Australian Government
Department of Health
Office of the Gene Technology Regulator

16 May 2017

# Risk Assessment and Risk Management Plan

(consultation version)

for

# **DIR 154** – Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT

## **Applicant** – Bioproperties Pty Ltd

**This RARMP is open for consultation until 27 June 2017**.

Written comments on the risks to human health and safety and the environment posed by this proposed release are invited. You may make your submission

via mail to: The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848, Canberra ACT 2601 or

via email to: ogtr@health.gov.au.

Please note that issues regarding food safety and labelling, and marketing and trade implications do **not** fall within the scope of these evaluations as they are the responsibilities of other agencies and authorities.

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# Summary of the Risk Assessment and Risk Management Plan (Consultation Version)

**for**

# Licence Application No. DIR 154

## *Introduction*

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). Bioproperties Pty Ltd (Bioproperties) proposes to conduct field trials to assess the efficacy and safety of a GM vaccine for protection of chickens from infectious laryngotracheitis disease.

Veterinary medicines must be approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which provides a national registration scheme for agricultural and veterinary chemical products under the *Agricultural and Veterinary Chemicals Code Act 1994* (AgVet Code). The APVMA has issued a permit to Bioproperties to supply and use the GM vaccine for the purpose of animal research.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

## *The application*

| | |
|---|---|
| Application number | DIR 154 |
| Applicant: | Bioproperties Pty Ltd |
| Project Title: | Limited and controlled release of a GM vaccine for Chickens, Vaxsafe® ILT |
| Parent organism: | Infectious laryngotracheitis virus (ILTV) |
| Modified genes: | Deletion of gene encoding glycoprotein G protein from the ILTV genome |
| Proposed release date: | Once all the required approvals have been granted |
| Proposed duration: | 5 years |
| Proposed locations: | Selected chicken farms in rural Victoria and New South Wales |
| Primary purpose: | To study the efficacy and safety of a GM vaccine against infectious laryngotracheitis disease in farmed broiler chickens. |

The proposed field trials would assess the efficacy and safety of the GM vaccine under field conditions, including likelihood of challenge with a range of distinct field strains. The field trials are proposed to take place at up to 40 selected broiler farms, potentially including free range farms, in rural Victoria and NSW. Up to 2,000,000 chickens would be inoculated with the GM vaccine over a 5 year period. As is common in veterinary vaccine trials, the vaccinated chickens could enter general commerce,

including use in human food or animal feed. At an appropriate time, the chickens inoculated by the GM vaccine would be transported from farms to poultry processing plants.

## *Risk assessment*

The risk assessment concludes that risks to the health and safety of the environment from the proposed release are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modifications and proposed activities conducted with the GM vaccine might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application (including proposed controls), relevant previous approvals and current scientific/technical knowledge. Both the short and long term impact are considered.

Credible pathways to potential harm that were considered included exposure of people or susceptible birds to the GMO, potential for recombination and establishment of the GMO outside the trial limits. Potential harms that were considered in relation these pathways included disease, toxicity or allergenicity to people and adverse impacts to desirable species in the environment.

The principal reasons for the conclusion of negligible risks are the attenuated phenotype of the GMO, ILTV's limited host range, APVMA permit conditions for the use of the GM vaccine, local council and state requirements for broiler farms, and suitability of the controls proposed by the applicant.

## *Risk management plan*

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft licence includes limits on the size, location and duration of the release, as well as a range of controls to minimise the potential for the GMO to spread in the environment. In addition, there are several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.

# Table of contents

**TABLE OF FIGURES**

# Abbreviations

| | |
|---|---|
| ACEC | Animal Care and Ethics Committee |
| ACMF | Australian Chicken Meat Federation |
| AgVet Code | *Agricultural and Veterinary Chemicals Code Act 1994* |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| BHV | *Bovine herpesvirus* |
| BOD | biological oxygen demand |
| bp | base pairs |
| cDNA | complementary DNA |
| CEK | chicken embryo kidney |
| CEO | chicken embryo origin |
| CMA | catchment management authorities |
| DAWR | Department of Agriculture and Water Resources |
| DIR | Dealings involving Intentional Release |
| DNA | deoxyribonucleic acid |
| eGFP | enhanced green fluorescent protein |
| EHV | *Equine herpesvirus* |
| ELISA | enzyme-linked immunosorbent assay |
| EPA | Environment Protection Authority |
| EP&A Act | *Environment Planning and Assessment Act 1979* |
| FeHV | *Feline herpesvirus* |
| FPV | *Fowlpox virus* |
| FSANZ | Food Standards Australia New Zealand |
| gC | glycoprotein C |
| gG | glycoprotein G |
| GM | genetically modified |
| GMO | genetically modified organism |
| GMP | Good Manufacturing Practice |
| GTTAC | Gene Technology Technical Advisory Committee |
| HACCP | Hazard Analysis of Critical Control Points |
| HEPA | High-Efficiency Particulate Air filter |
| HSV | *Herpes simplex virus* |
| HVT | *Herpesvirus of turkeys* |
| IBC | Institutional biosafety committee |
| ILTV | *Infectious laryngotracheitis virus* |
| IR | internal repeat |
| kb | kilo base pairs |

| | |
|---|---|
| L | litres |
| LMH | leghorn chicken hepatocellular carcinoma |
| LTS | Land Transport Standards |
| m | metres |
| ml | millilitres |
| mm | millimetres |
| mRNA | messenger ribonucleic acid |
| NLRD | Notifiable Low Risk Dealings |
| NSW | New South Wales |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| OGTR | Office of the Gene Technology Regulator |
| Ori | origin of replication |
| PCR | polymerase chain reaction |
| PC2 | Physical containment 2 |
| PFU | plaque forming unit |
| POEO Act | *Protection of the Environment Operations Act 1997 (NSW)* |
| PsHV | *Psittacid herpesvirus* |
| RARMP | Risk Assessment and Risk Management Plan |
| Regulations | Gene Technology Regulations 2001 |
| Regulator | Gene Technology Regulator |
| RFLP | Restriction Fragment Length Polymorphism |
| RMIT | Royal Melbourne Institute of Technology |
| qPCR | quantitative polymerase chain reaction |
| TCO | tissue culture origin |
| TGA | Therapeutic Goods Administration |
| the Act | *Gene Technology Act 2000* |
| TR | terminal repeat |
| $U_L$ | unique long |
| $U_S$ | unique short |
| US | United States |
| vCKBP | virus-encoded chemokine binding protein |
| v/v | volume/volume |

# Chapter 1 **Risk assessment context**

## Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

2. The Act in conjunction with the Gene Technology Regulations 2001 (the Regulations), an inter-governmental agreement and corresponding legislation in States and Territories, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

3. This chapter describes the parameters within which potential risks to the health and safety of people or the environment posed by the proposed release are assessed. The risk assessment context is established within the regulatory framework and considers application-specific parameters (Figure 1).

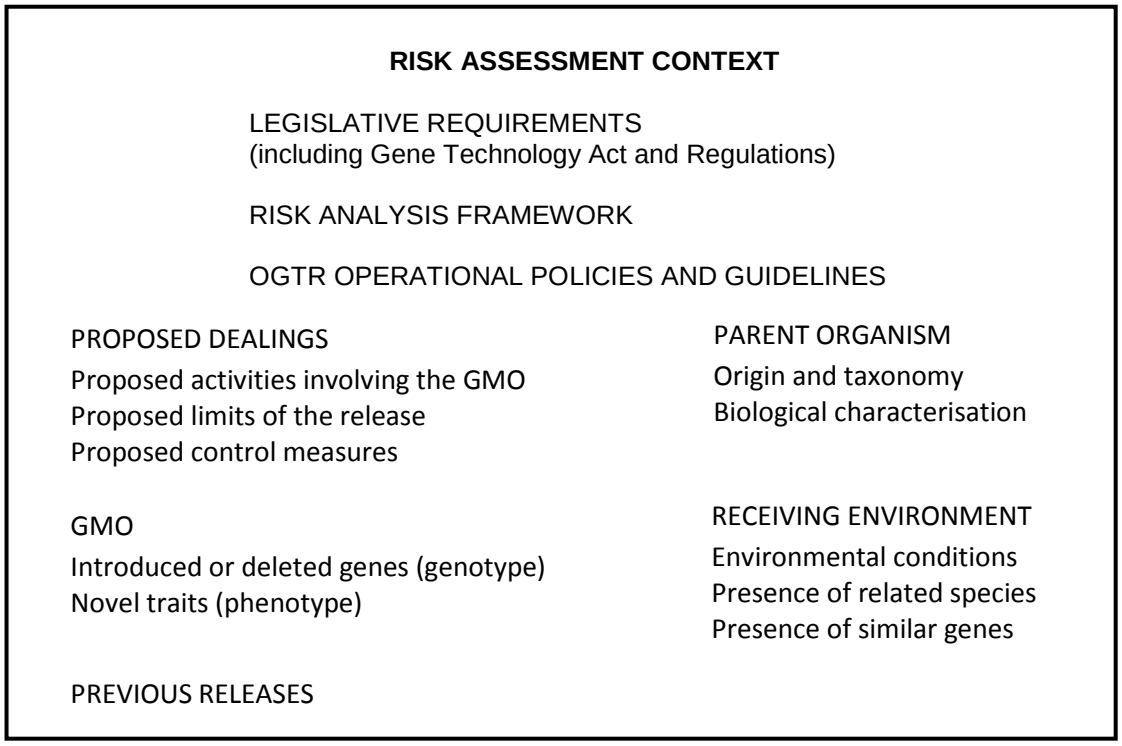


**Figure 1. Summary of parameters used to establish the risk assessment context**

## Section 2 Regulatory framework

4. Sections 50, 50A and 51 of the Act outline the matters which the Gene Technology Regulator (the Regulator) must take into account, and who must be consulted, when preparing the Risk Assessment and Risk Management Plans (RARMPs) that inform the decisions on licence applications. In addition, the Regulations outline further matters the Regulator must consider when preparing a RARMP.

5. In accordance with Section 50A of the Act, this application is considered to be a limited and controlled release application, as its principal purpose is to enable the applicant to conduct experiments and the applicant has proposed limits on the size, location and duration of the release, as well as controls to restrict the spread and persistence of the GMOs and their genetic material in the

environment. Therefore, the Regulator was not required to consult with prescribed experts, agencies and authorities before preparation of the RARMP.

6. Section 52 of the Act requires the Regulator to seek comment on the RARMP from the States and Territories, the Gene Technology Technical Advisory Committee, Commonwealth authorities or agencies prescribed in the Regulations, the Minister for the Environment, relevant local council(s), and the public.

7. The *Risk Analysis Framework* (OGTR 2013) explains the Regulator's approach to the preparation of RARMPs in accordance with the legislative requirements. Additionally, there are a number of operational policies and guidelines developed by the Office of the Gene Technology Regulator (OGTR) that are relevant to DIR licences. These documents are available from the OGTR website.

## 2.1 Interface with other regulatory schemes

8. Gene technology legislation operates in conjunction with other regulatory schemes that regulate GMOs or genetically modified (GM) products in Australia. Dealings conducted under a licence issued by the Regulator may also be regulated by the Therapeutic Goods Administration (TGA), Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Department of Agriculture and Water Resources (DAWR). Dealings may also be subject to the operation of State legislation declaring areas to be GM, GM-free, or both, for marketing purposes.

9. To avoid duplication of regulatory oversight, risks that have been considered by other regulatory agencies are generally not assessed by the Regulator.

10. The APVMA provides a national registration and permit scheme for agricultural and veterinary chemical products. It administers the provisions of the *Agricultural and Veterinary Chemicals Code Act 1994* (AgVet Code). For registration, the APVMA assesses whether a new veterinary vaccine meets the criteria set out in the AgVet Code before it is registered in the Register of Agricultural and Veterinary Chemical Products. A new veterinary vaccine that is not registered may be legally used, such as in animal trials, by obtaining a permit from the APVMA. As part of the permit process, the APVMA assesses the quality, safety and efficacy of the vaccine. Quality aspects could include batch-to-batch consistency in vaccine composition, purity and potency. The APVMA audits the Good Manufacturing Practice (GMP) record of the applicant. Safety aspects include the toxicological profile of the vaccine and its residues, including metabolites and degradation products. The APVMA approves the label, handling and directions for use of veterinary vaccines to ensure safe use. The APVMA may also impose conditions on a permit for the use of veterinary vaccines for research purposes.

11. The Regulator notes that as part of their safety assessment, the APVMA considers viral shedding and transmission to other susceptible birds not included in the field trials, as well as the potential for recombination. The Regulator does not assess vaccine excipients and would not assess manufacturing by-products and impurities unless they are GM products.

12. FSANZ develops the food standards in the Food Standards Code with advice from other government agencies and input from stakeholders. The Standards in the Food Standards Code are legislative instruments and the Food Standards cover the composition of some foods, such as dairy, meat and beverages. FSANZ is also responsible for labelling of packaged and unpackaged food, including specific mandatory warnings or advisory labels.

13. Food Standards are enforced by the states and territories (usually their health or human services departments) or, in some cases, by local government. These authorities regularly check food products for compliance with the Food Standards Code.

14. FSANZ has developed the Primary Production and Processing (PPP) Standard for Poultry Meat (Standard 4.2.2) (FSANZ 2010). PPP Standards (which only apply in Australia) aim to strengthen food safety and traceability throughout the food supply chain from paddock to plate. The standard

introduces new legal safeguards for growing live poultry and requires poultry growers to identify and control food safety hazards associated with poultry growing. Poultry processors are also required to identify and control food safety hazards associated with poultry processing (which includes the slaughtering process) and verify the effectiveness of the control measures.

## Section 3 Background to the DIR application

15. Bioproperties Pty Ltd (Bioproperties) proposes to conduct field trials using a live attenuated GM infectious larygotracheitis virus (ILTV) vaccine to inoculate broiler chickens. The GM vaccine to be trialled has a product name of Vaxsafe® ILT. This vaccine has been developed to protect chickens against infectious laryngotracheitis disease.

16. The APVMA has issued a permit to Bioproperties to supply and use the GM vaccine for the purpose of animal research[1]. The GM vaccine is a new veterinary chemical product that has never been used previously as a registered veterinary product in Australia or elsewhere in the world.

17. Broiler farms, potentially including free range farms, in rural Victoria and NSW would be selected to participate in the field trials. Up to 2,000,000 chickens would be inoculated with the GM vaccine over a 5 year period.

18. The most likely route for administration of the GM vaccine would be via drinking water, although the option of delivery by eye drop has also been included in the application. The GM vaccine would only be administered by a suitably trained person such as a farm manager under the supervision of a registered veterinarian.

19. As is common in veterinary vaccine trials, unless otherwise indicated on the APVMA permit, treated production animals would be allowed to enter the food chain. At an appropriate time, the chickens inoculated by the GM vaccine would be transported from farms to poultry processing plants. The processed chickens would normally be used for human and animal consumption.

## Section 4 The proposed field trials

20. Bioproperties proposes to conduct field trials to assess the efficacy of the GM vaccine for protection of chickens from infectious laryngotracheitis disease under field conditions, including likelihood of challenge with a range of distinct field strains. The field trials would also assess the safety of the vaccine including the capacity for transmission and recombination with other available live ILTV vaccines.

21. The dealings assessed by the Regulator are:

- conduct of experiments with the GMO;
- transport the GMO;
- disposal of the GMO; and

the possession, supply or use of the GMO for the purposes of, or in the course of, any of the above.

### 4.1 The proposed limits of the field trials (duration, scale, location and people)

22. The field trials are proposed to take place at approximately 40 selected broiler farms or sheds in rural Victoria and NSW, where intensive poultry production are concentrated. The trials would run

[1] APVMA permit number PER81178, in force from 11 March 2016 to 30 June 2021.

over a 5 year period from the date of issue of the licence until the trials have completed assessment of the efficacy and safety of the vaccine. Up to 2 million chickens are expected to be vaccinated. The GM vaccine would be administered by appropriately trained farm personnel in accordance with trial protocols and under the supervision of a registered veterinarian.

## 4.2 The proposed controls to restrict the spread and persistence of the GMO in the environment

23. The applicant has proposed a number of controls to restrict the spread and persistence of the GMO in the environment. These include:

- only vaccinating broiler chickens on commercial chicken farms, excluding layers and breeders
- employing strict biosecurity measures that commercial broiler farms typically follow, such as supplying and wearing overalls and high rubber boots to all shed visitors and workers, and disinfecting hands and boots when entering and exiting the shed
- controlling access and movement of vehicles and people at the farm
- disinfecting all contaminated equipment and materials such as bottles, vials, droppers, feed containers, water lines and tanks after use
- cleaning and disinfecting the shed after removal of a vaccinated flock and before another unvaccinated flock is introduced into the shed
- disposing litter and dead chickens by composting, burial, rendering or landfill following State/Territory and/or local council requirements.

24. In addition to the above controls, the APVMA permit also has a number of conditions to restrict the spread and persistence of the GMO in the environment, such as managing populations of pests (e.g. dogs, cats, rodents, wild birds and darkling beetles), and disinfecting sheds, vehicles and equipment after use.

## 4.3 Details of the proposed activities

### *4.3.1 Selection of chicken farms*

25. The field trials would take place in rural and semi-rural Victoria and NSW, where broiler farms are mainly concentrated. Conventional shed-based and free range broiler farms would be selected to participate in the trial from within the local government areas listed in Table 1.

**Table 1 Proposed local government areas**

| New South Wales | 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 |

26. The first phase of the trial is expected to be restricted to specifically-selected farms in Victoria that do not currently vaccinate, allowing assessment of vaccine safety by comparison with unvaccinated control sheds on the same farm.

27. Further, trial locations would be decided by Bioproperties, in consultation with farm managers. Specific locations of participating farms would be notified to the OGTR before any dealings with the vaccine commence at that site.

### *4.3.2 Study design*

28. Over the 5 year period, up to 2,000,000 broiler chickens would be vaccinated with the GM vaccine, representing approximately 40 farms or sheds, each holding approximately 50,000 chickens. The farm or shed would be the 'experimental subject'. This number of subjects is necessary to detect a small to moderate difference in mortality rate where the incidence of natural field challenge with ILTV is low.

29. The safety and efficacy of the GM vaccine would be assessed on a farm or shed basis depending on how the vaccine is allocated. Where a farm has multiple sheds, each shed may be randomly assigned to receive one of the ILTV vaccines, either the GM vaccine or another APVMA-registered vaccine against ILTV as an active control. There may be a shed(s) not vaccinated against ILTV as a negative control. Where a whole farm is vaccinated with the GM vaccine, a comparison would be made with other farms receiving the active or negative control treatment.

30. In the first phase of the trial, which is expected to last no longer than 12 months, a few farms (equivalent to up to 500,000 chickens) would be selected that do not currently vaccinate against ILTV and are more isolated from other poultry farms. These farms are ideal to assess the transmission and safety characteristics of the vaccine under field conditions. In the second phase of the trial, more farms would be selected in areas that have experienced ILTV outbreaks to assess the efficacy of the GM vaccine under field conditions.

### *4.3.3 Manufacture, supply and storage of the GMO*

31. The GM vaccine would be manufactured in Bioproperties' manufacturing facilities in Glenorie, NSW, which are APVMA-licenced and also certified by the Regulator. Manufacture would be done according to the *Australian Code of Good Manufacturing Practice (GMP) for Veterinary Chemical Products* (APVMA 2007).

32. The GM vaccine would be transported to Ringwood, Victoria for storage, then to farms included in the field trials using couriers. The GM vaccine would be supplied frozen in a 10 mL glass vial. These would be placed in trays, wrapped in plastic cling wrap, and into a Styrofoam box filled with dry ice and sealed with packaging tape. The Styrofoam box would be placed into a cardboard box. The primary container and external containers of the vaccine would be labelled to indicate the APVMA permit number, contents, purpose and storage requirements that have been approved by the APVMA. Transport and storage would be in accordance with the PC2 requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.*

33. Once the GM vaccine has arrived at the farm, the vaccine would be stored in a freezer (below -18°C) specifically used for veterinary medicines. The vaccine must be kept in a freezer or ice until it is ready to be reconstituted.

### *4.3.4 Preparation and administration of the GMO*

34. The GM vaccine would be used for inoculation of broiler chickens only. Long lived breeder or layer chickens would not be included in the trial. Broiler chickens would be inoculated at approximately 7 days of age. The product leaflet approved by APVMA specifies how the vaccine must be used. All broiler chickens in the flock would be vaccinated with the GM vaccine only once and must not have received vaccination with any other ILTV vaccine. No other ILT vaccine would be given to the flock after vaccinating with the GM vaccine.

