



Australian Government

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

NOTIFICATION OF APPLICATION

Receipt of licence application from Cauldron Molecules Pty Ltd for fermentation and processing of recombinant proteins using genetically modified Pichia pastoris

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 200) from Cauldron Molecules Pty Ltd to use genetically modified (GM) *Pichia pastoris* (yeast) for precision fermentation to produce bovine milk, chicken egg and silk fibre proteins. A summary of the application is posted on our [website](#) (search for [DIR 200](#)).

The proposed application is to optimise the scale-up fermentation process and characterise GM yeast used to produce recombinant animal proteins from a non-animal source (bovine milk, chicken egg and silk fibre proteins). The GM yeast will incorporate a protein expression cassette to produce recombinant proteins in their native form. The production process will involve fermentation of GM yeast cultures in large volumes (up to 10,000 L per tank) at Cauldron's purpose-built protein production facility in Borenore, New South Wales. The recombinant proteins will be purified and will not contain any GM yeast.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. This is expected to be released for public comment and advice from experts, agencies and authorities in **early November 2023**. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the full application or the summary, please contact the OGTR and quote the reference number DIR-200.

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