



OFFICIAL

**Australian Government**  
**Department of Health, Disability and Ageing**  
Office of the Gene Technology Regulator

11 February 2026

**Notification of decision on application DIR 221 from Melius MicroBiomics Pty Ltd for the Clinical trial of a genetically modified *Escherichia coli* for the treatment of ulcerative colitis**

The Regulator has issued licence DIR 221 to Melius MicroBiomics Pty Ltd, authorising the clinical trial of a genetically modified (GM) *Escherichia Coli* for the treatment of ulcerative colitis.

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 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 low risks to the health and safety of people and the environment, and therefore specific risk treatment measures have been imposed. Licence conditions have also been imposed to limit the number of trial participants, limit the location of the clinical trial to (hospitals and clinical trial sites), 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-221](#) 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](mailto:ogtr@health.gov.au)**

**[OGTR website](#)**

OFFICIAL