Australian Government
Department of Health
Office of the Gene Technology Regulator

January 2020

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 169

Decision

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed trial poses negligible risks to human health and safety and the environment, and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Application Number	DIR 169
Project Title	Limited and controlled release of microalgae genetically modified for increased production of fatty acids[1]
Parent organism	*Nannochloropsis oceanica*
Genes responsible for the modified traits	**Introduced gene conferring increased production of fatty acids** NTE – thioesterase gene from *Nannochloropsis oceanica* **Partial deletion of genes conferring inability to use nitrate as a nitrogen source** NRT – nitrate transporter gene NR – nitrate reductase gene
Genetic modification method	Electroporation
Number of lines	Up to five GM lines
Proposed location	The University of Queensland's Pinjarra Hills campus (Centre for Solar Biotechnology pilot plant), Brisbane City, Queensland
Proposed release size	Multiple batches of GM microalgae in up to six securely covered culture vessels with a volume of up to 600 litres per vessel
Proposed period of release	Several periods up to a total of 12 months, until the end of 2023[2]
Principal purpose	To assess and optimise growth characteristics and production conditions of the GM microalgae under outdoor conditions

[1] The original title for the application was 'Limited and controlled release of *Nannochloropsis oceanica* genetically modified for increased production of fatty acids'.

[2] During consultation, UQ amended their application to extend the proposed period.

Risk assessment

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application (including proposed limits and controls) and relevant previous approvals. Both short- and long-term impacts are considered.

Credible pathways to potential harm that were considered included exposure of people or other desirable organisms to the GM microalgae, and the potential for persistence or dispersal of the GMOs. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to desirable animals, and environmental harms due to reduced quality of the biotic environment or reduced establishment of desirable organisms.

The principal reasons for the conclusion of negligible risks are that the GM microalgae will not be used for human food or animal feed, and that the proposed limits and controls will effectively minimise exposure to and dispersal of the GMOs.

Risk management

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the licence includes limits on the size, location and duration of the release. Controls are included to prohibit the use of the GM microalgae in human food and animal feed, to minimise dispersal of the GMOs from the trial site, to transport GMOs in accordance with the Regulator's guidelines, and to destroy the GMOs at the end of the trial.