Australian Government
Department of Health
Office of the Gene Technology Regulator

1 August 2017

Issue of licence DIR 154 to Bioproperties Pty Ltd for the limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT

On 16 May 2017, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 154 from Bioproperties Pty Ltd.

The Regulator has now issued a licence in response to application DIR 154, authorising the field trials, under limited and controlled conditions, of a live attenuated GM vaccine, Vaxsafe® ILT, for the protection of chickens against infectious laryngotracheitis virus. The purpose of the trial is to assess the efficacy and safety of the vaccine under farm conditions.

The trial is authorised to take place on selected chicken farms in New South Wales and Victoria, 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.

Use of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA has issued a permit to Bioproperties Pty Ltd to allow the supply and limited use of the GM vaccine for the purposes of conducting research.

The Regulator's decision to issue the licence was made after consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment and Energy, the Gene Technology Technical Advisory Committee and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

The Regulator considered all submissions provided during the consultation process that related to the health and safety of people or the protection of the environment. The comments were considered in the context of current scientific information and used in finalising the RARMP. The finalised RARMP informed the Regulator's decision to issue the licence.

The finalised RARMP concludes that this limited and controlled release poses negligible risks to people and the environment and does not require specific risk treatment measures. However, licence conditions have been imposed to restrict spread and persistence of the GMOs and their genetic material in the environment and to limit the release in scale, location and duration, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the advice received from prescribed experts, agencies and authorities, and indicates how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document. No submissions were received from the public on the consultation RARMP.

The finalised RARMP, together with a summary of the RARMP, a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 154 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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