Australian Government
Department of Health
Office of the Gene Technology Regulator

8 June 2022

Summary of the Risk Assessment and Risk Management Plan

(Consultation Version) for

Licence Application No. DIR 190

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional, commercial scale release of genetically modified (GM) Indian mustard in Australia. 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 190
Applicant	BASF Australia Ltd (BASF)
Project title	Commercial release of Indian mustard genetically modified for herbicide tolerance (RF3 juncea canola)[1]
Parent organism	Indian mustard (*Brassica juncea* (L.) Czern. & Coss.)
Introduced genes and modified traits	• *bar* gene from *Streptomyces hygroscopicus* (for glufosinate tolerance) • *barstar* gene from *Bacillus amyloliquefaciens* (for restoration of male fertility)
Proposed locations	Australia-wide
Primary purpose	Commercial release for Indian mustard production

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.

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.

[1] The title of the application submitted by BASF is "Commercial release of RF3 canola quality *B. juncea* in the Australia cropping system, genetically modified for herbicide tolerance".

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM juncea canola; potential for increased weediness of the GM juncea canola relative to unmodified plants; and vertical transfer of the introduced genetic material to other sexually compatible plants.

The principal reasons for the conclusion of negligible risks are: the introduced proteins are not considered toxic or allergenic to people, or toxic to other desirable organisms; the parental GM canola line and other GM crops containing the introduced genes have a history of safe use in Australia and overseas; the introduced genes and proteins are widespread in the environment; the GM juncea canola and its progeny can be controlled using integrated weed management; the GM juncea canola is susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of juncea canola and the GM juncea canola has limited capacity to survive in natural habitats. In addition, food made from the GM juncea canola has been assessed and approved by Food Standards Australia New Zealand as safe for human consumption.

Risk management

The risk management plan concludes that risks from the proposed dealings can be managed 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 several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.