35. Chickens in the commercial industry are routinely vaccinated against bacterial and other viral pathogens. Details of all vaccinations would be recorded and maintained, as standard practice of the poultry company.

36. The GM vaccine would be supplied as a freeze-dried pellet in a glass vial, therefore, prior to administration, the vaccine needs to be reconstituted with sterile cold water. Reconstitution of the vaccine would take place in a room adjacent to the shed where the water tanks are located.

37. Each vial would contain approximately $10^8$ plaque forming units (PFU) of live GM vaccine, representing 1000 vaccine doses. Each chicken would receive approximately $10^5$ PFU. The APVMA permit allows vaccination by either eye drop or drinking water, but the most likely route would be via drinking water because this is a more efficient way to inoculate large numbers of birds.

38. Preparation and vaccination would be conducted by the farm manager with the aid of an assistant and under the direct supervision of a registered veterinarian.

39. For eye drop, the pellet must be reconstituted in 30 mL of water and 30 microlitres delivered to the eye using a dropper.

40. To prepare the vaccine for drinking, the volume of water to be consumed in 3 hours by all chickens in the shed must be calculated before reconstituting the vaccine. Sufficient doses of the vaccine for the whole flock would be reconstituted in a tank of water with skim milk as a stabiliser. The tank is connected to the drinking troughs within the shed. No additional water would be provided until all of the vaccine-containing water has been consumed.

### *4.3.5 Sample collection*

41. Vaccinated chickens would be monitored throughout the rearing period. Data on mortality rates at the farm would be collected. The registered veterinarian may conduct post-mortem examination and collect samples at the farm to determine the cause of mortality.

42. Tracheal swabs from randomly selected chickens and faecal samples from the litter would be collected at various time points after vaccination.

43. The samples collected from the farm would be transported as biological specimens, and in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.* Samples would be taken to facilities certified by the Regulator for testing and analysis.

44. Samples would be tested for the GMO or wild type ILTV DNA by quantitative polymerase chain reaction (qPCR). This would be performed until the likely extent of the persistence of the GMO has been determined, and would not be performed on all vaccinated flocks.

45. Some of the live vaccinated chickens would be transported from the farm to a certified facility in the University of Melbourne for research purposes. The tests, experiments and analyses undertaken at the University of Melbourne involving the live vaccinated chickens and samples would be conducted under a Notifiable Low Risk Dealing (NLRD) authorised by the University of Melbourne's institutional biosafety committee (IBC). The live vaccinated chickens would be transported according to the IBC and animal ethics committee requirements as well as the requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.* The Guidelines require that animals containing PC2 microorganisms be transported inside sealed, unbreakable primary and secondary containers with consideration given to whether the vents in the container should be HEPA-filtered.

### *4.3.6 Personal protective clothing*

46. Commercial broiler farms supply all visitors, workers and veterinarians with overalls and high rubber boots for use in poultry shed and free-range enclosures. Farm workers are also required to wear clean, laundered clothes each day.

47. Farm workers and manager preparing the vaccine would additionally wear gloves. The product leaflet recommends wearing eye protection and masks when preparing the GM vaccine.

48. Veterinarians conducting post-mortem examination routinely wear disposable gloves and overalls, and disinfect hands after examination.

### *4.3.7 Decontamination and disposal of the GMO*

49. A typical shed has an anteroom that is used for entering and exiting the shed. A footbath filled with fresh disinfectant and hand wash basin are available in the anteroom. When entering and exiting the shed, hands and boots would be disinfected against the GMO.

50. Multiple sheds on any farm containing chickens, treated with the GM vaccine or any of the other active controls or no ILTV vaccine treatment, would be clearly identified. To prevent cross-contamination, measures would be implemented including housing and managing each treatment group separately, and decontaminating equipment or materials when entering and exiting each shed.

51. The supplied overalls worn by workers would be laundered on-site and the rubber boots remain on the farm.

52. The APVMA permit states that water tanks, tubing or eye droppers used to deliver the product must be treated between flocks with an agent effective against the vaccine virus. The applicant proposes that after use, bottles, droppers, vials and other materials contaminated with the GM vaccine would be soaked in disinfectant solution such as Virkon (1% v/v) or sodium hypochlorite (0.5%) or quaternary ammonium chloride (0.01% v/v). After soaking in disinfectant, the waste materials would be wrapped in paper and placed in regular waste bins.

53. After all the chickens have been removed from the shed and during full shed clean-out, water lines and tanks used for drinking water vaccination would be cleaned with commercial virucidal oxidising agents such as iodophore, chlorine dioxide, or stabilised hydrogen peroxide-based products. These would be added to the water tanks at an appropriate concentration and allowed to run through

the water lines. The solution would be held within the water lines for the recommended contact time and then flushed using chlorinated water.

54. Due to the short growing period of broilers in the current industry, the re-use of litter for more than one flock is common practice in the industry. For the field trials, the applicant proposes to re-use litter only where the first flock is not vaccinated with ILT or where a vaccinated flock is followed by a vaccinated flock of the same vaccine. The applicant proposes that full cleanout of the shed and removal of litter would occur before an unvaccinated flock replaces a flock vaccinated with the GM vaccine. However, the APVMA permit states that the shed and litter are to be treated between flocks in a manner which is effective against the vaccine virus.

55. The applicant proposes to wash and disinfect vehicles, equipment, crates and bins after use with detergent and disinfectant solution.

56. For temporary storage of litter for disposal, dispersal would be restricted by covering the heaped litter with clean co-composting material and a tarpaulin. Chicken carcasses may be stored temporarily in a freezer prior to disposal by waste contractors or composting on farm land. For composting on farm land, the compost would be left for 3 to 6 months to ensure completion of the composting process.

57. The disposal of farm waste such as litter and chicken carcasses varies for each farm or poultry company. State legislation and local councils have requirements for disposal of waste generated in poultry farms, including free range farms (see Section 4.6).

#### *4.3.8 Training of personnel*

58. The entire field trial would be managed by a registered veterinarian consultant contracted by Bioproperties who manages the overarching protocol. The protocol for each site would be a version of the overarching protocol, modified to include the site location, names and contact details of the personnel participating at that site, and any minor changes required to accommodate farming practices at that site. A copy of the DIR licence would be attached to the protocol. The protocol would be prepared by Bioproperties Research and Development, and reviewed by Bioproperties Regulatory Affairs to ensure compliance with all regulatory conditions including the APVMA permit conditions and licence conditions that would be imposed by the Regulator. The Quality Assurance Manager would ensure that the protocol meets the Good Clinical Practice guidelines developed under the principles of International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH 2000). Each site would have a registered veterinarian who would ensure that the protocol is followed. The site veterinarian may be employed by the poultry company. All relevant personnel, their role and responsibilities, would be clearly indicated in the trial protocol.

59. The trial site protocol and the product leaflet also describe decontamination measures in response to spills of the GM vaccine. All farm workers and farm managers would be trained in decontaminating spills.

60. All workers responsible for handling the vaccine, inoculated chickens and contaminated equipment would be trained in handling the GMO. All farm workers would be trained in decontamination and disposal of the GMO in accordance with the trial protocol, any licence conditions imposed by the Regulator and the APVMA permit conditions.

#### *4.3.9 Adverse events*

61. The APVMA permit requires that Bioproperties must maintain a record of any adverse events, which includes any issues with the quality and safety of the product, and veterinary treatment must be sought as necessary.

62. Adverse events to vaccinated chickens would be reported to the Bioproperties Animal Care and Ethics Committee (ACEC) and the Regulatory Affairs Manager. The ACEC would provide advice on the steps to be taken to minimise any harm occurring to the chickens used in the field trials.

#### *4.3.10 Record keeping*

63. The APVMA requires that Bioproperties maintain a record of the trials performed under the permit. Specifically, details must include the date and location where the trials are conducted, commodities treated, rates and frequency of application, total amount of product used, and the names and addresses of persons conducting the trial, and any adverse events. These details must be maintained for a minimum period of two years from the date of expiry of the permit and must be made available to the APVMA upon request.

#### *4.3.11 Fate of chickens after field trials*

64. After the chickens are inoculated and reached the appropriate age for harvesting, they would be transported and processed in the same way as for other commercial broiler chickens (see Sections 4.4.7 and 4.4.8).

### 4.4 Background on broiler farming

65. To assist in identifying and assessing the risks associated with the proposed field trials (discussed in Chapter 2), understanding the context in which the commercial broiler industry operates is essential. This section describes the current commercial broiler farming and processing practices, and the relevant state and local council requirements and legislation.

66. NSW and Victorian broiler farms, including free range farms, must comply with a range of legislation designed to protect people and the environment. Local councils and/or state government agencies must approve intensive agriculture developments including free range broiler farms. Local councils are generally the responsible authority for the administration or enforcement of planning schemes. This means that councils would assess and determine farm planning permit applications. Councils are also responsible for monitoring and enforcing the compliance of broiler farm operators with their planning permit conditions.

67. Boundary setbacks may be required by councils and are defined as the distance between the nearest external edge of any new broiler chicken shed or litter stockpile or compost pile and the farm boundary. Boundary setbacks mitigate visual amenity issues and the immediate impact of odours, dust, aerosols and noise emissions from sheds, litter, or compost piles on the amenity of adjacent land and the surrounding area.

68. The separation distance is the distance from the nearest external edge of a broiler shed to the nearest external edge of a sensitive use (e.g. house or public building) on land beyond the broiler farm property. It excludes sensitive uses directly associated with the broiler farm operations – e.g. residential dwellings on the broiler farm property. Separation distances are used to reduce the effects of odour, dust, aerosols and noise. Separation distances usually extend across adjoining properties that are not owned by the farm owner. The greater the separation distance and the boundary setback, the lower the probability of offensive odour and dust adversely impacting the surrounding community.

69. A buffer is where the farm owner has legal control of the land needed to separate the poultry sheds from adjoining developments. A buffer may be open farmland, or a landscape area that hides views of the sheds or helps to disperse odours.

#### *4.4.1 NSW requirements*

70. The *Environment Planning and Assessment Act 1979* (NSW) (EP&A Act) is the major legislation governing land use and environmental assessments. The EP&A Act establishes a framework for local government zoning, assessment requirements, development control plans and development consent provisions. In addition, broiler farms in NSW that accommodate more than 250,000 chickens require a licence under the *Protection of the Environment Operations Act 1997* (NSW) (POEO Act).

71. The *Best Practice Management for Meat Chicken Production Manual* (the Manual) (NSW Department of Primary Industries 2012) provides guidance for the planning, design, construction and

management of shed based broiler farms in NSW, but not for free range farms. The Manual recommends that new poultry farms be a minimum of 1000 metres from other intensive poultry farms (500 metres when there are extenuating circumstances such as farms with a common owner or farms supplying the same processor); 3000 metres to commercial duck farms; and 5000 metres to poultry breeder farms. In addition, the Manual recommends that new farms be away from waterways and wetlands (ideally 3000 metres) that are used extensively by waterfowl.

72. In relation to protecting ground water or watercourses, the Manual recommends locating the broiler farmland above the 1-in-100-year flood line; avoiding locating the farm near major potable water supply storages and watercourses within drinking water catchments; and protecting riparian zones with appropriate buffer zones and vegetative filter strips. The Sydney Catchment Authority specifically requires that broiler farms not be located within 100 metres of a major potable water supply or reservoir, or within 40 metres of a watercourse in the Sydney drinking water catchment.

### *4.4.2 Victorian requirements*

73. In Victoria, broiler farms must be approved by local councils and the Victorian Department of Environment, Land, Water and Planning under the *Planning and Environment Act 1987*. In all Victorian planning schemes a planning permit is required to use and develop land for a broiler farm including free range broiler farms. Broiler farms including free range broiler farms are prohibited in all urban zones, Rural Conservation Zone, the Green Wedge A Zone and Rural Living Zone.

74. Compliance with the *Victorian Code for Broiler Farms 2009* (the Broiler Code) (Victoria Department of Economic Development 2009) is mandatory for the establishment of all new broiler farms and expansion of the capacity of existing broiler farms, but does not apply to free range farms. Broiler farms that were lawfully established before the introduction of the Broiler Code may continue to operate in conformity with their previous lawful operations and the conditions of any valid planning permit that pertains to the broiler farm. Where the Broiler Code does not apply, it may still be a useful reference for identifying relevant issues and responses to inform the preparation and consideration of a proposal.

75. The Broiler Code details requirements including the location, siting, design, site access, waste management, farm operation and management. In addition, broiler farms must meet the requirements of relevant state and local government regulations.

76. The Broiler Code uses a mathematical formula to calculate the required minimum separation distance, based on the proposed farm capacity for housing chickens. For example, a farm with a capacity of 100,000 chickens requires a minimum separation distance of 325 metres, and a farm with a 400,000 capacity requires a minimum separation distance of 686 metres.

77. The boundary setback is specified in the Broiler Code as at least 100 metres. The Broiler Code has several other requirements for distances of the farm to certain other areas depending on the zoning of the land.

### *4.4.3 Corporate structures*

78. The chicken meat industry is predominantly vertically integrated. This means that generally, individual companies own almost all aspects of production - breeding farms, multiplication farms, hatcheries, feed mills, some broiler farms, and processing plants. Two large integrated national companies supply more than 70% of Australia's broiler chickens - Baiada and Inghams Enterprises. Inghams and Baiada are privately owned, with farming and processing operations in most states. The rest are medium-sized, privately owned companies, and a myriad of smaller processors.

79. Growing broiler chickens, from day old chicks to the day of processing, is generally contracted out by processing companies to contract growers. Approximately 800 growers produce about 80% of Australia's broiler chickens under these contracts. Other broiler chickens are produced on large company farms, or on farms owned and managed by 'intermediary' companies which own a number

of farms, each managed by a farm manager, and who enter into contracts with processing companies to grow out chickens on a larger scale.

80. Contract growers own the farm and provide the management, shedding, equipment, labour, bedding and other inputs to rear chickens. The processing company provides (and owns) the chickens and provides feed, medication and technical advice (Australian Chicken Meat Federation Inc. 2013b).

81. Farms proposed to be included in the trial would be those controlled, owned or contracted by the major commercial poultry processors. The applicant stated that each company operates according to quality management systems incorporating standards such as GMP and the Hazard Analysis of Critical Control Points (HACCP), and in accordance with strict state environmental codes. The companies are members of peak organisations such as the Australian Chicken Meat Federation (ACMF). The applicant stated that they demonstrate a commitment to implementing standards and guidelines such as the National Farm Biosecurity Manual for Chicken Growers (Australian Chicken Meat Federation Inc. 2010), which are generally included within the company quality assurance program.

### *4.4.4 Broiler chicken farm (including free range farm) routine management in Australia*

Free range farms

82. Free range broiler chickens are produced using similar management, housing, rearing and feeding practices as conventional broiler chickens. Free range broiler chickens are harvested in the same timeframe as shed-based chickens. The major differences are that free range broiler chickens are allowed access to an outside run for part of each day (at least after the brooding period) and often have lower target stocking densities. Depending on the accreditation program adhered to, use of antibiotics to treat sick birds may preclude the meat from these chickens being sold as free range (Australian Chicken Meat Federation Inc. 2013a).

Shed housing

83. Broiler chickens are farmed in large open poultry houses, usually referred to as ‘sheds’, ‘houses’, ‘barns’ or ‘units’. Shed sizes vary, but a typical shed is about 150 metres long and 15 metres wide and holds about 40,000 adult chickens. The larger sheds can contain up to 60,000 chickens. There are often three to ten sheds on one farm. A typical new farm would house approximately 320,000 chickens, with eight sheds holding approximately 40,000 chickens each.

84. Traditionally, broiler sheds have been ‘naturally ventilated’, with the sides of the shed open to fresh air. The amount of air circulating through the shed is changed by raising/lowering curtains running along the side of the shed, or by a vent opening at the top of the shed. Fans are sometimes used to encourage air flow, and water misting systems cool the chickens by evaporative cooling in very hot conditions.

85. An increasing number of chicken sheds have ‘tunnel ventilation’. Tunnel ventilation sheds have fans at one end of the shed which draw air into the shed through cooling pads in the walls, over the chickens and out the far end of the shed at high speed. Three or four temperature sensors in the shed allow automatic control of the fan, heating and cooling settings.

86. Feed lines and pans run the length of the shed and are supplied automatically from silos outside the shed via pipes. Feed silos are kept secure against all pests, and any spillage around silos is cleaned up immediately to prevent attraction of pests. Water lines run the length of the shed, with drinkers at regular intervals. Water and feed are placed so that chickens are never more than about 2 metres from food and water. The water and feed lines can be raised or lowered within the shed to allow feeding, or for pick-up (harvest) or shed clean-out (Australian Chicken Meat Federation Inc. 2013a).

87. Bedding used is a thick layer of litter, such as sawdust, wood shavings, rice hulls or other materials spread across the floor.

88. For shed floors, the Broiler Code has requirements stipulating: that the base of the broiler shed should be constructed from low-permeability materials such as concrete, compacted clay or another sealed surface; the finished floor level of the broiler shed should be above the natural surface level to prevent the entry of stormwater run-off, or alternatively, the shed should be bunded or a surface drainage system installed to prevent the entry of stormwater run-off; and a concrete stand area should be located at the entrance to each broiler shed.

89. A number of structures are regularly inspected and maintained including shed walls, roofs, ventilation, cooling systems, automated environmental controllers, sensors, water reticulation systems, silos and feed-lines. The surrounding area must be maintained to ensure they are clean and tidy (NSW Department of Primary Industries 2012).

Chicken rearing

90. Day-old chicks are transported from the hatchery to broiler farms, usually in ventilated chick boxes in specially designed, temperature controlled trucks. On arrival at the broiler farm, chicks are placed onto the floor of the shed, where they are initially confined to about a half or one-third of the total shed area (the 'brooding area') and given supplementary heating from gas heaters or heat lamps.

91. For the first two days of the flock's life, the shed temperature is held at 31 - 32°C, the optimum temperature for chick comfort, health and survival. As the chickens grow, the shed temperature is gradually lowered by about 0.5°C each day, until it reaches 21 - 23°C at 21 days. The farmer aims to maintain shed temperatures within this range, although towards the end of grow-out period for large chickens, the temperature may be reduced.

92. As the chickens grow, the area available to them is increased until they have free run over the floor of the entire shed.

93. Generally, feed and clean water is available 24 hours a day, although some operators make feed available at specific 'meal times' only.

94. Farm workers regularly, at least once every day, monitor the flock's health and progress, remove any dead chickens, and cull any sick or injured ones. Farm workers also check feeders and water systems. Careful management of ventilation and water system helps keep the litter clean and dry, as poor litter affects air quality and can affect bird health and performance.

95. Over the life of the broiler flock about 4% of chickens die as a result of natural causes or selective culling (Australian Chicken Meat Federation Inc. 2013a).

Pick-up or harvest

96. In Australia, a percentage of chickens are harvested from most flocks on several occasions. Harvesting, also known as 'partial depopulation', 'thinning out', or 'multiple pick-up', may be done up to four times until all chickens have been removed from the shed. Thinning out sheds allows more space for the remaining chickens and reduces the natural temperatures in the shed. The first harvest might occur as early as 30-35 days and the last at 55-60 days.

97. Immediately before pick-up the sheds are cleared of all dead chickens and any chickens not suitable for catching. Feedlines are lifted not more than 3-6 hours before pick-up in accordance with the instructions given by the processor. Access to water is not removed until the pick-up crew arrives on the farm.

98. Chickens are often harvested at night as it is cooler and the chickens are more settled. They are generally picked up by specialised contracted pick-up crews under low lighting conditions so that they are calm and easy to handle. They are usually caught by hand and placed into plastic crates or aluminium modules designed for good ventilation and safety from bruising during transport. These crates or modules are handled by specialist forklift equipment and loaded onto trucks for transport to the processing plant. During pick-up, the farmer is available to help maintain all aspects of chicken welfare.

99. When all the chickens have been removed from the shed (after about 60 days), it is cleaned and prepared for the next batch of day-old chicks.

Shed clean-out

100. The next batch of chicks generally arrives in five days to two weeks, giving time to clean the shed and prepare for the next flock. The break also reduces the risk of common microorganisms being passed between batches as many pathogens die off. As each broiler flock spends 6 to 7 weeks in a shed and there is a two week break between batches, farmers run about 5.5 batches through a shed each year.

