Australian Government
Department of Health
Office of the Gene Technology Regulator

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Issue of licence DIR 159 to The University of Queensland for the limited and controlled release of GM vaccines for farmed crocodiles

On 5 March 2018, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 159 from The University of Queensland.

The Regulator has now issued a licence in response to application DIR 159, authorising the limited and controlled release (field trial) of two live genetically modified (GM) insect-specific viruses for the protection of crocodiles against Kunjin virus.

The field trial is authorised to take place between May 2018 and May 2023 in the Northern Territory, on two crocodile farms. The purpose of the field trial is to assess the efficacy and safety of the GM vaccines for crocodiles under farm conditions. Inoculated crocodiles could enter general commerce, including use in human food or animal feed, after being tested to show no GM vaccine remains.

Use of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The University of Queensland will need to apply to the APVMA for a permit to allow the supply and limited use of the GM vaccine for the purpose 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, 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 wishes to thank submitters for their contributions. She 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 the health and safety of 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 size, 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 Appendix B the submissions received from the public. The appendices indicate how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document.

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 159 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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