurring at a Participating farm that leads to run-off or dispersal of GMO from Trial area(s) in which the GMO may be present at the time;

Note: This includes areas which are in use by GMO-inoculated chickens or that have not been Decontaminated since use.

- (d) suspected or confirmed transmission of the GMO from GMO-inoculated chickens to other poultry (excluding transmission to Sentinel chickens);
- (e) detection of recombination between the GMO and another ILTV strain in poultry, including poultry not included in the field trials at the Participating farm;
- (f) an outbreak of infectious laryngotracheitis (ILT) disease occurring to poultry (including those inoculated with the GMO) that may potentially be linked to exposure to the GMO; and
- (g) escape, loss, or predation of GMO-inoculated chicken(s) from the Trial area or during transport.

Note: A contingency plan may be applicable to more than one Participating farm.

71. The Contingency Plans must include details of procedures to:

- (a) ensure the Regulator is notified as soon as reasonably possible after the licence holder becomes aware of the event; and
- (b) if there is a spill of the GMO outside a shed containing GMO-inoculated chickens, such as during preparation, transport or disposal, measures to:
 - i) contain the GMO to prevent further dispersal; and
 - ii) decontaminate the exposed area with an appropriate chemical disinfectant effective against the GMO; and
- (c) if an outbreak of infectious laryngotracheitis disease occurs that may potentially be linked to exposure to the GMO, measures to prevent the spread or persistence of the GMO.

Section 4 Reporting and Documentation Requirements

Notice of commencement and completion of the trials

72. The licence holder must notify the Regulator in writing at least 7 days before any dealings with the GMO commence at each Participating farm, and must include the following information:

- (a) the local government area, GPS coordinates of Participating farm, a street address or other directions;
- (b) whether it is a free-range farm;
- (c) brief description/diagram/map of the Participating farm, including the boundary of the Trial area and location of any Sheds, Ranges, houses or buildings, and what each structure is used for; and
- (d) location of areas used for composting or burying of farm waste.

73. The licence holder must notify the Regulator in writing at least 7 days before inoculation of each batch of Broiler chickens with the GMO at each Participating farm, and must include the following details:

- (a) expected dates of inoculation with the GMO;
- (b) number and age of Broiler chickens to be inoculated with the GMO;
- (c) intended method of GMO administration;
- (d) number of Sentinel chickens to be placed in the Shed or Range containing GMO-inoculated chickens, if any;
- (e) identification of the particular Shed and, if applicable, the Range where the GMO-inoculated chickens will be kept;
- (f) proposed Processing facilities for the GMO-inoculated chickens;
- (g) expected concurrent presence of other poultry, including whether they are, or are expected to be, inoculated with different vaccines against ILTV or remain unvaccinated;
- (h) expected date(s) of harvesting the GMO-inoculated chickens for transport to the Processing facilities; and
- (i) expected date of Decontamination of Sheds that have housed GMO-inoculated chickens.

Note: The notices required by conditions 72 and 73 may be combined for the first inoculation at a particular Participating farm, and a notice under condition 73 may cover more than one batch of chickens if the relevant details for each batch can be accurately provided.

74. With respect to each batch of GMO-inoculated chickens, as notified under Condition 73, the Licence holder must notify the Regulator in writing within 7 days after each harvest, and include the following information:

- (a) date(s) of each harvest and transport of GMO-inoculated chickens; and
- (b) transport route taken to the Processing facilities or PC2 facilities and the presence of any known poultry farms immediately adjacent to the transport route; and
- (c) number of live GMO-inoculated chickens and Sentinel chickens transported to Processing facilities; and
- (d) details of Processing facilities which received the GMO-inoculated chickens; and
- (e) actual date when sheds that have housed GMO-inoculated chickens have been Decontaminated.

Records to be maintained

75. The following records must be made and kept for the life of this licence, and made available to the Regulator on request:

- (a) measures taken to ensure that Sheds, Range and Participating farm fencing keep chickens securely enclosed, including inspection and maintenance activities, as applicable;
- (b) evidence of pest and wild or feral bird activity and details of pest and wild or feral bird management measures;
- (c) details of each batch of chickens inoculated with the GMO and Sentinel chickens as notified to the Regulator under Condition 73;
- (d) details of each harvest of GMO-inoculated chickens, whether partial or complete harvest of the Flock;
- (e) record of the delivery of each harvest of GMO-inoculated chickens at processing facilities;
- (f) number of GMO-inoculated broiler chickens or Sentinel chickens culled or which had died at the Trial Area(s) for each batch;
- (g) records of GMO-inoculated broiler chickens or Sentinel chickens displaying signs or symptoms of infectious laryngotracheitis during or after administration of the GMO; and
- (h) monitoring and testing data as required by Conditions 68 and 69.

*Note: Other reports and documents that will need to be sent to the Regulator are listed in **Attachment B***

DIR No: 154

Full Title: Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT

Organisation Details

Postal address: Bioproperties Pty Ltd
36 Charter Street
Ringwood
VIC 3134

Phone No: (03) 9876 0567

IBC Details

IBC Name: Bioproperties Institutional Biosafety Committee

GMO Description

GMOs covered by this licence:

Infectious laryngotracheitis virus genetically modified by deletion of the gene encoding glycoprotein G.

Parent Organism:

Common Name: *Infectious laryngotracheitis virus* (ILTV)

Scientific Name: *Gallid herpesvirus 1* (strain CSW-1)

Modified traits:

Categories: Vaccine – attenuation

Description: ILTV has been genetically modified to reduce pathogenicity and virulence, for potential use as live attenuated vaccine.