101. Some farms undertake a full cleanout after every batch. This includes removing bedding, brushing floors, scrubbing feed pans, cleaning out water lines, scrubbing fan blades and other equipment, and checking rodent stations. High pressure hoses clean the whole shed thoroughly at a standard rate of 6000 to 8000 litres of water per shed. Because low water volumes are used, there is little water run-off. The shed is disinfected, using low volumes of disinfectant which is sprayed throughout.

102. On other farms, a partial clean-up of the shed is done, including removing old litter and/or topping up with fresh litter and cleaning and sanitising all equipment. A full cleanout is done after every second or third batch of chickens (Australian Chicken Meat Federation Inc. 2013a).

103. An insecticidal treatment may be applied in areas where shed insects such as beetles are a problem.

104. Registered veterinarians or technicians may test the sheds after a full cleanout to confirm sheds have been adequately cleaned and potential disease agents removed.

#### *4.4.5 Water use*

105. Broiler chicken farms must comply with the relevant state legislation to prevent contamination of surface and ground water, watercourses or bores and catching overland overflow.

106. Broiler chicken sheds operate as closed systems with little or no water escaping to the outside environment. Any water spilt inside the shed from drinking equipment or during cleaning would subsequently evaporate.

107. The risk of ground water contamination is primarily avoided via appropriate site selection and by engineered construction and compaction of the shed floor (NSW Department of Primary Industries 2012).

#### *4.4.6 Environmental monitoring*

108. Environmental monitoring and recording form part of farm management to ensure that the requirements of relevant state legislation are met. Growers are encouraged to develop, document and implement an Environmental Management Plan for the farm (NSW Department of Primary Industries 2012).

109. During high-risk activities (such as shed clean-out) a record is kept of management actions to minimise the risks. Records must be made available to relevant regulatory authorities.

#### *4.4.7 Transport of live chickens to processing plant*

110. Chicken farms are generally within 100 kilometres of the processing plant. Poultry processing plants are usually close to markets and labour sources, with many of the largest operations within 50 km of a capital city.

111. When inoculated chickens reach a suitable size for market (typically around 8 weeks of age, or about 7 weeks post-inoculation), chickens would be placed in crates for transport in an open truck and transported in accordance with the relevant state legislation. Crates, trucks, equipment and other

materials used to transport the vaccinated chickens from the shed to the processing plants would be decontaminated with disinfectant after delivery of chickens.

112. In Victoria, live chickens taken from farms are transported in accordance with the *Australian Animal Welfare Land Transport of Livestock Standards and Guidelines*, referred to as the Land Transport Standards (LTS) (Animal Health Australia & Department of Agriculture 2012). The LTS has been adopted into the Victorian legislation under the *Livestock Management Act 2010* (Victoria).

113. In NSW, live chickens are transported in accordance with the *Prevention of Cruelty to Animals (Land Transport of Livestock) Standards 2013* which is required under the *Prevention of Cruelty to Animals Act 1979* (NSW). The provisions in the NSW Standards reflect those in the LTS.

114. The LTS has specific requirements for transporting poultry aimed at animal welfare, such as that container or crate openings must be 20 cm x 22 cm, containers must be stacked in a way that facilitates airflow, maintaining appropriate temperatures, preventing delays in transporting and unloading, and protecting poultry from various weather conditions.

### *4.4.8 Poultry processing plants*

115. The processing plants would slaughter, process and package chickens for wholesale or retail sale for human or animal consumption.

116. The processing plants are highly automated and adhere to high standards of cleanliness and hygiene. Meat processing plants must have documented procedures including those related to sanitation to ensure the safety of food. Meat processing plants are regulated by the state regulatory authorities.

117. In Victoria, some functions of PrimeSafe (the regulatory authority), as prescribed under the *Meat Industry Act 1993* (Victoria), include licensing meat processing facilities, reviewing the standards of meat produced for consumption or sale within the state, and reviewing the standards of the construction and hygiene of plant and equipment in a meat processing facility.

118. Likewise, meat processing plants in NSW must have a licence from the NSW Food Authority, which inspects the premises to ensure all buildings and equipment meet the relevant standards and requirements of the *Food Act 2003* (NSW). In addition, meat processing plants may require a licence from the NSW Environment Protection Authority (EPA).

119. Waste products from the processing of birds may be collected from the processing line and separated into three distinct waste streams comprising blood, feathers and internal organs/heads/feet (offal) for transport to a rendering plant. As well as regular flush and 'spot' cleaning of the plant during a shift, a full daily cleaning also occurs. All sections of the plant including the live bird area and the wastewater pits and pipes are cleaned and flushed daily. All internal factory areas and contaminated external areas usually drain to wastewater pits and then to the effluent treatment and disposal system.

120. At some poultry processing plants, wastewater may be directed to a compact effluent treatment system such as a dissolved air floatation unit to remove grease and solids before it is discharged to the sewer in accordance with trade waste agreement. Solid waste removed from the effluent by the dissolved air floatation system may be, for example, transported daily to the local landfill to minimise odours.

121. Chicken carcasses and waste products from processing may be taken to rendering plants. Rendering plants that process substances for human consumption are required to apply for a licence from the state regulatory authorities (e.g. PrimeSafe, NSW Food Authority), meet relevant standards such as the *Australian Standard* 5008 - *Hygienic Rendering of Animal Products* (Standards Australia 2007), comply with legislation such as *Food Act 2003* (NSW), and be inspected by the state regulatory authorities.

## 4.5 Biosecurity

122. To assist in the risk assessment of the proposed field trials (discussed in Chapter 2) and to understand the standard biosecurity measures employed by the commercial broiler industry, this section describes the biosecurity standards for poultry farms, and the relevant state and local council requirements and legislation.

### *4.5.1 Biosecurity legislation*

123. Each state and territory has their own biosecurity legislation. The *Biosecurity Act 2015* (NSW) provides tools and powers to manage animal and plant pests and diseases, weeds and contaminants that threaten the NSW economy, environment and community. The tools allow for practical responses proportionate to risk, and include: emergency powers in case of a significant biosecurity risks, as well as requiring people who deal with biosecurity, and who have knowledge of the biosecurity risks posed, to take reasonable steps to manage those risks. The Biosecurity Act includes strong enforcement tools, including significant penalty provisions especially for wilful or reckless acts. The *Livestock Disease Control Act 1994* (Victoria) provides for the prevention, monitoring and control of livestock diseases in Victoria, and also addresses issues related to licences, registrations and enforcement.

### *4.5.2 Poultry farm biosecurity standards*

124. As part of current arrangements between the Victorian government and industry, poultry producers are expected to implement on-farm biosecurity programs and follow them on a daily basis to reduce the risk of transmission of disease onto and between poultry farms (Victoria Department of Economic Development 2015).

125. A number of documents provide guidelines including *National Farm Biosecurity Manual for Poultry Production* (Department of Agriculture 2009), *National Farm Biosecurity Manual for Chicken Growers* (Australian Chicken Meat Federation Inc. 2010) and *NSW Biosecurity Guidelines for Free Range Poultry Farms* (NSW Department of Primary Industries 2007). These outline biosecurity standards applicable to all poultry producers including free range farms.

<u>Farm facilities – conventional and free range</u>

126. The biosecurity standards applicable to both conventional and free range broiler farms are summarised below.

127. Each farm must keep a copy of the *National Farm Biosecurity Manual for Poultry Production* (Department of Agriculture 2009) or a more detailed document that encompasses the manual that is readily accessible to workers. All workers must be trained in the relevant parts of the manual and such training is to be recorded.

128. The production area (sheds or free range area, feed storage and handling area, and area immediately surrounding the sheds including pick-up areas) must have a perimeter fence or otherwise well-defined boundary (e.g. creek, vegetation) establishing a clearly defined biosecurity zone.

129. If livestock graze on the property then the production area must have a stock proof fence. Grazing near sheds (i.e. on part of the production area) is only permitted where the grazing area is separated by a stock proof barrier from the area used by poultry.

130. The main entrance to the production area must be capable of being closed to vehicle traffic (e.g. lockable gate which should be kept locked at all times) and must display appropriate signage including 'Biosecure Area No Entry Unless Authorised' or similar wording. In addition, signage including contact numbers must direct visitors to contact the producer before proceeding.

131. There must be a change area away from sheds with clean protective clothing and boots provided. Entry to sheds must only be made through entrances with a footbath containing a suitable disinfectant. There must be provision for scraping the soles of boots before dipping to ensure the disinfectant makes contact with the soles of the boots. An alternative system using separate

production area- and shed-footwear may be used. Facilities for hand sanitation must also be placed at the entry to each shed.

132. Facilities should be available for the cleaning and disinfection of equipment before entry.

133. Feeding systems must wherever possible be closed to ensure that feed in silos and feed delivery systems are protected from access and contamination by wild birds and rodents. Feed spills should be cleaned up without delay to prevent the congregation of wild birds.

134. Drinking water should be accessed inside the shed; or, if watering stations are required outside, they should be of a type that cannot be easily accessed by wild birds (e.g. a nipple system). The watering system should be maintained, in order to prevent leakage and the creation of wet patches within or outside the shed. Water tanks should be checked regularly to ensure that they remain bird-proof.

135. Drinking water for poultry, as well as cooling water used in poultry sheds, must meet appropriate water standards. Water that does not meet the standard must be treated (e.g. chlorination, ultraviolet, iodine) to ensure that the standard is met. All surface water (dam, river etc.) must be treated before being used as drinking water for poultry. Treated water supply must be kept in a closed system from the point of treatment to the drinker.

136. All poultry housing must be designed and maintained so as to prevent the entry of wild birds and limit the access of vermin as far as is practical.

137. The production area should be adequately drained to prevent accumulation and stagnation of water likely to attract water fowl, especially in the areas around sheds.

138. Trees and shrubs should be selected to minimise wild bird attraction. The area around sheds must be kept free from debris and vegetation should be mown regularly. Vegetation buffers for environmental compliance should not be compromised.

139. An appropriate vermin control plan must be developed and implemented, including rodents, foxes, wild dogs and cats. A baiting program for rodents must be implemented where a risk assessment deems this necessary (e.g. live rodents, droppings, nests).

140. Beetle populations within shed litter should be controlled via an integrated pest management approach by using pesticides, composting and total shed and litter clean-out.

141. Only commercially produced avian species are to be kept in the production area and no other avian species (including aviary birds and pet birds) or pigs are to be kept on the property.

142. If more than one commercially produced avian species is kept in the production area, the species should be housed and managed separately, with suitable biosecurity arrangements for each species. Shared equipment should be cleaned and disinfected between uses.

143. Used litter and manure must not be stockpiled in the production area. Used litter and manure must be stored in an appropriately designed storage area away from the production area.

144. Dead bird disposal methods must conform with applicable environmental compliance requirements.

Free-range farms

145. The following biosecurity measures are specific for free-range farms.

146. Good fencing is required to prevent the entry of animals such as dogs, foxes and cats. In many situations, however, fencing alone is insufficient to stop such intrusions; therefore, some free range enterprises keep specially trained dogs with the chickens, as protection against other animals and against unauthorised human entry. Dogs must not enter sheds unless part of the flock security strategy. Guard dogs such as these are not regarded as a biosecurity risk but rather as a biosecurity tool.

147. Where footbaths are not appropriate for a free range paddock, a system should be documented and implemented to monitor and prevent any potential hazardous organic material or litter entering free range paddocks.

148. In free range farms, chickens may have some exposure to wild birds. Therefore, documented measures must be taken to minimise the congregation of waterfowl and the impact of wild birds. Wild bird attractiveness can be minimised by placing feeders and water inside the shed, rather than in the open range where wild birds would have easier access. Placement of bird netting in critical feeding areas may also reduce the risk.

149. In free range farms with sheds or other housing, manure deposits outside the hatch openings must be removed after each batch, and ramps used by chickens must be scraped and cleaned after each batch.

150. Grass on and around the farm must be kept cut to reduce rodent attraction.

Farm worker standards and visitors – conventional and free range

151. Production area personnel or any person residing on the property must not have contact with any other poultry, avian species or pigs unless they have a complete head-to-toe shower and change into new protective footwear and clothing prior to entering the production area.

152. Personnel must wear laundered clean clothes each day to work and ensure that they do not become contaminated by contact with avian species or pigs on their way to work. It is critical that boots worn in sheds are not worn or taken outside the production area.

153. Company service personnel visiting the production area must wear protective clothing and footwear, as approved by the production facility manager. Hands must be sanitised before entering sheds.

154. Contractors who have had contact with poultry or other birds that day or keep birds at their home must not enter sheds and/or ranges populated or ready to be populated with birds unless it is an emergency, and they have showered from head-to-toe, changed clothes and boots and wear hair covering. Tools taken into the production area must be cleaned before entry into sheds and must be free of dust and organic matter.

155. All persons must agree to comply with the entry conditions by signing the visitors' log and such visits must be approved by the manager before visitors may enter sheds and ranges. This requirement also applies to vaccination crews.

156. Pick-up crews work from youngest to oldest or all young birds or all old birds on a shift basis in accordance with the processing company's pick-up biosecurity procedures. Pick-up crews must not keep birds at their homes. Drivers must sanitise their hands and boots before and after each pick-up or delivery to a production area. Trucks carrying unused or used litter must be cleaned and disinfected between production areas.

157. A system for tracing movements of delivery personnel (e.g. through delivery dockets and feed company records) must be implemented.

### *4.5.3 High level biosecurity*

158. In the event of an outbreak of disease, the *National Farm Biosecurity Manual for Poultry Production* (Department of Agriculture 2009) recommends the following measures:

- limiting visitors from entering the production area unless absolutely essential;
- visitors who visit must have a head to toe shower before and after visit;
- used clothing and personal protective equipment must remain on property;

- any vehicle entering the property must be washed and disinfected before and after going onto the property; and
- poultry and litter must not be moved on or off property until disease status is clarified.

159. Farms require a contingency plan to cope with occurrences of high mortalities. An investigation must be conducted to ascertain the cause of death and the best option for the disposal of the dead birds. Where normal disposal methods are not feasible, the relevant regulatory authorities (e.g. the local council, the state EPA) may need to be contacted to help identify alternative options.

160. Subject to approval from local council, state EPA and other authorities, mass-death disposal options may include: rendering (if facilities are available), in-shed composting, external composting, disposal in a landfill site, or burial on-farm (see Section 4.6).

161. If the cause of the death is an Emergency Animal Disease, then the relevant Australian Veterinary Emergency Plan (Ausvetplan) would be activated and the appropriate authorities would be notified. Disposal of carcasses, used litter and feed, and decontamination of equipment, would be under the direct control of the state's Chief Veterinary Officer.

162. The *Biosecurity Incident Management System* (Biosecurity Emergency Preparedness Working Group 2012) provides guidance for the management of biosecurity incident response in Australia and can be applied to all biosecurity sectors. Typically the states and territories have primary responsibility for preparing and responding to biosecurity incidents within their borders. The DAWR has a role in providing national leadership and coordination in preparing for and responding to biosecurity incidents.

## 4.6 Waste management

163. To assist in the risk assessment of the proposed field trials (discussed in Chapter 2) and to understand the waste management practices of commercial broiler farms, this section describes the waste management practices, and the relevant state and local council requirements and legislation.

164. In NSW, the handling of litter and waste on the farm must meet the requirements of waste management legislation such as the POEO Act and may require a permit from the NSW EPA. For farms in the Sydney drinking water catchment area, the Sydney Catchment Authority does not permit the disposal of chicken carcasses on site, except during an outbreak of exotic disease that results in a farm being quarantined.

165. In Victoria, the state government, catchment management authorities and local councils each have roles and responsibilities that relate, directly or indirectly, to farm waste management. Management of waste including used litter and dead chickens must be conducted in accordance with the conditions of the planning permit. For example, farms may not stockpile, compost or spread litter if the planning permit conditions require removal of all litter directly off-farm.

166. Incineration is not the preferred practice because it is expensive and must be conducted only in authorised incinerators built for purpose. Burning carcasses in open fires is not permitted.

167. The *Best Practice Management for Meat Chicken Production Manual (NSW Department of Primary Industries 2012)* and the *Victorian Code for Broiler Farms 2009* (Victoria Department of Economic Development 2009) stipulate the following relevant measures for disposal of litter and dead chickens:

- litter must be removed from the farm or operational area immediately as sheds are being cleaned out and transported from the farm in covered vehicles to avoid spillage and dust emissions
- chicken carcasses must be removed from the sheds daily and disposed of, or stored appropriately (e.g. in freezers), within 24 hours of death

- for collection of chicken carcasses by waste contractors, the collection point for carcasses must be as far as practical away from the farm site to prevent the collection vehicle from entering the site, collection point must be weather-proof and easily cleanable, and the collection vehicles and containment systems must be leak-proof and vermin-proof
- where birds need to be frozen before collection, secured freezers with adequate space must be provided. Carcass-storage containers and the collection area must also be regularly cleaned and disinfected to minimise the spread of disease
- any spillage in the collection areas must be immediately cleaned and disinfected
- records of collection (date and mass) must be maintained
- personnel disposing of carcasses should be instructed on maintaining personal hygiene and environmental protection measures
- carcasses (or bird bins) must not be left in public view and must be disposed of at licensed composting facilities, rendering plants or landfills.

### *4.6.1 Composting*

168. Composting facilities and those on farm land must comply with the state requirements. Under the EP&A Act (NSW), approval for composting sites and on farm land may be required from an appropriate authority (usually the local council) or state EPA. Composting facilities must comply with legislation including the *Environment Protection Act 1970* (Victoria).

169. The Environmental Guidelines on *Composting and Related Organics Processing Facilities* (NSW Department of Environment and Conservation 2004) focus on the appropriate environmental management of commercial composting facilities in NSW. Composting in Victoria must be conducted in accordance with *Designing, Constructing and Operating Composting Facilities* (Victoria Environment Protection Authority 2015). Both the NSW and Victorian composting guidelines refer to the AS 4454 – *Composts, Soil Conditioners and Mulches* (Standards Australia 2012).

170. The composting guidelines from each state cover topics related to distances of compost area from other sensitive areas including wildlife parks and water areas, vermin control, management of compost and dispersal of debris. Compost containing different types of organic matter are categorised depending on the risk of harm to human health and/or the environment. Animal carcasses are placed in the highest risk category. The requirements for these high risk organics are more stringent in order to minimise their impact on various environmental aspects. The guidelines recommend that high risk organics be composted in an enclosed environment with a high level of secondary odour controls.

171. The *Best Practice Management for Meat Chicken Production Manual (NSW Department of Primary Industries 2012)* and the *Victorian Code for Broiler Farms 2009* (Victoria Department of Economic Development 2009) stipulate the following relevant measures for composting on farm land:

- if litter is stored on farm (or composted) it must be managed to avoid contamination of surface waters, stormwater drains, waterways, catchments and ground waters, and avoid excessive fly breeding;
- bunding may be required to prevent entry and contamination of stormwater run-off;
- temporary litter stockpiles or compost piles must be separated by at least 100 metres from any broiler shed on the subject land, or sited and managed as otherwise stipulated by the processor to meet biosecurity requirements;
- if re-using litter on farm, the litter application site must not be on land subject to flooding, steep slopes, rocky, slaking or highly erodible land or highly impermeable soils where there is any risk of nutrient run-off to waterways, groundwater and surrounding land;

- nutrient-rich run-off from temporary litter stockpiles or compost piles must be collected in a sump or dam and may be re-used to add moisture to the pile.

Composting process

172. Composting is the microbiological transformation of organic materials under controlled aerobic conditions. There are two phases to the composting process which have different processing parameters. First is **pasteurisation** which generates heat within the material to significantly reduce the number of viable pathogens and plant propagules. This is followed by **maturation** which sees the decline in temperatures and moisture levels, slowing of microbial activity and an increase in biological stability of the organic material (Victoria Environment Protection Authority 2015).

173. Current composting practices use either purpose-built compost bins, which may be rotary, or composting bays or piles. Small volumes can be composted in bins. The size and number of compost rotary units required depend on the size of the operation and normal levels of bird mortality (3% to 5%). Rotary units require careful management to ensure that an aerobic environment is maintained in order to reduce the possibility of excessive odour generation.

174. Litter makes up the greatest part of the composted waste by volume. The litter and chicken carcasses from several sheds may be incorporated into a long windrow in open land, along with additional organic material such as sawdust/mill waste or green waste. The litter and carcasses must be covered with at least 300 mm of clean co-compost material to exclude flies or birds. The windrows may be 100 metres long, 3-4 metres in width and 2-3 metres high.

175. Intermediate volumes may be composted in piles or in bays formed from hay bales. Fencing is used to exclude stock that may disrupt the windrows or piles. Compost in large bays, piles or windrows need to be mixed or turned using earth moving equipment.

