



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of genetically modified *Lactobacillus brevis* bacteria

The Gene Technology Regulator is assessing an application from Novotech (Australia) Pty Ltd to conduct a clinical trial of genetically modified *Lactobacillus brevis* bacteria for treatment of inflammatory bowel disease. The trial is proposed to take place at medical facilities and the homes of clinical trial participants. Up to 60 trial participants would be treated over a period of 7 years.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via our website (search for [DIR 197](#)), or from the contacts below. Submissions should reference DIR 197 and be received by **25 August 2023**.

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