Purpose of the dealings with the GMOs:

The purpose of the field trials is to assess the efficacy and safety of the GMO under field conditions for protection of chickens from infectious laryngotracheitis disease, including likelihood of challenge with a range of distinct field ILTV strains. The field trials would also assess the capacity of the GMO for transmission and recombination with other ILTV strains.

Checklist of documents and notifications that must be sent to the Regulator:

When	What	Condition	Timeframe of reporting
Duration of licence	Changes to contact details of contact person/s or project supervisor/s	10	As soon as practically possible
Duration of licence	Changes to the conditions included in the permit PER81178 from the APVMA, including dosage, administration route, usage, handling, storage, transport or disposal of the GMO	11	Within 14 days of the change occurring
Duration of licence	Any relevant conviction of the licence holder occurring after the issue of this licence 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 Any event or circumstances occurring after the issue of this licence that would affect the capacity of the holder of this licence to meet the conditions in it	13(a)	Immediately in writing
Duration of licence	Provide any information related to the licence holder's ongoing suitability to hold a licence	13(b)	If requested, within the stipulated timeframe
Prior to conducting any dealings with the GMO	Names of all organisations and persons or functions or positions of the persons who will be engaged in the field trial covered by the licence, with a description of their responsibilities Details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions or Compliance Management Plan applicable to them Written methodology to reliably detect the GMO, or the presence of the genetic modification in a recipient organism Written procedure for monitoring of clinical signs and symptoms of infectious laryngotracheitis and testing for the GMO in a GMO-naïve Flock as required by Conditions 68 and 69	15	Immediately in writing
Prior to inoculating chickens at each participating farm	Provide a Compliance Management Plan for that Participating farm	16	At least 14 days prior to inoculation of chickens with the GMO at each participating farm
Duration of licence	Any changes to the information in Compliance Management Plan	17	At least 14 days of the change occurring

When	What	Condition	Timeframe of reporting
Duration of licence	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	23	without delay
	Any contraventions of the licence by a person covered by the licence		
	Any unintended effects of the dealings authorised by the licence		
Duration of licence	If clinical signs or symptoms of infectious laryngotracheitis are detected in chickens under Condition 68, the chickens must be tested for the unintended presence of the GMO. Any positive finding must be reported to the Regulator as soon as practical.	68 and 69	As soon as practical
Prior to inoculating chickens at each participating farm	Contingency Plan	70	At least 14 days prior to inoculation of chickens
Prior to commencing any dealings at each Participating farm (Participating Farms notification)	The local government area, and GPS coordinates of Participating farm, and a street address or other directions	72	At least 7 days before dealings commence
	Whether the Participating farm is a free-range farm		
	Brief description/diagram/map of the Participating farm, including the boundary of the Trial area and location of any Sheds, Ranges, houses or buildings, and what each structure is used for		
	Location of areas used for any composting or burying of farm waste		
Prior to inoculation of each batch at each Participating farm (Intention to treat notification)	Expected dates of inoculation with the GMO	73	At least 7 days before inoculation of each batch
	Number and age of Broiler chickens to be inoculated with the GMO		
	Intended method of GMO administration		
	Number of Sentinel chickens to be placed in the Shed or Range containing GMO-inoculated chickens		
	Identification of the particular Shed and, if applicable, the Range where the GMO-inoculated chickens will be kept		
	Proposed Processing facilities for the GMO-inoculated chickens		
	Expected concurrent presence of other poultry, including whether they are, or are expected to be, inoculated with different vaccines against ILTV or remain unvaccinated		
	Expected date(s) of harvesting the GMO-inoculated chickens for transport to the Processing facilities		

When	What	Condition	Timeframe of reporting
	Expected date of Decontamination of Sheds that have housed GMO-inoculated chickens		
After removal of the batch from the Trial area (Completion of harvest notification)	Date(s) of each harvest and transport of GMO-inoculated chickens	74	In writing within 7 days after each harvest from the Trial area
	Transport route taken to the Processing facilities and the presence of any known poultry farms immediately adjacent to the transport route		
	Number of live GMO-inoculated chickens transported to Processing facilities		
	Details of Processing facilities which received the GMO-inoculated chickens		
	Actual date when sheds that have housed GMO-inoculated chickens have been Decontaminated		

Checklist of other documents that must be maintained:

When	What	Condition
Duration of licence	Record of all persons covered by this licence who are engaged in the field trial on a Participating farm (including for transport to or from a Participating farm), and must keep a record of the contact details of the project supervisor(s) for the licence. <i>Note: Where contractors are used to conduct transport or decontamination/disposal, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.</i>	9
Duration of licence	Copies of signed and dated statements	20
Duration of licence	Measures taken to ensure that Sheds, Range and Participating farm fencing keep chickens securely enclosed, including inspection and maintenance activities, as applicable	75
	Evidence of pest and wild or feral bird activity and details of pest and wild or feral bird management measures	
	Details of each batch of chickens inoculated with the GMO and Sentinel chickens as notified to the Regulator under Condition 73	
	Details of each harvest of GMO-inoculated chickens, whether partial or complete harvest of the Flock	
	Record of the delivery of each harvest of GMO-inoculated chickens at processing facilities	
	Number of GMO-inoculated broiler chickens or Sentinel chickens culled or which had died at the Trial Area(s) for each batch	
	Records of GMO-inoculated chickens or Sentinel chickens displaying signs or symptoms of infectious laryngotracheitis during or after administration of the GMO	
	Monitoring and testing data as required by Conditions 68 and 69	