176. The temperature to effectively achieve pasteurisation ranges from 55°C to 75°C. The temperature reached by composting material influences the rate of decomposition, oxygen demand and microbial population. Other pasteurisation parameters include carbon to nitrogen ratio, total moisture levels, oxygen content, pH, porosity and bulk density.

177. The Victorian composting guidelines (Victoria Environment Protection Authority 2015) and the AS 4454 – *Composts, Soil Conditioners and Mulches* (Standards Australia 2012) require that for compost containing high risk materials (e.g. manure, carcasses), the core temperature must be maintained at 55˚C or higher for a period of 15 days or longer; and during this period of high temperature, the whole compost mass must be turned a minimum of five times.

178. After the completion of the composting process, the compost may later be sold and used in pastures to increase nutrients and add organic matter.

### *4.6.2 Burial on the farm*

179. Burial was a traditional and economical option for disposal of carcasses. However, not all soil types or locations are suitable for on-site burial; for instance, areas may have a high risk of water table contamination or shallow soils. Disposal of chicken carcasses via burial is also unlikely to be suitable in more closely settled areas and on smaller properties, owing to the higher risk of odour or of predation by domestic animals.

180. On-site burial of dead chickens on the farm is currently undertaken only in an emergency situation or with the approval of the relevant authorities such as the state EPA or the Chief Veterinary Officer.

181. The state EPA recommends burial of carcasses on the farm to be undertaken at an area at least 100-300 m away from houses and water sources (e.g. ground water, surface water), that has good access to the site for earthmoving machinery and stock transport unless the stock are to be walked in for slaughter, has a pit base with at least 1-2 m above the level of the watertable, and covered with at

least 2 m of heavy soil of low permeability and good stability (NSW Environment Protection Authority 2013; Victoria Department of Economic Development 2016).

### *4.6.3 Landfill*

182. Contaminated farm waste including dead chickens may be disposed of at landfill sites.

183. Landfills may require a licence from the relevant authorities such as the state EPA to dispose of dead chickens from the poultry industry and must be done according to the requirements of the state EPA. The Victorian EPA *Landfill Licensing* guideline (Victoria Environment Protection Authority 2016) and the NSW EPA *Environmental Guidelines – Solid Waste Landfills* (NSW Environment Protection Authority 2016) have requirements in relation to managing waste in landfills to minimise environmental impact, such as segregating active landfill sites from surface water or groundwater, controlling debris, covering waste (such as carcasses) daily with soil or other material at least 0.15 - 0.30 metres thick, and controlling vermin in landfills.

### *4.6.4 Rendering plants*

184. The *Best Practice Management for Meat Chicken Production Manual* recommends removal of chicken carcasses for rendering if a rendering plant is located close to the farm (typically within 100 kilometres).

185. Rendering plants may require a licence from the state EPA to dispose of dead birds from the poultry industry. The NSW EPA has recommendations for managing rendering plants such as cleaning spilled material in the premises, storage of rendering material, cleaning all equipment, machinery and bins, waste management and effluent treatment. In addition, the state EPA may impose licence requirements or conditions on the rendering plant e.g. treatment of the effluent.

186. Rendering is the process of separating the lipids or fats from animal tissue and water under the influence of heat and sometimes pressure. Variations in the process of rendering are employed by each rendering plant. Animal carcasses are usually processed as soon as they are delivered to the rendering plant. Generally, there are two principal methods of rendering.

187. In the wet rendering process the tissue is ground to a small particle size of about 12 mm and preheated at around 95°C for between 5 and 60 minutes depending on the individual system. The heated slurry is then pressed or centrifugally separated into liquid and solid phases. The liquid which consists of lipids and water is then centrifugally separated into separate streams. The wet solids are dried then milled to a free-flowing meal.

188. In the dry rendering process, the tissue is ground to a particle size of about 30-40 mm then heated in a jacketed container, mechanical agitation is provided and the water evaporated either at atmospheric or increased pressure. The fat and solids are then separated over a screen. The fat is refined to remove any fine particles of solids remaining. The solids are pressed to remove excess fat then milled to a free-flowing meal.

189. In either case, continuous or batch processes may be utilised. Depending on the grade, the fat can be used for pharmaceuticals, food, soap or stock feed. The meal can be used in the pet food and fertiliser industries (Australian Renderers Association Inc. 2014).

190. Vapours from the condenser and those collected by hoods over the cookers and presses within the plant should be ducted to a treatment system such as a biofilter or afterburner. All wastewater, including washdown water and condensate not reused in boilers, is directed to an effluent treatment system (NSW Environment Protection Authority 2003).

## Section 5 Parent organism

191. The parent organism of the GMO is *infectious laryngotracheitis virus* (ILTV). The ILTV strain, CSW-1, from which the GMO was derived, was originally isolated from the Glenfield, NSW outbreak in 1959.

192. ILTV is a member of the *Iltovirus* genus of the subfamily *Alphaherpesvirinae,* family *Herpesviridae*. ILTV is also known as *Gallid herpesvirus 1* (Thureen & Keeler 2006).

193. ILTV infects the trachea and conjunctiva causing respiratory disease and conjunctivitis in chickens, although pheasants, peafowl and turkeys can also be infected with ILTV (Crawshaw & Boycott 1982; Portz et al. 2008). The virus can establish latent infection in the neurons innervating the trachea and be re-activated by stress (Garcia et al. 2013; Hidalgo 2004; Ou & Giambrone 2012). ILTV does not infect humans or other animals.

194. ILT disease has been known to affect poultry for decades. ILT disease was first reported in 1925 in Canada, followed by the USA in 1926, Australia and Great Britain in 1935, and Europe in 1940. By 1962, the disease had been described in at least 40 countries across North and South America, Middle East, Africa, Australia and Asia (Agnew-Crumpton et al. 2016; Blacker et al. 2011; Menendez et al. 2014; Moreno et al. 2010; Sellers et al. 2004; Volkova et al. 2012; Linares et al. 1994).

195. ILT disease is notifiable under NSW (*Stock Diseases Act 1923*) and Victorian (*Livestock Disease Control Act 1994*) legislation, creating a legal obligation to notify authorities if an animal is known or suspected of having ILT disease.

196. There is no treatment for ILT disease. Vaccines are currently used to protect chickens from ILT disease. Two of the currently available live attenuated vaccines in Australia, A20 and SA2, were derived from an Australian ILTV strain. The Serva vaccine strain, also used in Australia, was derived from a European strain. These strains are able to recombine with each other and with wild type ILTV resulting in virulent ILTV that have caused outbreaks in Australia.

## 5.1 Basic Biology

197. ILTV has a linear double-stranded DNA genome approximately 155 kilo base pairs (kb) in length. The genome consists of unique long ($U_L$) and short ($U_S$) segments, and inverted repeats – internal repeat and terminal repeat (IR and TR). The IR and TR flank the $U_S$ region (see Figure 2) (Johnson et al. 1991). ILTV possesses three origins of viral DNA replication, one ($Ori_L$) located within the $U_L$ region, and two $Ori_S$ within the $U_S$ region (Fuchs et al. 2007).


**Figure 2. Organisation of ILTV genome**

Wild type ILTV genome organisation. IR: internal inverted repeat. ORI: origin of replication. $U_L$: unique long. $U_S$: unique short. TR: terminal inverted repeat.

198. The virus is comprised of four distinct structural elements: envelope, tegument, capsid and core. The lipid envelope contains glycoprotein spikes which are responsible for stimulating humoral and cell-mediated immune responses. ILTV encodes ten structural glycoproteins (Thureen & Keeler 2006). Contained within the envelope is the capsid, which surrounds the core comprising the viral DNA packed at high density without internal proteins. The region between the envelope and capsid is the tegument which contains more than 20 viral proteins likely to have important roles in modulating virus-host interactions. The size of the particle varies between 200 and 350 nm, since ILTV incorporates large but variable amounts of tegument proteins (Fuchs et al. 2007; Davison & Clements 2009).

199. Infection is initiated by attachment of virus glycoprotein to the cell membrane receptor, heparan sulphate, followed by fusion of the envelope with the host cell plasma membrane. Within the cell, viral DNA is released from the capsid and migrates into the nucleus through nuclear pores.

200. Transcription and replication of viral DNA occur within the nucleus but the viral DNA does not integrate into the host genome. Transcription of ILTV DNA occurs in a highly regulated, sequentially ordered cascade similar to that of other alphaherpesviruses. The first ILTV peptides are detectable at 4 hours after infection (Prideaux et al. 1992). Several of the virus-encoded proteins are enzymes and DNA-binding proteins that regulate viral DNA replication, but most are viral structural proteins. Viral DNA replication occurs by a rolling circle mechanism with the formation of concatemers which are cleaved into monomeric units and packaged into preformed capsids within the nucleus (Hidalgo 2004).

201. DNA-filled nucleocapsids acquire an envelope as they migrate through the nuclear membrane to the cytoplasm where the capsids associate with the tegument proteins. The nucleocapsids are re-enveloped in the Golgi region, followed by release of mature particles by exocytosis (Fuchs et al. 2007; Hidalgo 2004).

202. The natural route of entry for ILTV is through the upper respiratory tract and conjunctiva. Ingestion may be another mode of infection, although exposure of nasal epithelium following ingestion is necessary for infection (Garcia et al. 2013). ILTV infects the trachea and conjunctiva, but other tissues may be susceptible as well. The DNA of SA2 and A20 vaccine strains were detected by qPCR in the chicken's Harderian gland, lungs and kidneys over a 28 day period after oral administration of these vaccines (Roy et al. 2015). DNA of various ILTV strains including an ILTV vaccine were detected in the conjunctiva, sinuses, trachea, cecal tonsils, thymus and cloaca, with peak genome copy numbers detected at 4-5 days post-inoculation (Oldoni et al. 2009).

## 5.2 Host range

203. The chicken is the primary host and reservoir for ILTV. Natural infection has also been observed in pheasants and peafowl (Crawshaw & Boycott 1982). ILT disease and some mortality in peafowl and pheasants have been reported in a shed in Canada housing many bird species. ILT disease also occurred in Malay argus pheasants and chickens, but not in other species housed in the same shed including ocellated turkeys, Chinese painted quails, common guineafowls, fulvous tree ducks, African hornbills and several species of macaws and cockatoos (Crawshaw & Boycott 1982).

204. Turkeys are also naturally infected with ILTV, displaying clinical signs of nasal discharge, marked dyspnea, depression and tracheitis. Turkeys inoculated intratracheally with ILTV showed similar clinical signs of the disease (Portz et al. 2008).

205. Attempts to experimentally infect other birds such as ducks, starlings, sparrows, crows and pigeons have been largely unsuccessful (Beach 1931).

206. Ducks experimentally exposed to ILTV did not show signs of disease and appeared normal. However, neutralizing antibodies against the ILTV were detected 7 to 14 days after exposure. Growth of ILTV in embryonated duck eggs experimentally inoculated with ILTV was achieved (Yamada et al. 1980).

207. ILTV is not known to infect humans, other non-avian vertebrates and other organisms including invertebrates, plants, microorganisms and aquatic organisms.

## 5.3 Clinical signs

208. ILT is a viral respiratory tract infection which produces severe production losses due to decreased weight gain, decreased egg production and mortality of infected chickens. Clinical signs generally appear between 6-12 days following natural exposure (Hidalgo 2004; Bagust et al. 2000). Experimental inoculation of a live attenuated ILTV vaccine or wild type strains onto the eye and into the nostril of chickens results in clinical signs to appear between 3-12 days post-inoculation (Oldoni et al. 2009). Generally, most chickens recover in 10-14 days after clinical signs begin to appear, but it can take as long as 3 weeks in some cases (Garcia et al. 2013).

209. Characteristic clinical signs include marked dyspnea, nasal discharge, moist rales, coughing, gasping, sneezing, depression, swelling of infraorbital sinuses and conjunctivitis. In severe forms of the disease, signs also include laboured breathing and expectoration of blood-stained mucus. Birds die from this disease due to suffocation, as the windpipe becomes completely blocked. Mortality rate varies between 5-70%, with most in the range of 10-20%, but can be as high as 90-100% in severe cases (Garcia et al. 2013; Hidalgo 2004; Ou & Giambrone 2012).

## 5.4 Latency

210. Latency establishment after infection is the major biological survival mechanism of herpesviruses, enabling evasion of host immune surveillance. As is the case for other herpesviruses, ILTV establishes latent infections. The trigeminal ganglion is the main site of latency for ILTV. The trigeminal ganglion provides the main sensory innervation to the tissues of the upper respiratory tract including the trachea. In clinically recovered chickens infected with ILTV, ILTV DNA was detected by PCR in the trigeminal ganglion on 31, 46 and 61 days post-infection (Williams et al. 1992).

211. In addition, both CSW-1 ILTV and SA2 vaccine strain can readily establish long-term latent infections in the trachea. Chickens with latent infections that have recovered from ILT disease no longer showed signs of the disease. After treating latently infected chickens with immunosuppressive drugs, CSW-1 ILTV was reactivated 15 months after infection, while the SA2 strain can be reactivated up to 10 months post-infection and the virus was detected no earlier than 6 weeks after immunosuppressive drug treatment. Following reactivation, virus was re-isolated from tracheal samples of infected chickens. The ability of the CSW-1 and the SA2 strain to establish long-term latent infections allows infected chickens to become long-term carriers and may be a source of new infection following reactivation and resumption of shedding (Bagust 1986).

## 5.5 Shedding

212. ILTV is shed from infected birds in tracheal exudates. Virus shed in the trachea can be released into the environment by aerosolisation or expectoration of tracheal exudates. The rate and titres of virus shed can be increased in situations of stress such as egg laying (Bagust et al. 2000).

213. Chickens infected with wild type ILTV strains shed the virus from the conjunctiva, sinuses and trachea between 2 and 9 days post-inoculation. Shedding at these sites was detected by PCR and viral isolation using chicken kidney cells (Oldoni et al. 2009).

214. Shedding of two live attenuated ILTV vaccine DNA have been detected by PCR at various sites including the eye conjunctiva, trachea and cloaca from 2-14 days after chickens were vaccinated, and the cecal tonsils for up to 21 days post-vaccination. Peak genome copy numbers were detected from 4-6 days post-vaccination in the conjunctiva and trachea, declining to low genome copy numbers after that period. The virus was isolated from the conjunctiva and trachea from 2-6 days post-vaccination (Rodriguez-Avila et al. 2007). The DNA SA2 and A20 vaccine strains have been detected in faeces from 2-28 days post-vaccination, with a peak at 5 days post-vaccination (Roy et al. 2015).

## 5.6 Transmission

215. Transmission of ILTV can occur via contact with ILTV shed in tracheal exudates, contaminated inanimate objects such as equipment and clothing, contaminated litter, manure and infected carcasses. Egg transmission of the virus has not been demonstrated. The virus may spread by aerosol movement or wind (Garcia et al. 2013; Hidalgo 2004; Bagust et al. 2000).

216. Risk factors have been identified that may have led to outbreaks in broiler farms in Mississippi, USA during 2002-2003. Based on the responses to a retrospective survey questionnaire, the report found that farm suppliers such as gas company representatives, who are likely to visit farms, and farm workers who visit other chicken farms, are likely vehicles of ILTV introduction onto broiler farms. Sharing of equipment used to remove broiler litter between subsequent flocks may also serve as an

important vehicle of ILTV transmission. During the outbreak, shared litter removal equipment was associated with ILTV transmission despite a requirement being put in place for litter decontamination. Tunnel-ventilated broiler houses with inlets toward neighbouring poultry farm are likely to get infected with ILTV. The report suggested risk mitigation measures including following biosecurity procedures, showering and changing footwear prior to entering broiler houses on their own farm, and that practices such as wearing plastic boots or changing boots may be more effective than footbaths in preventing ILTV transmission (Volkova et al. 2012).

217. The larvae and adult darkling beetles (*Alphitobius diaperinus*) are prevalent in poultry facilities. These beetles consume feed, water, poultry carcasses and faeces. The beetles live in compacted earth and litter, and can damage poultry house structures. Chickens may consume beetles rather than feed. ILTV DNA and virus were detected in adult beetles and larvae taken from the farms up to 42 days after an ILTV outbreak in commercial poultry farms in the USA. Ingestion of ILTV-positive beetles could lead to infection of chickens and therefore may serve as a source of ILTV transmission. The study did not show that beetles were infected with ILTV (Ou et al. 2012).

## 5.7 ILTV vaccines

218. The vaccines now commonly used in commercial poultry flocks worldwide include attenuated live vaccines developed by consecutive passage of virulent virus in cell cultures (tissue culture origin [TCO]) or in embryonated hen eggs (chicken embryo origin [CEO]). Recombinant vaccines have also been produced using *herpesvirus of turkeys* (HVT) or *fowlpox virus* (FPV) modified to express ILTV glycoproteins that can elicit protective immune responses in vaccinated birds, and are now used commercially in some poultry-producing regions around the world (Coppo et al. 2013).

219. Currently in Australia, there are three APVMA registered vaccine strains against ILT: A20, SA2 and Serva vaccine strains. The three vaccines are live attenuated CEO vaccines.

220. The SA2 vaccine strain is an attenuated ILTV field strain of Australian origin. The A20 vaccine strain was produced by serial passages of the SA2 strain in primary chick embryo cell cultures and embryonated eggs in order to decrease its residual virulence. The Serva vaccine strain originated in Europe.

## 5.8 ILTV classes and recombination between types

221. Based on the data obtained from whole genome sequence analysis of the A20, SA2 and Serva vaccine strains, SA2 and A20 genomes are divergent from the Serva genome with only 99.2% of the sequence identical to Serva genome (Lee et al. 2011a; Lee et al. 2011b).

222. The genome size of CSW-1 ILTV strain (151,671 bp) is smaller compared with the Serva strain (153,645 bp) due to large deletions within the $U_L$ region and in both the internal and terminal inverted repeats (Lee et al. 2013).

223. Using the BLAST online tool (National Center for Biotechnology Information (NCBI) 2017), the nucleotide sequence identity of the whole genome of CSW-1 strain[2] was compared with other ILTV strains. The results showed that CSW-1 has 99.82% identity with the Serva[3], 99.70% identity with the SA2[4] and 99.69% identity with the A20 strain[5].

[2] (Genbank accession number: JX646899.1)
[3] (Genbank accession number: HQ630064)
[4] (Genbank accession number: JN596962.1)

224. Sequence analysis revealed that the UL21, 32, 34 and 43 genes of CSW-1, Serva and SA2 strains share 100% nucleotide and amino acid sequence identity (Lee et al. 2013). The ICP4, UL27, UL36, US5 and US8 genes showed the greatest nucleotide and amino acid sequence variability among the three ILTV strains. The phylogenetic relationships between CSW-1, SA2 and Serva strains vary depending on which gene was analysed.

225. ILTV strains can be categorised into different classes based on restriction fragment length polymorphism (RFLP) PCR of certain ILTV genes and genomic regions. ILTV strains with the same RFLP pattern were placed into one class. In Australia, this method has been used to identify ten different genotypes or classes of ILTV (Agnew-Crumpton et al. 2016; Blacker et al. 2011; Kirkpatrick et al. 2006).

226. The A20 and SA2 strains belong to class 1. ILTV classes 2, 3 and 5 comprise other strains isolated from outbreaks in commercial flocks in Australia and were found to be distinct from class 1. Class 4 comprises CSW-1 strain (Blacker et al. 2011; Kirkpatrick et al. 2006).

227. Class 7 corresponds to the Serva vaccine strain. ILTV classes 8 and 9 are phylogenetically close to class 7, indicating a close genetic relationship between these classes (Blacker et al. 2011). Furthermore, a comparative sequence analysis has revealed that class 8 is also largely similar to both A20 and SA2, while class 9 was derived from recombination between A20 and Serva strains. The results suggest that recombination occurred between the co-circulating A20, SA2 and Serva strains giving rise to class 8 and 9 (Lee et al. 2012).

228. Class 10 was isolated from Australian disease outbreaks in NSW in 2013. The samples used in this analysis were obtained mostly from commercial poultry flocks and a few backyard flocks. These flocks were vaccinated with one or a combination of the three available ILTV vaccines. Analyses of class 10 revealed a mosaic pattern, with some regions showing a high level of identity to specific field or vaccine strains of ILTV, while other regions were identical to a different field or vaccine strain. Class 10 shares genomic regions with classes 1, 7, 2 and 8 suggesting that class 10 may have emerged as a result of recombination events involving a previously recombined ILTV class (Agnew-Crumpton et al. 2016).

