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

What does this licence allow?

This licence allows Cauldron Molecules Pty Ltd to conduct a fermentation trial of GM yeast (*Komagataella phaffi,* previously known as *Pichia pastoris)* for production of recombinant animal proteins (bovine milk, chicken egg and silk fibre). 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. GM yeast from the trial would not be used in human food. However, killed and denatured GM yeast may be used as a soil conditioner or in animal feed preparations.

What controls are imposed for this release?

The 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 imposed 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 licence conditions are available in the RARMP and licence.

Want more information?

A number of documents relating to this decision are available on the DIR 200 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

The Office of the Gene Technology Regulator

OGTR Website

Tel: 1800 181 030 E-mail: ogtr@health.gov.au