



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

20 February 2024

Notification of decision on application DIR 200 from Cauldron Molecules Pty Ltd for fermentation and processing of recombinant proteins using genetically modified *Pichia pastoris*

The Regulator has issued licence DIR 200 to Cauldron Molecules Pty Ltd, authorising fermentation and processing of recombinant proteins using genetically modified *Komagataella phaffii*, previously known as *Pichia pastoris*, for production of recombinant animal proteins (bovine milk, chicken egg and silk fibre).

The production is authorised to take place at a facility in Borenore (Cabonne Shire Council, New South Wales) over five years.

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 the local council. 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 there are negligible risks associated with the proposed application to the health and safety of people and the environment, thus it does not require specific risk treatment measures. However, licence conditions have been imposed to limit the size, location and duration of the release and to restrict spread and persistence of the GMOs and their genetic material 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 200](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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