229. It is possible that recombination may have been facilitated by the conditions under which the ILTV vaccines were used, including using a combination of the three different ILTV vaccines on a single flock contrary to the APVMA approved directions for use[6], inappropriate use of the vaccines and the mass delivery of multiple vaccines to large numbers of intensively housed birds. This finding highlights the risk associated with the use of multiple attenuated ILT vaccines under conditions imposing high selective pressures, which may foster recombination between co-circulating viruses and selection of more virulent or transmissible progeny (Agnew-Crumpton et al. 2016; Coppo et al. 2013).

## 5.9 Recent outbreaks in Australia

230. ILTV outbreaks in chicken farms that commonly recur in Victoria and NSW have been caused by different classes of ILTV. From 2007 to 2009, ILTV class 2 was responsible for a large number of

[5] (Genbank accession number: JN596963.1)

[6] The APVMA takes into consideration the risk of recombination from the use of the viral vaccines. The product leaflets approved by the APVMA for the use of A20 and SA2 vaccine strains do not recommend concurrently using ILTV originating from genetically distinct strains in a flock or on a site.

outbreaks mainly in Victoria. Class 8 was responsible for the majority of outbreaks in NSW in the same period. However, class 4 (CSW-1) and 5 were not identified as causing outbreaks in NSW or Victoria during this period (Blacker et al. 2011).

231. Between 2009 and 2015, however, class 2 was very rarely detected and instead class 9 caused the largest number of ILTV outbreaks in Victoria. Since 2009, except for 2011, class 8 was replaced by class 9 as the predominant ILTV in Australia including NSW. Class 4 (CSW-1) was not identified as causing outbreaks in Australia between 2009 and 2015 (Agnew-Crumpton et al. 2016).

## 5.10 Environmental stability, decontamination methods

232. Survival of ILTV in different conditions varies depending on the amount of virus initially present, the medium in which it occurs, pH, temperature and exposure to light. At 13-23°C, ILTV in tracheal exudates survived up to 110 days in the dark, but this was reduced to 7 hours in direct sunlight. At 4-10°C in the dark, ILTV in the trachea of chicken carcasses survived for 30 days. At 4°C, ILTV survived in desiccated tracheal exudate for at least 24 years (Jordan 1966).

233. ILTV is sensitive to heat, ether, chloroform, and other lipolytic solvents. The virus was destroyed in 1 minute by treatment with 3% cresol or a 1% lye solution. Storage media containing glycerol or sterile skim milk greatly increases survival (Ou & Giambrone 2012).

234. ILTV vaccine DNA has been detected at high levels in dust from laboratory chicken cages at 28 days after inoculation of chickens with either A20 or SA2 vaccine. Litter samples from these laboratory chicken cages also contained ILTV vaccine DNA which was shed from the vaccinated chickens (Roy et al. 2015). However, the infectivity of the vaccine strains detected from dust and litter was not investigated.

235. Biofilms in drinking water lines have been suspected of being a source of ILTV in the field. A common method of administering ILTV vaccine is through the drinking water. After running ILTV vaccine mixed with water into lines and flushing the lines with tap water three times, ILTV vaccine DNA was still detected from the lines for up to 21 days. Chickens drinking from this water line tested positive for ILTV DNA up to 21 days after flushing with water. After the vaccine application and flushing with water, a sanitising solution was held for 24 hours in the water lines and then flushed with tap water. A comparison of the different sanitising solutions revealed that ILTV vaccine was not detected in the water lines after sanitising with sodium bisulfate (0.31 mL/L) or hydrogen peroxide (30 mL/L) solution. However, ILTV vaccine was still detected after treatment with citric acid (3.05 mL/L) or sodium hypochlorite (0.19 mL/L). Chickens tested positive for ILTV DNA after drinking from the water lines treated with citric acid or sodium hypochlorite, while they tested negative after sodium bisulfate or hydrogen peroxide (Ou et al. 2011).

236. After an ILT outbreak in California affecting over 50 chicken farms, it was shown that ILTV was no longer isolated from chickens introduced into the farms that employed a thorough decontamination regime. This regime involved heating the farm shed to a minimum of 37°C for 100 hours, thorough cleaning and disinfection of the farm facilities and all equipment, heating again to a minimum of 37°C for 100 hours and downtime of 21 days of not letting flocks into the farm (Chin et al. 2009).

237. Litter containing ILTV heated at 38°C for 24 hours in an oven or in a room, or composting for 120 hours resulted in failure to detect ILTV by PCR. Similarly, ILTV was not detected after addition of commercial litter treatment chemicals (e.g. aluminium sulphate (Al+Clear®)) that reduces ammonia and pH in litter (Giambrone et al. 2008).

# Section 6 The GMO – nature and effect of genetic modifications

## 6.1 The genetic modification

238. The wild type parent strain was originally derived from the virulent strain isolated from a field outbreak of ILT in Glenfield, NSW in 1959 (NSW virulent G strain). The virulent G strain was later renamed CSW-1 after about 10 passages in chicken kidney cell culture. The CSW-1 strain underwent a further three passages in chicken embryo kidney (CEK), then one passage in leghorn chicken liver tumour (LMH) cell line, and another passage in CEK cell line before the genetic modifications were carried out as described below.

239. The GMO is a live attenuated virus with a deletion of the gene encoding glycoprotein G (gG). The gG gene was removed by a series of targeted homologous recombination steps (Figure 3). Initially the gG gene was replaced with the enhanced green fluorescent protein (eGFP) gene, resulting in ΔgG(eGFP) ILTV. This eGFP gene was then removed from the ΔgG(eGFP) ILTV genome to create the GMO (ΔgG ILTV) (Devlin et al. 2006).

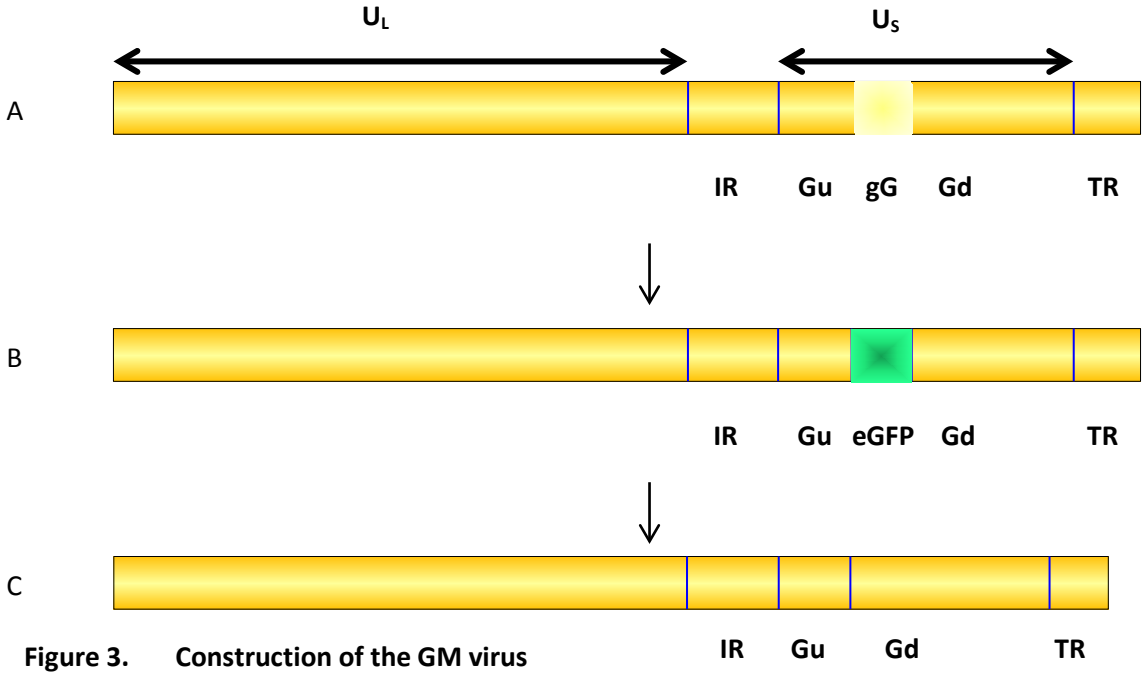


**Figure 3. Construction of the GM virus**

A. Wild type ILTV genome with gG gene flanked by upstream and downstream sequences.
B. gG was replaced with eGFP resulting in ΔgG(eGFP) ILTV.
C. eGFP was removed from ΔgG(eGFP) ILTV genome resulting in ΔgG ILTV (the GMO).

IR: internal inverted repeat. TR: terminal inverted repeat. gG: coding region of gG gene. Gu: US2, PK and UL47 genes upstream of gG. Gd: gJ, gD, gI, gE, and US9 genes downstream of gG. eGFP: enhanced green fluorescent protein.

240. The region of the GMO genome flanking the deletion was sequenced. The sequence data indicate that the gG transcription start and termination sequences are intact, and theoretically, transcription of an approximately 150 nucleotide mRNA could occur. As the translation initiation (ATG) codon remains in the transcript, this mRNA could theoretically result in the translation of a 27 amino acid non-functional protein corresponding to non-coding regions of the gG mRNA. The potential expression of the mRNA and protein has not been investigated.

241. Compared with the CSW-1 strain, the GMO also has a two base-pair deletion in the non-coding sequence four base pairs 5' to the initiation codon, and a single A to G transition in the non-coding sequence approximately 700 base pairs 5' to the initiation codon.

## 6.2 Glycoprotein G

242. Glycoprotein G is conserved in most members of the *Alphaherpesvirinae* subfamily. Glycoprotein G is secreted or anchored on the plasma membrane of the infected cell (Bryant et al. 2003). The role of gG appears to vary in different alphaherpesviruses. Studies on *equine herpesvirus* 1 and 4 (EHV-1 and 4) with gG deletion have shown that gG is not essential for virus growth *in vitro* (Huang et al. 2005). *Bovine herpesvirus* 1 (BHV-1) with an inactivated gG exhibited defects in plaque formation and reduced *in vitro* growth (Nakamichi et al. 2001). Furthermore, gG in BHV-1 facilitates viral cell-to-cell spread by maintaining cell-to-cell junctions of infected cells (Nakamichi et al. 2002). For *herpes simplex virus* (HSV), both gG and gC are required for efficient infection of the apical surfaces of corneal epithelial cells *in vitro* (Tran et al. 2000). For some herpes viruses, such as *Feline herpesvirus* 1 (FeHV-1), EHV-1 and BHV-1, gG functions as a virus-encoded chemokine binding protein (vCKBP) that prevents chemokines interacting with their cellular receptors. As a result, an advantage may be conferred to the virus by inhibiting chemokine-mediated inflammatory reactions (Bryant et al. 2003; Costes et al. 2005).

## 6.3 Characterisation of the GMO

### *6.3.1 In vitro studies*

243. Inoculation of LMH cells at a multiplicity of infection (MOI) of 0.002 showed no significant difference in the *in vitro* growth kinetics of the GMO and the CSW-1 parent strain, displaying peak titres at 4 days post-inoculation. The removal of gG did not affect transcription of the upstream and downstream sequences immediately adjacent to gG. The ability of the virus to spread cell-to-cell as measured in plaque assays was similar to CSW-1 (Devlin et al. 2006).

### *6.3.2 Virulence*

244. Attenuation of the GMO as a result of the gG gene deletion was demonstrated in a study by Devlin et al (2006). At 4 days post-inoculation, chickens inoculated with the GMO showed milder ILT disease symptoms and had greater weight gain compared to those inoculated with CSW-1 ILTV (Devlin et al. 2006).

245. Chickens inoculated with the GMO had similar titres of the virus isolated from the trachea as those inoculated with CSW-1 ILTV, suggesting that the capacity for *in vivo* replication was not affected by the loss of gG (Devlin et al. 2006).

246. Chickens inoculated with the GMO had greater tracheal mucosal thickness than those inoculated with CSW-1 ILTV. The increase in mucosal thickness is consistent with increased inflammatory cell infiltrate in the mucosa. This suggests that gG may play a role in influencing the inflammatory response at the site of ILTV infection (Devlin et al. 2006).

247. Mortality rates in chickens inoculated with the GMO were lower (2 out of 8) than for CSW-1 ILTV (5 out of 8) in this study (Devlin et al. 2006). In another study by the same group (Devlin et al. 2007), pathogenicity of the GMO was compared to that of the SA2 and A20 ILTV vaccine strains. In this study, mortality for chickens inoculated with the GMO (2 out of 8) was similar to that for the A20 strain (1 out of 8) at 21 days post-inoculation, and less than for the SA2 strain (7 out of 8 at day 8 post-inoculation, at which time this group was discontinued). Each chicken was inoculated with a similar dose of these strains. Based on these results, deletion of the gG gene results in a less virulent ILTV. It remains to be investigated whether gG functions as a virus-encoded chemokine binding protein.

### *6.3.3 Immunogenicity*

248. A study by Devlin et al (2007) investigated the protective immune response generated by the GMO. Chickens were first vaccinated with the GMO, then 28 days post-vaccination, they were challenged with a CSW-1 ILTV strain. Chickens previously inoculated with the GMO had significantly less severe clinical ILT signs and tracheal histopathology compared to chickens without prior inoculation. After challenge with wild type ILTV, greater weight gains were observed in chickens previously inoculated with the GMO compared to unvaccinated chickens. Using PCR and plaque assay

in LMH cells, no ILTV was detected in the trachea of previously vaccinated chickens four days after challenge with CSW-1 ILTV.

249. At 21 days after inoculation with the GMO without subsequent ILTV challenge, antibodies against ILTV were detected by ELISA in chickens inoculated with the GMO. Chickens inoculated with the A20 vaccine had significantly higher antibodies against ILTV compared to those inoculated with the GMO. However, the antibody titres were not considered by the authors to correlate with protection against ILT disease because local cell-mediated immune responses may be responsible for ILT disease protection (Devlin et al. 2007).

250. The protective immunity provided by the GMO was assessed in the laboratory by studying Transmission of the CSW-1 ILTV strain to chickens previously vaccinated with the GMO (Devlin et al. 2011). Chickens were first inoculated with the GMO (3000 PFU) 3 weeks before one chicken infected with the CSW-1 strain was introduced into the same cage. After 6 days of exposure, only one out of 30 vaccinated chickens tested positive for CSW-1 ILTV DNA. This suggests that wild type ILTV would not spread among vaccinated chickens.

### *6.3.4 Efficacy*

251. The efficacy of the GMO in protecting chickens after challenge with CSW-1 was compared with other live attenuated vaccine strains, A20, SA2 and Serva (Coppo et al. 2011). Each treatment group, comprising 20 or 21 chickens, was inoculated with the vaccine [dose at $10^{3.48}$ PFU (GMO), $10^{3.70}$ PFU (A20), $10^{4.10}$ PFU (SA2), $10^{2.50}$ median tissue culture infective dose (Serva)] 21 days prior to challenge with CSW-1 ILTV ($10^{3.65}$ PFU). Five days after challenge, chickens inoculated with the GMO displayed similar clinical ILT signs compared with the A20, SA2 and Serva group.

252. At 6 days after challenge, the chickens were sacrificed. Each chicken was weighed to calculate the weight gain, and tracheal histopathology was examined under the light microscope. The weight gain of chickens inoculated with A20 vaccine was the highest of all the groups, but the weight gains were similar between the SA2, Serva and the GMO. Tracheal histopathology was similar between the different vaccine groups (Coppo et al. 2011).

### *6.3.5 Transmission*

253. To study transmission of the GMO, chickens that had been inoculated with either the GMO or CSW-1 ILTV (4500 PFU) 4 days earlier were introduced into cages with naïve chickens (3 replicates of 10 naïve chickens for each ILTV strain) for 6 days. Across the three replicates, 8 of the 30 in-contact chickens became infected with the GMO, while 4 in-contact chickens became infected with the CSW-1 ILTV strain. In one replicate in each experimental group no transmission was observed, and transmission of the GMO and CSW-1 were not found to be statistically significantly different (Devlin et al. 2011).

### *6.3.6 Phenotype stability*

254. As a measure of the stability of the GMO's attenuated phenotype, weight was measured in naïve chickens before they were housed in the same cages as the GMO-inoculated chickens and at the end of the transmission study (Devlin et al. 2011). Weight gain of naïve, in-contact chickens that became infected with the GMO was similar to those of naïve, in-contact chickens that did not become infected. This suggests that after one *in vivo* passage in chickens, the GMO remained attenuated.

### *6.3.7 In vivo stability*

255. A study by Coppo et al (2011) took tracheal swabs from chickens inoculated with the GMO, A20, SA2 and Serva at 21 days post-inoculation to examine viral DNA presence using qPCR. GMO DNA was detected in 2 out of 21 chickens inoculated with the GMO at 21 days, with a mean of 2.17 $\log_{10}$ viral DNA copies in the trachea. Chickens inoculated with the A20 vaccine (9 out 19) had the lowest mean viral DNA copies (1.98 $\log_{10}$). Chickens inoculated with the SA2 vaccine (15 out 19) had the highest

mean viral DNA copies (2.95 $\log_{10}$), followed by the Serva vaccine (2.46 $\log_{10}$ in 9 out of 20 chickens). The results show that the commercial vaccine strains persisted longer at 21 days than the GMO.

# Section 7 Receiving environment

256. The receiving environment forms part of the context for assessing risks associated with dealings with GMOs. It informs the consideration of potential exposure pathways, including the likelihood of the GMOs spreading or persisting outside the site of release.

## 7.1 Site of release

257. The most likely route of administration of the GM vaccine would be via the drinking water system in commercial broiler chicken sheds as this is a more efficient way of vaccination than by eye drop. Even if the farm is free range, water would be provided inside the shed to minimise wild birds accessing water.

258. In the first phase of the field trial, only a few farms in Victoria that currently do not vaccinate against ILTV and are more isolated would be selected. In the second phase of the trial, more farms in NSW and Victoria would be selected in areas that have experienced previous ILTV outbreaks.

259. The routes by which the GMO may enter the wider environment include shedding of the GMO in tracheal exudates and faeces of vaccinated chickens.

## 7.2 Related viral species in the receiving environment

260. The presence of related viral species may offer an opportunity for genetic recombination in the environment.

261. Three live attenuated ILTV vaccines are registered for use in chicken farms in Australia. From 2007-2015, ILTV outbreaks in NSW and Victoria have been caused by different classes of ILTV including those originally derived from the vaccine strains (see Section 5.9). ILT disease continues to be a problem in Australia with recent reports of ILT disease in both backyard and commercial poultry in NSW and Victoria (NSW Department of Primary Industries 2016; Victoria Department of Economic Development 2017). Information about the ILTV classes seen in Australian outbreaks is provided in Section 5.9.

262. Another virus belonging to the subfamily *Alphaherpesvirinae* that commonly infects poultry including chickens are *Gallid herpesvirus* type 2 (Marek's disease virus). Marek's disease affects both commercial and backyard poultry and is endemic in Australia.

263. *Psittacid herpesvirus 1* (PsHV-1) also belongs to the *Iltovirus* genus in the subfamily *Alphaherpesvirinae*. PsHV-1 causes Pacheco's disease, an acute and potentially lethal respiratory infection in psittacine birds including macaws, parrots and cockatoos. Based on sequence analysis of PsHV-1 and ILTV, these viruses are relatively phylogenetically closely related. The similarity of their genomes suggests that they represent a class of avian alphaherpesviruses that diverged early from a common ancestor and are distinct from the Marek's disease virus (Thureen & Keeler 2006). However, PsHV-1 and ILTV do not share the same host species.

264. There are also several other avian herpesviruses known but the herpesviruses tend to be host-specific. It is unlikely that recombination between different species of herpesviruses occur.

## 7.3 Potential hosts in the environment

265. The potential for ILTV to infect other susceptible hosts that may be present at or near the proposed trial sites is taken into account in the risk assessment (Chapter 2). The primary host for ILTV is the chicken. ILT disease in turkeys, pheasants and peafowl are rarely reported (see Section 5.2).

Throughout its long history since its initial reports in various parts of the world, ILTV outbreaks have occurred mostly in chicken farms.

266. In Australia, chicken farms are usually separated by a large distance from other poultry farms and residential areas, and located in rural or semi-rural areas. State and local council requirements set separation distances between sheds and houses external to the farm.

267. Chickens and other birds are likely to be kept in backyards outside the required separation distances imposed by local councils and/or state governments.

268. For biosecurity reasons, poultry farms only keep birds used for production. Some chicken farms may also rear, grow and sell turkeys, pheasants or game birds commercially. If more than one species of birds are produced on the farm, these must be housed and managed separately with suitable biosecurity arrangements for each species (Department of Agriculture 2009).

