Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

23 June 2023

Notification of decision on application DIR 195 from the University of Tasmania for the trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils.

The Regulator has issued licence DIR 195 to the University of Tasmania, authorising the trial of a genetically modified (GM) vaccine for the prevention and/or treatment of devil facial tumour disease in Tasmanian devils.

The GM vaccine would be administered to Tasmanian devils kept in enclosures within trial sites in Tasmania.

The Risk Assessment and Risk Management Plan (RARMP) was 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 A and Appendix B 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 finalising the RARMP.

The finalised RARMP concludes that this trial poses negligible risks to the health and safety of people and the environment, and thus it does not require specific risk treatment measures. However, licence conditions have been imposed to limit the number of animals included in the trial, the location and duration of the trial, and specify a range of controls to minimise the potential for the GM vaccine to spread in the environment, as these were important considerations for the RARMP.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the DIR 195 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

Office of the Gene Technology Regulator
MDP 54 GPO Box 9848 CANBERRA ACT 2601 Tel: 1800 181 030 E-mail: ogtr@health.gov.au
OGTR website