Questions & Answers on licence application DIR 200 – Precision fermentation using genetically modified *Pichia pastoris*

What is this application for?

Cauldron Molecules Pty Ltd is seeking approval to grow genetically modified (GM) yeast for production of specific proteins. The work would be conducted at Borenore (Cabonne Shire Council) New South Wales. GM yeast would be cultured in several batches in closed fermentation vessels over five years.

What is yeast?

Yeasts are a diverse group of organisms that are commonly used in the food manufacturing industry. For example, the closely related baker's yeast is used for making bread and in the brewing industry. They are a popular tool in research and in the biotechnology industry for producing recombinant proteins. This particular yeast is generally found in decaying plant material and are not known to cause harm to people or the environment.

How has the GM yeast been modified?

Yeast will be genetically modified to express one type of protein from cow's milk, chicken egg or spider silk. These genes will not confer any advantageous trait leading to spread or persistence of the yeast. The GM yeast may also contain a selectable marker gene which confers resistance to an antibiotic. This marker gene is useful for selecting GM yeast during early stages of development and does not have any function when yeasts are grown in culture.

What is the purpose of the trial?

The trial is to assess and optimise the fermentation process and characterise GM yeast during production of animal proteins. No material from the trial would be used in human food. However, killed GM yeast may be used as a soil conditioner or in animal feed preparation.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the fermentation trial poses negligible risks to people or the environment. As this is a trial under limited and controlled conditions, a number of licence conditions have been proposed to restrict when and where the trial can take place, limit the size of the trial, and restrict the GM yeast to the production facility. There are conditions to isolate the GM yeast by growing it in closed culture vessels, transfering liquids via closed stainless-steel pipes, to securely transport and store the GMOs, and to inspect the production facility at regular intervals for any leakage, as well as at the end of the trial checking that all GM yeast are destroyed. Full details of the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 200 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed application. Comments must be received by the close of the consultation period on **22 December 2023**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

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