269. Production sheds on farms are designed to exclude wild birds and various biosecurity measures are in place to minimise wild birds accessing the production areas.

270. Australia has feral chickens, turkeys, pheasants and peafowls, from the family *Phasianidae*. Feral peafowls are declared as pests in Kangaroo Island, South Australia (South Australia Department of Environment 2017). Australia also has 3 native species in the *Phasianidae* family (ABRS 2009), however their susceptibility to ILTV is unknown.

# Section 8 Previous authorisations

## 8.1 Australian authorisations

271. The APVMA has issued a permit for the use of the GM vaccine for research only. The GM vaccine has never been registered in Australia or elsewhere.

272. Work to develop the GMO in the laboratory including testing and preliminary experiments have been authorised under the Act as Notifiable Low Risk Dealings (NLRDs) conducted by the University of Melbourne and Royal Melbourne Institute of Technology (RMIT).

## 8.2 International authorisations and experience

273. No application for the use or marketing of the GMO has been submitted to overseas regulatory authorities.

# Chapter 2 **Risk Assessment**

## Section 1 Introduction

274. Risk assessment identifies and characterises risks to the health and safety of people or to the environment from dealings with GMOs (Figure 4). Risks are identified within the established risk context (see Chapter 1) and take into account current scientific and technical knowledge. Uncertainty and in particular, knowledge gaps, is considered throughout the risk assessment process.

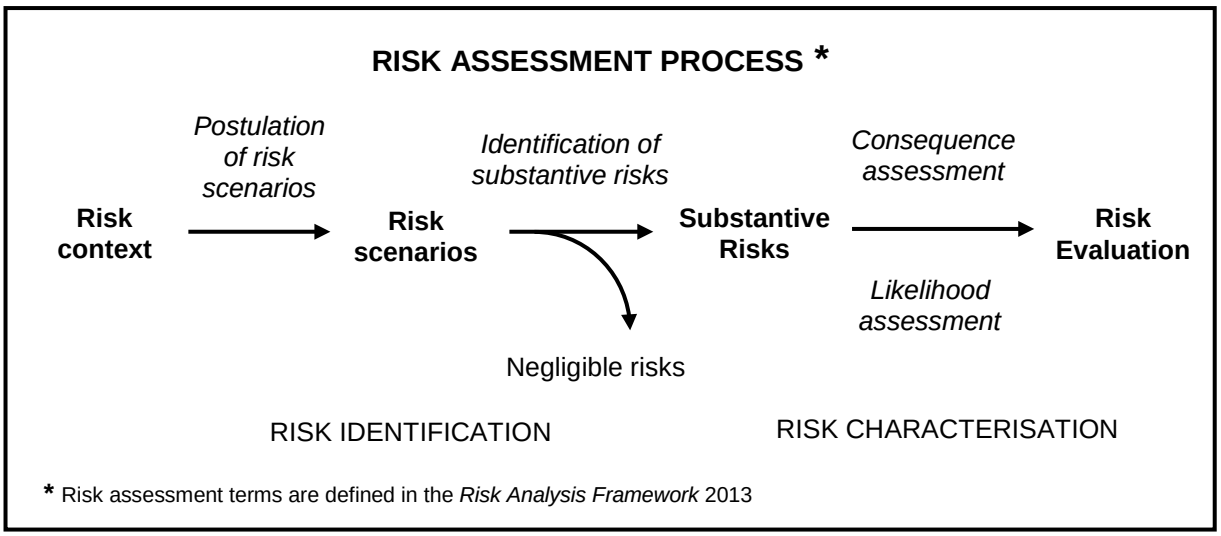


**Figure 4. The risk assessment process**

275. Risk identification first considers a wide range of circumstances whereby the GMO, or the introduced genetic material, could come into contact with people or the environment. Consideration of these circumstances leads to postulating plausible causal or exposure pathways whereby dealings with a GMO (risk scenarios) may, in the short and long term, harm people or the environment.

276. Postulated risk scenarios are screened to identify substantive risks that warrant detailed characterisation. Substantive risks are further assessed when a risk scenario is considered to have some reasonable chance of causing harm. Pathways that do not lead to harm, or could not plausibly occur, do not advance in the risk assessment process.

277. Risk identification techniques used by the Regulator and evaluators at the OGTR include checklists, brainstorming, reported international experience and consultation. In conjunction with these techniques, risk scenarios postulated in RARMPs prepared previously for licence applications of the same and similar GMOs are also considered.

278. Substantive risks (i.e. those identified for further assessment) are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). The level of risk is then estimated from a combination of the Consequence and Likelihood assessments. Risk evaluation then combines the Consequence and Likelihood assessments to determine level of risk and whether risk treatment measures are required. The potential for interactions between risks is also considered.

## Section 2 Risk Identification

279. Postulated risk scenarios are comprised of three components (Figure 5):

i. Source of potential harm (risk source)

ii. Plausible causal linkage to potential harm (causal pathway) and

iii. Potential harm to an object of value (people or the environment).

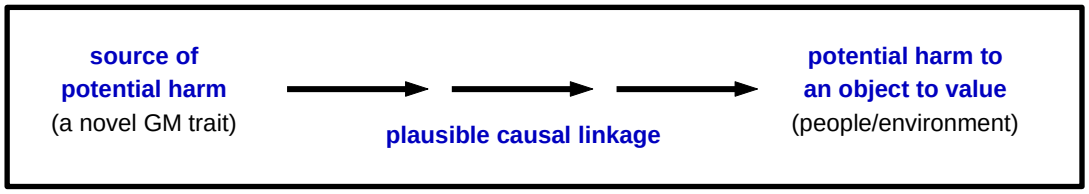


**Figure 5. Components of a risk scenario**

280. In addition, the following factors are taken into account when postulating relevant risk scenarios for this licence application:

- the proposed dealings, which are conduct experiments with the GMO, transport and disposal of the GMO, and possession (including storage), supply and use in the course of any of these dealings
- restrictions placed on conduct of the experiments with the GMO, transport and disposal of GMO by other regulatory agencies, the relevant States and local councils
- characteristics of the parent organism
- routes of exposure to the GMO
- potential for transmission
- potential exposure to the same gene from environmental sources
- the release environment and
- practices during and after administration of the GM vaccine including broiler farming practices.

281. The APVMA has assessed the environmental safety and trade risks associated with the research trial use of the GM vaccine under APVMA permit in accordance with the AgVet Code and have determined they are satisfied that the risks associated with the use of the vaccine are acceptable when used in accordance with the conditions on the permit and in conjunction with OGTR approval. . The APVMA has also considered the risk of recombination from the use of viral vaccines including the GM vaccine and requires that experiments be conducted to assess the ability of the GMO to recombine with other ILTV strains. The permit for the use of the GM vaccine addresses the following aspects:

- requirements for the directions for use, labelling, packaging, storage and disposal of the GMO, contaminated materials and equipment, and chicken carcasses to ensure the safety of birds including non-target birds by limiting the spread and persistence of the GMO.

282. The current assessment focuses on risks posed to the environment, including spread and persistence of the GMO beyond the field trials which may arise from inoculation of chickens, transport of live inoculated chickens, human and animal consumption of chickens, and transport and disposal of waste.

## 2.1 Postulated risk scenarios

283. Five risk scenarios were postulated, as summarised in Table 2. These risk scenarios were evaluated considering both short and long term effects, restrictions imposed by APVMA, the current state and local council requirements, and in the context of practices proposed by the applicant. Detailed evaluations of these scenarios are provided later in this section. None of the risk scenarios were identified as a risk that could be greater than negligible and warranting further scrutiny.

**Table 2 Summary of risk scenarios from dealings with GMO**

| # | Risk source | Causal pathway | Potential harm | Substantive risk? | Reason |
|---|---|---|---|---|---|
| 1 | GM ILTV vaccine | Exposure of people handling the GMO or GMO-treated chickens during rearing, transport, processing or disposal | Disease, toxicity or allergenicity | No | • ILTV has a very narrow host range, is not a human pathogen and is not expected to cause disease, toxicity or allergenicity in people<br>• ILTV is endemic in Australia but does not cause ill-health in people<br>• Other ILTV vaccines have a history of safe use with no adverse effects in people<br>• Vaccination would be conducted under the supervision of registered veterinarian<br>• Only trained personnel would be allowed to handle the GMO<br>• Handling procedures in poultry industry follow strict biosecurity measures<br>• Shedding of the GMO is expected to have ceased or declined to a very low level at the time of collection for processing<br>• Collection and transport of chickens to processing facilities minimise stress to protect animal welfare<br>• Processing facilities adhere to high standards of cleanliness and hygiene |

| # | Risk source | Causal pathway | Potential harm | Substantive risk? | Reason |
|---|---|---|---|---|---|
| 2 | GM ILTV vaccine | Exposure of people to the GMO when preparing or consuming meat from GMO-treated chickens | Disease, toxicity or allergenicity | No | • ILTV has a very narrow host range, is not a human pathogen and is not expected to cause disease, toxicity or allergenicity in people<br>• People are already exposed to meat that has come from chickens infected by ILTV strains or other ILTV vaccines, with no adverse effects<br>• Shedding of the GMO is expected to have ceased or declined to a very low level at the time of collection for processing<br>• Collection and transport of chickens to processing facilities minimise stress to protect animal welfare<br>• Processing plants employ hygiene and sanitation standards to ensure food safety as required by state authorities<br>• Chicken sold for human consumption lack the internal organs, gastrointestinal tract and head, which are the sites of infection of the GMO<br>• Cooking would destroy the GMO<br>• All food businesses in Australia are required to comply with the Food Safety Standards within the Food Standards Code, which includes cooking poultry thoroughly. |

| # | Risk source | Causal pathway | Potential harm | Substantive risk? | Reason |
|---|---|---|---|---|---|
| 3 | GM ILTV vaccine | Exposure of susceptible wild birds to the GMO<br>⬇<br>Exposed birds become infected and develop a protective immune response<br>⬇<br>Reduced infection with virulent ILTV strains<br>⬇<br>Increase numbers of feral/pest birds | Adverse impacts on desirable species | No | • ILTV has a very narrow host range<br>• Chickens, pheasants and turkeys are not major pests in Australia<br>• Vaccination would be conducted under the supervision of registered veterinarian<br>• Only trained personnel allowed to handle the GMO<br>• Vaccine spills would be disinfected<br>• Strict biosecurity measures are routinely exercised in chicken farms including free range farms<br>• Measures are in place to minimise wild birds accessing sheds and water tanks where vaccination is conducted<br>• APVMA requires management of potential carriers<br>• Contaminated equipment, materials and vehicles would be disinfected after use<br>• Storage and disposal of used litter, carcasses and other contaminated farm waste would be done according to local council and state requirements<br>• Local council and state requirements impose conditions to prevent contamination of water sources<br>• Titres of infectious virus shed are expected to be low, so feral or pest birds are unlikely to be challenged with a sufficient dose of GMO to induce a protective immune response<br>• A large number of feral or pest birds would have to be exposed to the GMO and develop a protective immune response to impact other species |

| # | Risk source | Causal pathway | Potential harm | Substantive risk? | Reason |
|---|---|---|---|---|---|
| 4 | GM ILTV vaccine | Chickens are co-infected with the GMO and another ILTV strain<br>⬇<br>Recombination between GMO and other strain<br>⬇<br>Generation of a new virulent ILTV strain<br>⬇<br>Infection of chickens and/or other susceptible avian species | Increased disease burden in chickens and other susceptible avian species | No | • APVMA requirements include not using any other ILTV vaccine in a flock inoculated with the GMO, not vaccinating unhealthy birds and isolating treated flocks from susceptible populations of chickens not included in the trials<br>• Flocks vaccinated with other registered live attenuated vaccines as active controls would be housed in separate sheds and managed separately<br>• After the treated chickens have been removed from the shed and before a new batch of chickens is introduced, the shed would be fully cleaned<br>• State requirements to separate broiler farms from other poultry farms and sensitive uses<br>• Strict high level biosecurity measures and notification requirements for ILT disease would limit the spread of a virulent strain to susceptible flocks |

| # | Risk source | Causal pathway | Potential harm | Substantive risk? | Reason |
|---|---|---|---|---|---|
| 5 | GM ILTV vaccine | Establishment of the GMO outside the trial limits<br>⬇<br>Exposure of people, animals and susceptible birds to the GMO leading to risk scenarios 1-4 | As per Risk scenarios 1-4 | No | • Transport and storage of the vaccine and samples would be in accordance with the PC2 Requirements of the Regulator's *Guidelines for Transport, Storage and Disposal of GMOs*<br>• Vaccine administration would take place in sheds<br>• All contaminated materials, equipment, sheds and vehicles would be disinfected after use<br>• APVMA requires disinfection of drinking system, cleaning of spills and management of potential carriers<br>• Strict biosecurity measures are routinely exercised in chicken farms including free range farms<br>• Collection and transport of chickens to processing facilities minimise stress to protect animal welfare<br>• Titres of infectious virus shed are expected to be low, so birds are unlikely to be challenged with a sufficient dose of GMO to induce a protective immune response<br>• Temporary storage of used litter and carcasses and disposal of contaminated farm waste would be done according to local council and state requirements<br>• Local council and state requirements that impose conditions to prevent contamination of water sources<br>• State requirements to separate broiler farms from other poultry farms and sensitive uses<br>• Survival of the GMO is low at ambient conditions and in sunlight |

### *2.1.1 Risk scenario 1 – Exposure of people to the GMO*

| | |
|---|---|
| *Risk source* | GM ILTV vaccine |
| *Causal pathway* | Exposure of people handling the GMO or GMO-treated chickens during rearing, transport, processing or disposal |
| *Potential harm* | Disease, toxicity or allergenicity |

**Risk source**

284. The source of potential harm for this postulated risk scenario is the GM ILTV vaccine strain.

**Causal Pathway**

285. There are a number of ways that people may be exposed to the GMO while undertaking the dealings as part of this field trial or during subsequent processing of the chickens in commercial facilities.

286. People may be exposed directly to the GM vaccine during transportation of the GM vaccine to the farms. The GM vaccine is supplied as a freeze-dried pellet in a glass vial which makes it unlikely to leak. The applicant proposes to double-contain the GM vaccine, and this is also a requirement of the APVMA permit. Transport and storage of the GM vaccine would be in accordance requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*. These measures would reduce the likelihood of exposure of people to the GMO during transport.

287. The extent of exposure to people would be limited during inoculation and handling of chickens to specific farms located in NSW and Victoria, and processing plants close to each trial farm.

288. Exposure to people may also occur via inhalation of aerosols or splash during preparation of the GMO for administration. The freeze-dried vaccine needs to be reconstituted in water and, if the vaccine is to be administered via drinking water, the reconstituted vaccine would be diluted in a mixture of water and skim milk powder. The APVMA permit requires the operator to wear eye protection and a mask while preparing and administering the GM vaccine. In the event of a spill of the prepared GMO, the APVMA permit also requires that the spill area be treated using disinfectant. The applicant additionally proposes that workers preparing the vaccine or cleaning spills would wear gloves.

289. Prior to inoculation, workers would be trained in handling, preparing and administering the GM vaccine. Inoculation would be conducted under the supervision of a registered veterinarian and the workers must follow the vaccine label, APVMA permit conditions and trial protocol(s). After administration of the GMO, the APVMA permit requires any unused vaccine to be rendered non-viable. All contaminated vials, eye droppers, bottles and other materials would be soaked in disinfectant prior to disposal in the normal waste bin. These measures would minimise the likelihood of exposure to the GMO.

290. Once the GM vaccine has been administered to the chickens, shedding of GMO into the environment is likely to occur for a limited time while the GMO is actively replicating. As discussed in Chapter 1, the GMO was detected in the trachea of chickens inoculated with the GMO up to 21 days, with high levels at 4 days post-inoculation (Coppo et al. 2011; Devlin et al. 2006). Studies have shown that chickens inoculated with wild type or other live attenuated ILTV vaccine strains shed the virus from 2 to 28 days post-inoculation, with peak shedding occurring from 4-6 days post-inoculation, then declining after that (Oldoni et al. 2009; Rodriguez-Avila et al. 2007; Roy et al. 2015). It is likely that the GMO would be shed for a similar period. Stress may re-activate the virus and lead to further shedding, however re-activation takes some time. When chickens that had recovered from infection with the SA2 vaccine strain were treated with immunosuppressive drugs, the virus was detected no earlier than 6 weeks after treatment (Bagust 1986). Any exposure to the GMO from treated chickens shedding it is likely to be lower than the dose intentionally administered to chickens.

291. Shedding of the GMO from treated chickens means that people working at or visiting the trial sites (sheds and free range fields) may be exposed to the GMO. This could occur when handling the GMO-treated chickens (alive or dead carcasses) or cleaning sheds, vehicles and equipment used on site, and moving litter or waste. Strict biosecurity measures are followed at broiler farms including free range farms (refer to Chapter 1, Section 4.5 for more information). All workers and visitors must wear overalls and high rubber boots before entering sheds. Hands and boots are disinfected before and after entering the sheds. Veterinarians conducting post-mortem examination wear gloves and overalls, and disinfect hands after examination. Disposal of farm waste such as litter and chicken carcasses must be done in accordance with the state and/or local council requirements. These measures would reduce exposure to the GMO, but some exposure is still expected.

292. People could be exposed to the GMO shed from treated chickens when collecting them from the farm, transporting them to processing facilities and when handling chickens at these facilities. Chickens are proposed to be inoculated with the GM vaccine at approximately 7 days old. Harvesting of broiler chickens usually commence from the age of 30-35 days. By the time the broiler chickens would be collected, shedding of the GMO is expected to have ceased or declined to a very low level.

293. After the chickens have recovered from ILT disease, the GMO may become latent, such that it can be reactivated by stressful situations and resume shedding. However chickens that are not fit for transport are removed before pick-up, so only healthy chickens are transported to processing facilities, and collection is usually conducted at night under dim light to minimise stress on chickens. Transport of live chickens to the processing facilities would be in accordance with the state legislation to protect their welfare and minimise stress during transport.

294. Disposal of chicken carcasses at rendering facilities is conducted in accordance with state or local council requirements, ensuring high standards of cleanliness and hygiene. Processing and rendering facilities, where slaughter of chickens is conducted, are highly automated with minimal direct manual contact with chickens, minimising worker exposure to any microbiological contaminants. The rendering process would destroy any GMOs that may still be present.

295. As discussed in Chapter 1, Section 5.10, ILTV has been shown to survive only 7 hours in direct sunlight at ambient temperatures but would survive much longer in the dark and at low temperatures. Stability of the GMO when shed by chickens has not been studied but is expected to be similar to wild type ILTV strains, and therefore would deteriorate over time in field conditions.

**Potential harm**

296. ILTV has a very narrow host range and is not a human pathogen. ILTV occurs naturally in the environment, and live attenuated ILTV vaccines are widely used in poultry, so people working in the poultry industry are currently exposed with no reports of disease, infection (clinical or subclinical), toxicity or allergic reactions.

297. The GMO does not contain any new genetic material and the sequence is highly similar to the parent ILTV strain, with one gene deleted. As discussed in Chapter 1, Section 6.1, sequencing of the region of the genome from which the gG gene was deleted indicates that there is a theoretical potential for a novel 150 nucleotide mRNA transcript from across the deletion site, encoding a 27 amino acid protein. The expression of these has not been investigated. As the genome sequences are not novel and exposure to the GMO is expected to be minimal, even if these products are expressed they are not expected to lead to any toxic or allergenic reactions. The small size of the potential protein makes it extremely unlikely to act as an allergen, as to elicit an allergic reaction a protein must contain at least two antibody binding sites, each 15 amino acids long, to facilitate cross-linking of antibodies. This gives a theoretical minimum size of approximately 30 amino acids (Huby et al. 2000).

**Conclusion**

298. Risk scenario 1 is not identified as a substantive risk because exposure is limited by standard industry handling and decontamination practices, including state-legislated practices, and the GMO is not expected to cause disease or other harms in people who are exposed. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

### *2.1.2 Risk scenario 2 – People consuming GM-vaccinated chickens*

| | |
|---|---|
| *Risk source* | GM ILTV vaccine |
| *Causal pathway* | Exposure of people to the GMO when preparing or consuming meat from GMO-treated chickens |
| *Potential harm* | Disease, toxicity or allergenicity |

**Risk source**

299. The source of potential harm for this postulated risk scenario is the GM ILTV vaccine strain.

**Causal Pathway**

300. It is proposed that broiler chickens treated with the GMO would enter the human food supply. Therefore people may be exposed to the GMO, or to material from the GMO, when preparing or consuming meat from GMO-treated chickens.

