Australian Government
Department of Health
Office of the Gene Technology Regulator

1 August 2017

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 154

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. The licence authorises conduct of experiments, transport and disposal of a GM vaccine to protect chickens against infectious laryngotracheitis for the purpose of field trials.

A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the requirements of the *Gene Technology Act 2000* (the Act) and corresponding State and Territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that the field trials pose negligible risks to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

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 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) CSW-1 strain
Modified genes	Deletion of gene encoding glycoprotein G protein from the ILTV genome
Proposed release date	August 2017 – August 2022
Proposed duration	5 years
Proposed locations	Selected chicken farms in rural Victoria and New South Wales
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 people, or the environment, from the proposed dealings, either in the short or long term, 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.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the 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.