

24 April 2023

Notification of decision on application DIR 193 from Bioproperties Pty Ltd for the commercial supply of a genetically modified vaccine against infectious laryngotracheitis in chickens

The Regulator has issued licence DIR 193 to Bioproperties Pty Ltd, authorising the transport, storage, disposal and testing of various modes of administration associated with the commercial supply of a genetically modified (GM) vaccine against infectious laryngotracheitis virus in chickens within Australia.

Approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA) is also required for the conduct of experiments and the commercial supply of the vaccine.

The Risk Assessment and Risk Management Plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

Submissions are summarised in Appendix B and C of the RARMP, together with information about how the issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the RARMP.

The finalised RARMP concludes that this commercial release poses negligible risks to people and low to moderate risks to the environment. The environmental risks required specific risk treatment measures which were imposed via the licence conditions. Additionally, general licence conditions have also been imposed to ensure ongoing oversight of the release.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the <u>DIR-193</u> page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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