Australian Government
Department of Health
Office of the Gene Technology Regulator

16 May 2017

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.