



Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 178

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of genetically modified (GM) canola in Australia. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the requirements of the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this commercial release poses negligible risks to human health and safety and the environment and no specific risk treatment measures are imposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

The application

Application number	DIR 178
Applicant	BASF Australia Ltd (BASF)
Project title	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11 × RF3 and MS11 × RF3 × MON 88302) ¹
Parent organism	<i>Brassica napus</i> L. (canola)
Introduced genes and modified traits	Two genes for herbicide tolerance: <ul style="list-style-type: none">• <i>bar</i> gene from <i>Streptomyces hygroscopicus</i> for glufosinate tolerance• <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4 for glyphosate tolerance Two genes for a hybrid breeding system: <ul style="list-style-type: none">• <i>barnase</i> gene from <i>Bacillus amyloliquefaciens</i> for male sterility• <i>barstar</i> gene from <i>Bacillus amyloliquefaciens</i> for fertility restoration
Proposed locations	Australia-wide
Primary purpose	Commercial release for canola production

¹ The title of the application submitted by BASF is “Commercial release of MS11 × RF3 *B. napus* and MS11 × RF3 × MON 88302 *B. napus* in the Australia cropping system, genetically modified for herbicide tolerance and a hybrid breeding system”.

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.

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM canola; potential for increased weediness of the GM 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 lines 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 canola lines and their progeny can be controlled using integrated weed management; the GM canola lines are susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of canola and the GM canola has limited capacity to survive in natural habitats. In addition, food made from the GM canola lines 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 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 imposed 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 licence 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.