301. As discussed in Risk Scenario 1, shedding of the GMO is expected to have ceased or declined to a very low level by the time harvest of broiler chickens normally commences at 30-35 days of age. Shedding may resume in stressed chickens, however re-activation of shedding takes considerable time, and stress is minimised by only harvesting healthy chickens, usually collecting chickens at night under dim light, and by transport in accordance with the state legislation designed to protect animal welfare.

302. As discussed in Chapter 1, Section 5.1, tissues in which ILTV may be found include the trachea, conjunctiva and Harderian gland in the eye, sinuses, thymus, lungs, kidneys, cecal tonsils and cloaca. ILTV is not known to replicate in chicken skeletal muscle. The GMO is expected to be found in these same tissues as other ILTV strains during active infection.

303. Also as discussed in Chapter 1, Section 5.10, ILTV in the trachea of chicken carcasses has been documented to survive at low temperatures for 30 days (Jordan 1966). However, processing facilities adhere to high standards of cleanliness and hygiene to ensure food safety. Furthermore, chicken meat sold for human consumption lack the internal organs, gastrointestinal tract and the head where the GMO may be present. Overall, the practices employed from collection of live chickens at the farm, transport and processing would minimise any residual GMO in the chicken meat or products derived from treated chickens. Any trace amount of GMO present would not survive cooking. All food businesses in Australia are required to comply with the Food Safety Standards within the Food Standards Code, which specifies what steps food businesses must take to ensure food is handled safely, including cooking poultry thoroughly (FSANZ 2010). Therefore, exposure to any GMO while preparing or consuming GMO-treated chickens is highly unlikely.

**Potential harm**

304. As described in Risk Scenario 1, ILTV is not a human pathogen, and the GMO is not expected to cause toxicity or allergenicity in people.

**Conclusion**

305. Risk scenario 2 is not identified as a substantive risk because minimal, if any, exposure of people to the GMO from consumption of GMO-treated chickens is expected, and the GMO is not expected to cause disease or other harms in people who are exposed. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

### *2.1.3 Risk scenario 3 – Exposure of susceptible bird species to the GMO*

| | |
|---|---|
| *Risk source* | GM ILTV vaccine |
| *Causal pathway* | Exposure of susceptible wild birds<br>⬇<br>Exposed birds become infected and develop a protective immune response<br>⬇<br>Reduced infection with virulent ILTV strains<br>⬇<br>Increase numbers of feral/pest birds |
| *Potential harm* | Adverse impacts on desirable species in the environment |

**Risk source**

306. The source of potential harm for this postulated risk scenario is the GM ILTV vaccine strain.

**Causal Pathway**

307. There are several potential pathways by which susceptible feral/pest bird species could come into contact with the GMO. Birds could be exposed to the GMO through drinking water containing the GMO provided for treatment of chickens, through contact with spilt GMO or contaminated materials during disposal at the farm, by direct contact with vaccinated chickens, contact with other pests carrying the GMO (e.g. invertebrates), accessing areas used by treated chickens, drinking from surrounding waterways contaminated with the GMO, or via aerosols from a treated flock.

308. Vaccination of broiler chickens with the GM vaccine would be performed according to the trial protocol(s), APVMA permit conditions and label instructions. The GM vaccine would be administered inside a shed (this includes free range farms), most likely by drinking water. Sheds are designed to limit access by wild birds. When administered in drinking water, the GM vaccine would be provided in an amount of water calculated to be consumed within 3-4 hours, and no additional water would be supplied until all of the GMO-containing water had been consumed. After administration of the GM vaccine, the APVMA permit requires any unused vaccine to be rendered non-viable. The APVMA also requires that in the event of a spill, the area must be treated with disinfectant. All contaminated bottles, vials, eye droppers, and other materials would be soaked in disinfectant prior to disposal in the normal waste bin at the farm. These measures would greatly minimise the potential for exposure of feral/pest birds to the GMO prepared for treatment.

309. As discussed in Chapter 1, Section 6.3, chickens treated with the GMO can transmit the GMO to other chickens in close physical contact. The proposed field trials would study transmission of the GMO in the field.

310. It is possible that susceptible feral/pest birds could have access to production areas, particularly free range fields containing GMO-treated chickens. However, as discussed in Chapter 1, Section 5.10, ILTV does not survive well at ambient temperatures or when exposed to sunlight. For example, ILTV in tracheal exudates survived for 7 hours in direct sunlight (Jordan 1966). Therefore exposure to viable GM virus would be low and only likely when treated chickens are present or for a short period afterwards. The APVMA permit requires that populations of wild birds and potential carriers, such as rodents and beetles, to be managed. Furthermore, current biosecurity measures require all broiler farms to control and manage vermin or pests at the farm, and to restrict access of wild birds to the production area including sheds or housing, water and feed. Sheds would be cleaned and decontaminated after removal of GMO-treated chickens. These measures would reduce the opportunity for exposure of wild susceptible birds to the GMO.

311. Susceptible feral/pest birds could be exposed to the GMO at disposal sites containing contaminated farm waste at the farm or off-site. Used litter and chicken carcasses may be temporarily

stored at the farm prior to disposal. Transport of litter and carcasses would be in a covered truck to prevent dispersal. Temporary storage of used litter prior to disposal would be covered with clean co-compost material and a tarpaulin, and chicken carcasses would be temporarily stored in a freezer. There are state and local council requirements for the temporary storage of chicken carcasses and used litter to minimise the spread of pathogens.

312. Disposal of contaminated farm waste, including litter, manure and chicken carcasses are conducted according to state and local council requirements (see Chapter 1, Section 4.6 for more information). Such waste may be disposed of at the farm by composting or burial, or taken off-site to a landfill or a commercial composting facility or, for carcasses, to a rendering facility. Compost in piles or open windrows is covered with at least 300 mm thickness of clean co-compost material to exclude birds accessing the litter and carcasses. Studies have shown that composting for 120 hours or heating litter to 38°C for 24 hours renders ILTV undetectable by the highly sensitive PCR method (Giambrone et al. 2008). Burial at the farm is uncommon but if conducted, waste would be covered by at least 2 m of soil. Landfills are required to cover the carcasses daily with at least 150 - 300 mm of soil or other material. There are a number of state requirements to minimise access of vermin including birds at these disposal sites. These measures would reduce exposure of susceptible feral/pest birds to the GMO at these waste storage or disposal sites.

313. Waste or stormwater run-off from sheds, outdoor areas used by GMO-treated chickens or waste disposal areas may be contaminated with the GMO, leading to contamination of various water sources used by susceptible feral or pest birds. However, as discussed in Chapter 1, local councils and state authorities have a number of regulations to ensure that water sources and catchment areas are not contaminated with run-off from the waste facilities, disposal sites and poultry farms.

314. ILTV may also be spread by aerosols. As indicated in Chapter 1, Section 5.10, ILTV can be spread between nearby commercial poultry shed by air movement, particularly when tunnel ventilation is used. The capacity for transmission of the GMO has not been assessed in the field, however aerosols may also lead to infection of other birds close to sheds housing GMO-treated chickens. Transmission to wild birds is expected to be less likely than transmission to a nearby shed employing tunnel ventilation because susceptible birds are not expected to be present in high numbers or densities, and would not remain in one place such that prolonged exposure may occur, particularly during the day when chickens in the shed would be active and therefore shedding would be highest.

315. Susceptible birds exposed to the GMO may become infected. The minimum infective dose of the GMO has not been determined. A bird that has been infected with the GMO and recovered may be protected from later infection by another ILTV strain.

316. As discussed in Chapter 1, Section 5.2, ILTV has a very narrow host range, with the chicken being the primary host and reservoir, and the only other bird species observed to be naturally infected by ILTV are pheasants, peafowl and turkeys, all members of the family *Phasianidae* (Crawshaw & Boycott 1982; Portz et al. 2008).

**Potential harm**

317. As discussed in Chapter 1, Section 6.3, the GMO has been shown to cause milder ILT disease in chickens and a lower death rate than the parent ILTV strain (Devlin et al. 2006). Furthermore, chickens inoculated with the GMO did not become infected with the CSW-1 ILTV strain when later exposed (Devlin et al. 2011). Susceptible birds that were unintentionally infected with the GMO may similarly be protected from other virulent ILTV strains present in the field. This may lead to increased survival of pest birds that have been exposed to the GMO, particularly during an ILTV outbreak. Increased numbers of pest birds in the environment could adversely impact other, desirable, species.

318. For this scenario to lead to harm to the environment, a large number of feral or pest birds would have to become infected with the GMO, and ILTV would need to be an important factor limiting the pest bird population. However, as discussed above, ILTV has a very narrow host range limited to

chickens, pheasants, peafowls and turkeys, which are not significant pests in mainland Australia and not found in large numbers near commercial broiler farms.

**Conclusion**

319. Risk scenario 3 is not identified as a substantive risk because unintentional exposure of susceptible feral or pest birds to the GMO is expected to be low and the potential harm to the environment from unintentional exposure is minimal as susceptible species are not significant pests. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

### *2.1.4 Risk scenario 4 – Recombination between GMO and viruses*

| | |
|---|---|
| *Risk source* | GM ILTV vaccine |
| *Causal pathway* | Chickens are co-infected with the GMO and another ILTV strain<br>⬇<br>Recombination between the GMO and other strain<br>⬇<br>Generation of a new virulent ILTV strain<br>⬇<br>Infection of chickens and/or other susceptible avian species |
| *Potential harm* | Increased disease burden in chickens and other susceptible avian species |

**Risk source**

320. The source of potential harm for this postulated risk scenario is the GM ILTV vaccine strain.

**Causal Pathway**

321. The probability of recombination occurring in viruses is dependent on co-circulation of different viruses in the same geographical area, genetic similarity between the viruses, rate of co-infection of a host with both viruses and viral population size within the infected host.

322. As discussed in Chapter 1, Section 5.8, ILTV is endemic in Australia with different classes of ILTV circulating in NSW and Victoria, and there are three registered live attenuated ILTV vaccine strains (ie. SA2, A20 and Serva) currently used. New classes of ILTV that have caused outbreaks in Australian in recent years may have resulted from recombination between wild type ILTV and ILTV vaccine strains (Agnew-Crumpton et al. 2016; Blacker et al. 2011; Lee et al. 2012). Therefore, co-infection of a host cell by different ILTV strains does occur, however recombination may have been facilitated by using a combination of the three ILTV vaccines on a single flock (Agnew-Crumpton et al. 2016; Coppo et al. 2013).

323. At the trial sites, GM-vaccinated broiler chickens may be inadvertently exposed to circulating ILTV. However, the APVMA permit only allows the GMO to be given to healthy chickens, all chickens in a treated flock must receive the GMO, vaccination of the same flock with another type of ILTV vaccine is not permitted and treated flocks must be isolated from susceptible populations of chickens that are not involved in the trial. Flocks treated with the GMO are expected to develop protective immunity to other ILTV strains. In addition, biosecurity measures would also minimise the likelihood of exposure of GMO-treated chickens to other ILTV strains circulating in the environment during the trial. This would reduce the likelihood of co-infection and recombination with other ILTV strains.

324. During the trials, where a broiler farm has multiple sheds, different flocks in different sheds may be given the GMO or another ILTV vaccine, or remain unvaccinated. Each shed would be clearly identified and managed separately. To avoid cross-contamination, people entering/exiting sheds must disinfect hands and boots, movement of people and vehicles would be controlled and all contaminated

equipment must be disinfected after use. This would reduce the likelihood of co-infection of broiler chickens at the trial sites with different vaccine strains.

325. After one flock of GMO-treated chickens has been removed from a shed and before a new flock is introduced, the shed would be fully cleaned and disinfected to avoid unintentionally infecting the new flock with the GMO. As discussed in Risk Scenarios 1, 2 and 3, the controls proposed by the applicant, the APVMA permit conditions, local council and state requirements and the strict biosecurity measures employed at broiler farms would minimise the likelihood of unintentional exposure of chickens to the GMO. Furthermore, local council and/or state authorities require broiler farms including free range farms to be physically separated from other poultry farms and residential areas. These would reduce the potential for co-infection of chickens, including those in other poultry farms or backyards, with the GMO and other ILTV strains, thereby minimising the potential for recombination.

**Potential harm**

326. Recombination between the GMO and another ILTV strain could result in viral progeny having any permutation of genomic segments of the two parent strains. Recombination could produce a less, similar or more virulent phenotype than either parent strain.

327. The CSW-1 strain is derived from an Australian field isolate from 1959, so is not novel to Australia. The class of ILTV to which CSW-1 belongs has not been identified in recent outbreaks, so it is not clear if it is currently circulating. However, it has been prevalent in the past and is likely to have contributed to the genetic makeup of current strains through past recombinations, so it is not expected to add a significant level of genetic variation to the current pool of circulating viruses. Comparison of the full genomic sequences of CSW-1 to the other live attenuated ILTV vaccine strains reveals that they are between 99.69% and 99.82% identical. The GMO does not contain any novel sequences or genes, with the only modification being deletion of the gG gene. Any recombinant carrying the gG gene deletion is expected to retain the associated attenuated phenotype of the GMO. These factors make the likely outcome of any recombination between the GMO and another ILTV strain to be a virus of similar or lower virulence than the other strain involved.

328. The APVMA requires that experiments be conducted to assess the ability of the GM vaccine to recombine with other ILTV strains. This would be taken into consideration by the APVMA in assessing the risks of using the GM vaccine.

329. In the unlikely event of a novel virulent ILTV strain arising from recombination between the GMO and another ILTV strain within a farm participating in the trial, the opportunity for it to spread to other susceptible birds would be restricted by higher level of biosecurity measures and notification requirements for ILT disease.

**Conclusion**

330. Risk Scenario 4 is not identified as a substantive risk as the opportunity for recombination is restricted by the biosecurity measures employed and recombination between the GMO and another ILTV strain is expected to result in a virus of less or similar virulence than the current circulating ILTV strains. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

### *2.1.5 Risk scenario 5 – Spread and Persistence of the GMO*

| | |
|---|---|
| *Risk source* | GM ILTV vaccine |
| *Causal pathway* | Establishment of the GMO outside the trial limits<br>⬇<br>Exposure of people, animals and susceptible birds to the GMO leading to risk scenarios 1-4 |
| *Potential harm* | As per risk scenarios 1-4 |

**Risk source**

331. The source of potential harm for this postulated risk scenario is the GM ILTV vaccine strain.

**Causal Pathway**

332. The GMO could be dispersed in the wider environment via pathways discussed in Risk Scenarios 1-4, and may persist in the environment if it is able to establish an infection cycle in susceptible wild birds or farmed poultry.

333. As discussed for these scenarios, the limits and controls proposed by the applicant, APVMA permit conditions, biosecurity measures, and local council and state requirements would limit the dispersal of the GMO in the environment. For the GMO to establish it must be able to be transmitted efficiently between flocks. The capacity of the GMO to be transmitted between birds in close contact has been demonstrated in the laboratory, however transmission has not been assessed in the field.

334. Establishment of the GMO in the wider environment may lead to ongoing exposure of susceptible birds in the wild, commercial or backyard poultry, other animals and people beyond the trial limits.

**Potential harm**

335. If the GMO were to establish outside of the trial limits, ongoing exposure is not expected to cause harm to people or the environment. The GMO is less virulent than circulating ILTV strains, so would cause less-severe disease in exposed susceptible birds than these strains. Other potential harms are not expected to be significant for the reasons discussed in risk scenarios 1-4.

**Conclusion**

336. Risk scenario 5 is not identified as a substantive risk because spread of the GMO outside the trial limits would be minimised by the limits and controls proposed by the applicant, State, local council and APVMA requirements, and no significant adverse effects from the GMO have been identified. Therefore, this risk could not be greater than negligible and does not warrant further detailed assessment.

## Section 3 Uncertainty

337. Uncertainty is an intrinsic part of risk analysis[7]. There can be uncertainty in identifying the risk source, the causal linkage to harm, the type and degree of harm, the likelihood of harm or the level of risk. In relation to risk management, there can be uncertainty about the effectiveness, efficiency and practicality of controls.

[7] A more detailed discussion is contained in the Regulator's *Risk Analysis Framework* available from the OGTR website or via Free call 1800 181 030.

338. Risk analysis can be considered as part of a structured, transparent process to analyse and address uncertainty when identifying, characterising and evaluating risk (first tier uncertainty analysis). However, residual uncertainty always remains and if it is critical to decision making, it could be further analysed (second tier uncertainty analysis) through building 'worst case' scenarios, or by combining results from several studies (meta-analysis).

339. There are several types of uncertainty in risk analysis (Bammer & Smithson 2008; Clark & Brinkley 2001; Hayes 2004). These include:

- uncertainty about facts:
  - knowledge – data gaps, errors, small sample size, use of surrogate data
  - variability – inherent fluctuations or differences over time, space or group, associated with diversity and heterogeneity
- uncertainty about ideas:
  - description – expression of ideas with symbols, language or models can be subject to vagueness, ambiguity, context dependence, indeterminacy or under-specificity
  - perception – processing and interpreting risk is shaped by our mental processes and social/cultural circumstances, which vary between individuals and over time.

340. Uncertainty is addressed by approaches such as balance of evidence, conservative assumptions, and applying risk management measures that reduce the potential for risk scenarios involving uncertainty to lead to harm. If there is residual uncertainty that is important to estimating the level of risk, the Regulator will take this uncertainty into account in making decisions.

341. As field trials of GMOs are designed to gather data, there are generally data gaps when assessing the risks of a field trial application. However, field trial applications are required to be limited and controlled. Even if there is uncertainty about the characteristics of a GMO, limits and controls restrict exposure to the GMO, and thus decrease the likelihood of harm.

342. For DIR 154, uncertainty is noted particularly in relation to:

- the degree of attenuation of the GMO under field conditions
- the level of shedding of infectious GMO from inoculated chickens
- the ability of the GMO to be transmitted from inoculated chickens to other chickens or other birds in the natural environment
- the ability to the GMO to establish an infection cycle and persist in the environment.

343. These areas of uncertainty have been accommodated in the risk assessment by assuming that shedding, transmission and persistence may be equal to other ILTV strains which are able to spread and persist in the environment. Accommodating this uncertainty resulted in an estimate of risk of negligible.

344. Additional data, including information to address these uncertainties, may be required to assess possible future applications with reduced limits and controls, such as a commercial release of the GMO.

## Section 4 Risk evaluation

345. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

346. Factors used to determine which risks need treatment may include:

- risk criteria

- level of risk
- uncertainty associated with risk characterisation
- interactions between substantive risks.

347. Five risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. In the context of the current release sites, limits and controls proposed by the applicant, the APVMA permit conditions, biosecurity measures, local council and state requirements, and considering both the short and long term consequences, none of these scenarios were identified as substantive risks. The principal reasons for these conclusions are summarised in Table 2 and include:

- attenuated phenotype of the GMO
- ILTV's limited host range
- APVMA permit conditions for the use of GM vaccine
- local council and state requirements for broiler farms, processing and rendering facilities, and waste disposal
- suitability of the controls proposed by the applicant.

348. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GMO into the environment are considered to be negligible. The Risk Analysis Framework, which guides the risk assessment and risk management process, defines negligible risks as risks of no discernible concern with no present need to invoke actions for mitigation. Therefore, no controls are required to treat these negligible risks. Hence, the Regulator considers that the dealings involved in this proposed release do not pose a significant risk to either people or the environment[8].

[8] As none of the proposed dealings are considered to pose a significant risk to people or the environment, Section 52(2)(d)(ii) of the Act mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator has allowed up to 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

# Chapter 3 **Risk management plan**

## Section 1 Background

349. 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 addresses risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through licence conditions.

350. Under Section 56 of the Act, the Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

351. All licences are subject to three conditions prescribed in the Act. Section 63 of the Act requires that each licence holder inform relevant people of their obligations under the licence. The other statutory conditions allow the Regulator to maintain oversight of licensed dealings: Section 64 requires the licence holder to provide access to premises to OGTR inspectors and Section 65 requires the licence holder to report any information about risks or unintended effects of the dealing to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder are also required to be reported to the Regulator.

352. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in Section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under Section 152 of the Act.

## Section 2 Risk treatment measures for substantive risks

353. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people and the environment from the proposed trial of the GM vaccine. These risk scenarios were considered in the context of the scale of the proposed release and the proposed containment measures (which include standard industry practice, APVMA permit conditions, and state and local requirements), and considering both the short and the long term. The risk evaluation concluded that no specific risk treatment measures are required to treat these negligible risks. Limits and controls proposed by the applicant and other general risk management measures are discussed below.

