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

29 September 2023

Notification of decision on application DIR 197 from Novotech (Australia) Pty Ltd for a clinical trial of genetically modified *Lactobacillus brevis*

The Regulator has issued licence DIR 197 to Novotech (Australia) Pty Ltd, authorising the clinical trial of *Lactobacillus brevis* bacteria genetically modified (GM) for treatment of inflammatory bowel disease.

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 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 clinical trial poses negligible to moderate risks to the health and safety of people and the environment, and requires specific risk treatment measures. Strict licence conditions have been imposed to limit the number of trial participants, limit the location of the clinical trial, limit the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread in the environment.

The finalised RARMP, a summary of the RARMP, the licence, and Questions and Answers about this decision can be obtained online from the DIR 197 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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