



Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 139

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of herbicide tolerant 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 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 proposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

The application

Application number	DIR 139
Applicant	Pioneer Hi-Bred Australia Pty Ltd (Pioneer)
Project title	Commercial release of canola genetically modified for herbicide tolerance ¹
Parent organism	<i>Brassica napus</i> L. (canola)
Introduced gene and modified trait	Glyphosate acetyltransferase (<i>gat4621</i>) gene derived from the bacterium <i>Bacillus licheniformis</i> for tolerance to the herbicide glyphosate
Proposed locations	Australia-wide
Primary purpose	Commercial release of the GM canola

Risk assessment

The risk assessment concludes that there are negligible risks to the health and safety of people, or the environment, from the proposed release.

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 were 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

¹ The title of the licence application submitted by Pioneer is “General release of canola genetically modified for optimal herbicide tolerance”.

from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term impact were 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 protein is not considered toxic or allergenic to people or toxic to other desirable organisms; proteins similar to the introduced protein are widespread in the environment; the GM canola has been grown in field trials in Australia since 2012 without adverse or unexpected effects; the GM canola and its progeny can be controlled using integrated weed management; and the GM canola has limited capacity to establish in undisturbed natural habitats. In addition, food made from the GM canola has been assessed and approved by Food Standards Australia New Zealand as safe for human consumption.

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 assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions 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.