## Section 3 General risk management

354. The limits and controls proposed in the application were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and the environment are negligible. Therefore, to maintain the risk context, licence conditions have been drafted to limit the release to the proposed size, location and duration, and to restrict the spread and persistence of the GMO and its genetic material in the environment. The conditions are discussed and summarised in this Chapter and listed in detail in Chapter 4 (the draft licence).

### 3.1 Draft licence conditions to limit and control the release

#### *3.1.1 Consideration of limits and controls proposed by Bioproperties*

355. Chapter 1 provide details of the limits and controls proposed by Bioproperties in their application. Many of these are discussed in the five risk scenarios characterised for the proposed release in Chapter 2. The appropriateness of these controls is considered further below.

356. The applicant proposes that a maximum of 40 broiler chicken farms would be included in the field trials in NSW and Victoria and the duration of the field trials would be limited to five years. The

applicant proposes inoculating up to 2 million broiler chickens, and would exclude layers and breeders. Access to the farms participating in the trial would be controlled. These measures would limit the potential exposure of humans and other organisms to the GMO (Risk scenarios 1, 2 and 3), and are included in the draft licence.

357. The APVMA permit for the GM vaccine requires the operator to wear eye protection and a mask while preparing and administering the GM vaccine, which would reduce the likelihood of the GM vaccine entering a person's eyes and mouth as well as being inhaled. The applicant also proposes that workers preparing the GM vaccine would wear gloves (Risk scenario 1). These measures would reduce exposure of workers to the GMO and are included in the draft licence. Additionally, vaccination would be conducted by trained farm workers under the supervision of a registered veterinarian, ensuring that workers handle the GM vaccine appropriately.

358. The applicant has stated that the administration age of the chickens being inoculated is approximately 7 days old. As discussed in Chapter 1, live attenuated ILT vaccines can be shed from chickens for up to 28 days post-inoculation, with peak shedding occurring within the first week. To minimise the exposure of people outside the trial areas to the GMO (Risk scenarios 1 and 2) and the potential for dispersal of the GMO (Risk scenarios 3 and 5), a condition has been included in the draft licence which prohibits the harvesting of GMO-treated chickens within 28 days of inoculation with the GMO. This would ensure minimal shedding of the GMO at harvest.

359. The APVMA permit only allows the GM vaccine to be given to healthy chickens, vaccination with any other ILTV vaccine is not permitted and requires GMO-treated chickens to be isolated and all chickens in the flock to be vaccinated with the GM vaccine (Risk scenario 4). If a farm has multiple sheds and each shed may be vaccinated with different ILTV vaccines, the applicant proposes that each shed would be managed separately, people must disinfect their hands and boots when entering/exiting the shed, movement of people would be controlled and contaminated equipment disinfected after use. These measures would reduce the potential for recombination. The draft licence has conditions including segregating GMO-treated chickens from all other poultry and requires that a Compliance Management Plan, addressing cross-contamination and segregation of treated flocks, be provided to the Regulator.

360. The GMO-treated chicken would be confined to sheds, and if relevant, to free range fields until the time of harvest. Effective containment of live GMO-treated chickens as well as employing biosecurity measures at the trial areas would reduce exposure of susceptible birds to the GMO and dispersal of the GMO in the environment (Risk scenarios 3, 4 and 5). Conditions are included in the draft licence requiring that experimentation with the GMO, GMO-treated chickens or samples may only be undertaken within a trial area, and a contingency plan addressing any escape or predation of GMO-treated chickens be provided to the Regulator.

361. Strict biosecurity and waste management measures as well as other effective broiler farm management are routinely applied in broiler farms to minimise pathogen occurrence and spread, and to protect people and the environment. Many measures are required under State legislation, local council regulations or the APVMA permit relevant to this trial. These measures combined minimise exposure to, and dispersal of, the GMO and are discussed in detail below.

362. State legislation and local council requirements stipulate various proximity distances of broiler farms or disposal sites to water sources (Risk scenarios 3 and 5). Therefore, draft licence conditions require the trial areas to be at least 50 m from waterways (notwithstanding requirements of state and council regulations). A draft licence condition has also been included requiring immediate notification of any extreme weather conditions affecting the trial area to allow assessment and management of any risks.

363. Decontamination measures for people, sheds and equipment are proposed by the applicant. For people, this includes supplying and wearing overalls and high rubber boots to all shed visitors and workers, and disinfecting hands and boots when entering and exiting the shed. All equipment and

materials contaminated with the GMO such as bottles, vials, droppers and other GMO-contaminated materials would be disinfected after use. Vehicles and equipment used during transport would be disinfected after use. Litter and dead chickens would be disposed of by composting, burial, rendering or landfill following State/Territory and/or local council requirements. These measures would limit spread and persistence of the GMO (Risk scenario 5). The draft licence requires that a Compliance Management Plan, addressing decontamination measures and entry/exit procedures, be provided to the Regulator.

364. The APVMA permit states 'the shed and litter are to be treated between flocks in a manner which is effective against the vaccine virus'. To minimise spread and persistence of the GMO, conditions have been proposed in the draft licence requiring decontaminating sheds between batches of chickens and not permitting the re-use of litter.

365. The APVMA permit has a requirement to manage pests that are potential carriers of the GMO (e.g. dogs, cats, rodents, wild birds and darkling beetles). This would minimise the transmission of the GMO to susceptible feral/pest birds (Risk Scenario 3) and spread of the GMO in the environment (Risk Scenario 5). The draft licence requires that a Compliance Management Plan, addressing pest, vermin and wild bird management, be provided to the Regulator.

366. Live GMO-treated chickens would be transported to processing facilities as well as to laboratories for analysis. Transport to processing facilities would be in accordance with the relevant state legislation, which includes use of ventilated crates and transport in an open truck. GMO-treated chickens may be transported to research facilities for further study. The draft licence requires that a Compliance Management Plan, addressing collection and transport of live GMO-treated chickens, be provided to the Regulator.

367. The GM vaccine and samples containing the GMO (excluding live GMO-treated chickens) would be transported and stored according to the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*. These are standard protocols for the handling of GMOs to minimise exposure to the GMOs (Risk Scenarios 1 and 3), and dispersal into the environment (Risk Scenario 5). The draft licence requires that transport and storage of the GM vaccine and samples be in accordance with the Guidelines.

368. The applicant proposes to destroy any GMO-treated chickens not required for experimentation or transported to processing facilities. This would minimise the spread and persistence of the GMO (Risk scenario 5), and has been included in the draft licence.

369. If a licence were issued, Bioproperties would be required to submit a Compliance Management Plan to the Regulator before dealing with the GMO. This plan would detail how the licence holder intends to comply with the licence conditions, including decontamination processes and compliance with State, local council and industry requirements/guidelines.

### *3.1.2 Summary of draft licence conditions to be implemented to limit and control the release*

370. A number of licence conditions have been drafted to limit and control the proposed release, based on the above considerations. These include requirements to:

- limit the field trials to a maximum of 40 farms in NSW and Victoria, from the date of licence issue to August 2022
- locate the trial sites at least 50 m away from waterways
- prohibit the harvesting of GMO inoculated chickens within 28 days of inoculation
- manage pests, vermin and other animals
- decontaminate all sheds and equipment that have been contaminated with the GMO and peoples' hands and footwear upon exit of shed or range
- not allow the use of other vaccines against ILTV in GMO-treated chickens
- transport and store the GMO and samples from GMO-treated chickens in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, in force at the time

- demonstrate compliance with a range of relevant State and local requirements and guidelines
- destroy all GMO-treated chickens not required for further analysis or transported to processing facilities.

## 3.2 Other risk management considerations

371. All DIR licences issued by the Regulator contain a number of conditions that relate to general risk management. These include conditions relating to:

- applicant suitability
- contingency plans
- identification of the persons or classes of persons covered by the licence
- reporting requirements
- access for the purpose of monitoring for compliance.

### *3.2.1 Applicant suitability*

372. In making a decision whether or not to issue a licence, the Regulator must have regard to the suitability of the applicant to hold a licence. Under Section 58 of the Act, matters that the Regulator must take into account include:

- any relevant convictions of the applicant
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country
- the capacity of the applicant to meet the conditions of the licence.

373. If a licence were issued, the conditions would include a requirement for the licence holder to inform the Regulator of any information that would affect their suitability.

374. In addition, the applicant organisation must have access to a properly constituted Institutional Biosafety Committee and be an accredited organisation under the Act.

### *3.2.2 Contingency Plan*

375. If a licence were issued, Bioproperties would be required to submit a contingency plan to the Regulator before dealing with the GMOs. This plan would detail measures to be undertaken in the event of unintentional release of the GMO (e.g. a spill), loss of the GMO stock, severe weather conditions at the trial areas, transmission of the GMO to poultry other than the GMO-treated chickens, an outbreak of ILT disease that may potentially be linked to GMO exposure, and escape, loss or predation of GMO-treated chickens.

376. Bioproperties would also be required to provide the Regulator with a method to reliably detect the GMO or the presence of the genetic modification in a recipient organism. This methodology would be required before dealing the GMO.

### *3.2.3 Identification of the persons or classes of persons covered by the licence*

377. If a licence were issued, the persons covered by the licence would be 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 the licence. Prior to dealing with the GMO, Bioproperties would be required to provide a list of people and organisations that would be covered by the licence, or the function or position where names are not known at the time.

### *3.2.4 Reporting requirements*

378. If issued, the licence would require the licence holder to immediately report any of the following to the Regulator:

- any additional information regarding risks to the health and safety of people or the environment associated with the dealings
- any contraventions of the licence by persons covered by the licence
- any unintended effects of the release.

379. A number of written notices would also be required under the licence regarding dealings with the GMO at each farm, and inoculation of each batch of broiler chickens with the GMO at each farm to assist the Regulator in designing and implementing a monitoring program for all licensed dealings. The notices would include:

- local government area, address of the farm, GPS coordinates of farm
- whether the farm is free-range
- brief description/diagram/map of the farm and any associated sheds, ranges, houses or buildings (if relevant) in the trial area and what each is used for
- expected date of inoculation with the GMO
- number and age of broiler chickens to be inoculated with the GMO
- intended method of GMO administration
- identification of the particular shed/range where the GMO-inoculated chickens will be kept
- proposed processing facilities for the GMO-inoculated chickens
- expected concurrent presence of other poultry
- expected dates of harvesting the GMO-inoculated chickens for transport to the processing facilities
- expected date of decontamination of sheds that have housed the GMO-inoculated chickens.

### *3.2.5 Monitoring for Compliance*

380. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing. Post-release monitoring continues until the Regulator is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

381. If monitoring activities identify changes in the risks associated with the authorised dealings, the Regulator may also vary licence conditions, or if necessary, suspend or cancel the licence.

382. In cases of non-compliance with licence conditions, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. The Act provides for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the licence or directions from the Regulator, especially where significant damage to the health and safety of people or the environment could result.

## Section 4 Issues to be addressed for future releases

383. Additional information has been identified that may be required to assess an application for a commercial release of the GMO, or to justify a reduction in limits and controls. This includes:

- the degree of attenuation of the GMO under field conditions
- the ability of the GMO to establish an infection cycle and persist in the environment.

## Section 5 Conclusions of the consultation RARMP

384. The risk assessment concludes that the proposed limited and controlled release of the GMO poses negligible risks to the health and safety of people or the environment as a result of gene technology. These negligible risks do not require specific risk treatment measures.

385. If a licence were issued, conditions would be imposed to limit the release to the proposed scale, location and duration, and to restrict the spread and persistence of the GMO and its genetic material in the environment, as these were important considerations in establishing the context for assessing the risks.

# Chapter 4 **Draft licence conditions**

## Section 1 Interpretations and Definitions

1. In this licence:

- unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- words importing a gender include any other gender;
- words in the singular include the plural and words in the plural include the singular;
- words importing persons include a partnership and a body whether corporate or otherwise;
- 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;
- 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;
- 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.

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

'**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 for subsequent analysis.

**'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.

*Note: Attachment A is not included in the draft licence as the GMO has been described in the Risk Assessment and Risk Management Plan.*

5. The dealings authorised by this licence are:

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.

*Note: No 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*.

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.*

## 2.1 Obligations of the Licence Holder

10. The licence holder must notify the Regulator in writing as soon as practically and reasonably 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 conditions included in 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) details of how the licence holder will access and control Trial Areas 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.*

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

(e) a contingency plan as specified in Condition 62.

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 procedures to be implemented to achieve compliance with:

(a) conditions in Section 3 of this licence;

(b) APVMA permit number PER81178;

(c) routine biosecurity procedures of the National Farm Biosecurity Manual for Poultry Production (Department of Agriculture and Water Resources, 2009); and

(d) 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.

*Note: The Compliance Management Plan for each farm must address at least the following in relation to the GMO, GMO-contaminated waste or GMO-inoculated chickens, as applicable to the Participating farm and activity:*

*(a) training of persons engaged in the trial covered by this licence;*

*(b) storage and handling of the GMO prior to and during administration, and disposal of any remaining unused GMO;*

*(c) Shed and Range biosecurity measures, including entry, exit and cleaning procedures;*

*(d) maintenance of Sheds and Range fencing to ensure chickens are securely enclosed;*

*(e) segregation of the GMO-inoculated chickens from other poultry on the farm, so as to prevent cross-contamination between flocks inoculated with different vaccines against ILTV and unvaccinated flocks;*

*(f) procedures for farm personnel, visitors, contractors and pick-up crews entering and exiting the Trial area(s);*

*(g) measures taken to ensure farm personnel, visitors, contractors and pick-up crews do not have contact with birds outside the Participating farm unless appropriate decontamination has occurred;*

*(h) cleaning of equipment;*

*(i) pest, predators and wild bird management;*

*(j) management of livestock other than poultry;*

*(k) temporary storage, transport and disposal of used litter;*

*(l) temporary storage, transport and disposal of carcasses;*

*(m) decontamination of litter and carcasses on- or off-farm;*

*(n) handling, collection and transport of live GMO-inoculated chickens; and*

*(o) record keeping as required by Conditions 9, 15, 20, 64, 65, 66 and 67.*

17. Any changes to the information provided under Condition 15 and 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. Subject to Condition 21, 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 is not required to comply with any part of paragraph (b) of Condition 20 in relation to contractors who are engaged solely for transport of the GMO stock or Samples provided the transport is in accordance with the PC2 micro-organism requirements of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, as current at the time of transport.

22. The licence holder must ensure that only persons who adhere to relevant biosecurity procedures as documented in the Compliance Management Plan are engaged to transport live GMO-inoculated chickens from a Participating farm, or for transport and treatment of waste potentially contaminated with the GMO from a Participating farm.

*Note: No particular conditions of this licence apply to persons conducting the activities described in Condition 22 but the licence holder is responsible for ensuring only people who follow appropriate procedures, in accordance with the Compliance Management Plan, are permitted to conduct the activities. This may involve, for example, contractual arrangements, keeping records and auditing of practices.*

23. 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.

### 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 and risk management plan is communicated to the Regulator.*

24. 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 24(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 24(b) or 24(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.*

25. 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.*

26. 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.

### 2.3 Obligations of persons covered by the licence

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

28. 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.*

## 3.1 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.*

29. 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 |

30. Only healthy Broiler chickens may be inoculated with the GMO. A cumulative maximum of 2,000,000 Broiler chickens may be inoculated with the GMO.

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

32. Dealings with the GMO at Participating farms must be completed by 1 August 2022.

33. GMO-inoculated chickens must be either killed or transferred to facilities certified by the Regulator to PC2 by 1 August 2022.

34. GMOs not required for further experimentation must be Decontaminated on or before expiration of the licence.

35. Experimentation or analysis with the GMO, GMO-inoculated chickens or Samples may only be undertaken within a Trial Area.

## 3.2 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.*

### *3.2.1 Participating Farms*

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

37. Sheds and fencing for Ranges 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 entrances to Trial Areas.

### *3.2.2 Inoculation with GMO*

40. Only healthy Broiler chickens that have not received any other vaccine against ILTV may be inoculated with the GMO.

41. If any chicken in a flock is inoculated with the GMO, all chickens in the flock must be inoculated.

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

43. Persons preparing the GMO for administration must be a registered veterinarian or trained and supervised by a registered veterinarian.

44. Persons preparing the GMO for administration must wear a face mask, eye protection and gloves.

45. Persons must decontaminate hands after preparing the GMO, administering the GMO or handling GMO-inoculated chickens.

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

47. GMO-inoculated chickens must be segregated from all other poultry.

### *3.2.3 Work practices at the Participating farm*

48. The Compliance Management Plan must be implemented at each Participating farm.

49. If any of the events described in Condition 62 occur, the appropriate procedure(s) from the Contingency Plan must be implemented.

50. 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.

51. All persons exiting a Shed or Range containing GMO-inoculated chickens must decontaminate their hands and footwear.

52. Overalls and footwear worn at the Trial area(s) must remain within the Trial area(s) unless they are decontaminated upon exit or are being transported for laundering.

53. All Equipment that may be contaminated with the GMO must be decontaminated according to the Compliance Management Plan after use, or when entering and exiting a Shed or Range containing GMO-inoculated chickens.

54. 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.

**Transport and storage of GMO stock and Samples**

55. 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 22 requires the licence holder to ensure that only persons who adhere to relevant biosecurity procedures as documented in the Compliance Management Plan are engaged for transport of GMO-inoculated chickens from a Participating farm.*

56. Live GMO-inoculated chickens must not be harvested for transport to Processing facilities within 28 days of being inoculated with the GMO.

57. Live GMO-inoculated chickens must only be transported to Processing facilities or to facilities certified by the Regulator to PC2.

58. The licence holder must have accounting procedures to record delivery of GMO-inoculated chickens at their intended destination.

**Decontamination of the GMO**

59. Any areas at a Participating farm 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.

60. After the removal of all GMO-inoculated chickens, used litter must be removed from the Shed, and the entire shed including feed containers, water tanks and water lines Decontaminated according to the Compliance Management Plan, before the next batch of birds is placed in the shed.

61. 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 22 requires the licence holder to ensure that only persons who adhere to relevant biosecurity procedures as documented in the Compliance Management Plan are engaged for transport and decontamination*.

### *3.2.4 Contingency plans*

62. Prior to conducting any dealings, 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 to poultry other than Broiler chickens intentionally inoculated with the GMO;

    (e) 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

    (f) 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.*

63. 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, 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;

    (c) if an outbreak of ILT 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

### 4.1 Notice of commencement and completion of the trials

64. 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 farm, a street address or other directions;

    (b) whether it is a free-range farm; and

    (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.

65. 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 a Participating farm, and must include the following details:

    (a) expected date 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) identification of the particular Shed and, if applicable, the Range where the GMO-inoculated chickens will be kept;

    (e) proposed Processing facilities for the GMO-inoculated chickens;

    (f) expected concurrent presence of other poultry, including whether they are, or are expected to be, inoculated with different vaccines against ILTV or remain unvaccinated;

    (g) expected date(s) of harvesting the GMO-inoculated chickens for transport to the Processing facilities; and

    (h) expected date of Decontamination of Sheds that have housed GMO-inoculated chickens.

*Note: The notices required by conditions 64 and 65 may be combined for the first inoculation at a particular Participating farm, and a notice under condition 65 may cover more than one batch of chickens if the relevant details for each batch can be accurately provided.*

66. With respect to each batch of GMO-inoculated chickens, as notified under Condition 65, the Licence holder must notify the Regulator in writing within 7 days after removal of the batch from the Trial area, and include the following information:

    (a) date(s) of harvest and transport of GMO-inoculated chickens;

(b) number of live GMO-inoculated chickens transported to Processing facilities;

(c) details of Processing facilities receiving the live GMO-inoculated chickens; and

(d) actual or expected date when sheds that have housed GMO-inoculated chickens have been or will be Decontaminated.

## 4.2 Records to be maintained

67. 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 and Range fencing keep chickens securely enclosed, including inspection and maintenance activities, as applicable;

(b) evidence of pest activity and details of and pest management measures;

(c) details of each batch of chickens inoculated with the GMO as notified to the Regulator under Condition 65 and 66;

(d) details of each harvest of GMO-inoculated chicken, whether partial or complete harvest of the batch;

(e) record of the delivery of each harvest of GMO-inoculated chickens at processing facilities; and

(f) number of GMO-inoculated broiler chickens culled or which had died at the Trial Area(s) for each batch.

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