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

October 2022

Summary of the Risk Assessment and Risk Management Plan (Consultation Version)

for

Licence Application No. DIR 191

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for intentional, commercial-scale import and distribution of genetically modified (GM) chrysanthemum cut flowers. The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed release poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed release. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Application number	DIR 191
Applicant	International Flower Developments Pty Ltd
Project title	Commercial import and distribution of chrysanthemum genetically modified for altered flower colour[1]
Parent organism	Chrysanthemum (*Chrysanthemum* x *morifolium*)
Introduced genes and modified traits	Two genes conferring blue or violet flower colour: • *F3'5'H* - flavonoid 3',5'-hydroxylase gene from *Campanula medium* • *A3'5'GT* - anthocyanin 3',5'-glucosyltransferase gene from *Clitoria ternatea* One selectable marker gene: • *nptII* – antibiotic resistance gene from *Escherichia coli*
Proposed locations	Australia-wide
Primary purpose	Commercial import and distribution of cut flowers of GM chrysanthemum for ornamental use

Risk assessment

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

[1] The title of the licence application submitted by International Flower Developments Pty Ltd is "Application for commercial import of flowers of five genetically modified chrysanthemum varieties; 2B, 3C, 4A, 5A and 8D".

The risk assessment process considers how the genetic modification and activities conducted with the GMO 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 information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term risks are considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM chrysanthemum cut flowers, transfer of the introduced genetic material to sexually compatible plants, and accidental or deliberate propagation of the GM chrysanthemums. The potential harms considered were increased toxicity, allergenicity or weediness of the GM chrysanthemums compared to unmodified plants.

The principal reasons for the conclusion of negligible risks are that the GM chrysanthemums will not be used in commercial human food or animal feed, pollinators would have little access to pollen from the GM chrysanthemum cut flowers, imported chrysanthemum cut flowers must be devitalised, the introduced proteins and their pigment products are not expected to be toxic or allergenic, and chrysanthemums have very low potential to survive outside cultivation.

Risk management

The risk management plan concludes that risks from the proposed dealings can be managed so as to protect people and the environment by imposing general conditions to ensure that there is ongoing oversight of the release.

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has drafted licence conditions regarding post-release review (PRR) to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP. The draft licence, detailed in Chapter 4 of the consultation RARMP, also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.