



Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 138

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 138
Applicant	Bayer CropScience Pty Ltd (Bayer)
Project title	Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system (InVigor® x TruFlex™ Roundup Ready®) ¹
Parent organism	<i>Brassica napus</i> L. (canola)
Introduced genes and modified traits	<ul style="list-style-type: none">• phosphinothricin acetyl transferase (<i>bar</i>) gene derived from the bacterium <i>Streptomyces hygroscopicus</i> (tolerance to herbicide glufosinate)• 5-enolpyruvylshikimate-3-phosphate synthase (<i>cp4 epsps</i>) gene derived from the bacterium <i>Agrobacterium</i> sp. strain CP4 (tolerance to herbicide glyphosate)• ribonuclease (<i>barnase</i>) gene derived from the bacterium <i>Bacillus amyloliquefaciens</i> (confers male sterility)• ribonuclease inhibitor (<i>barstar</i>) gene derived from the bacterium <i>B. amyloliquefaciens</i> (restores fertility)• antibiotic resistance gene (<i>nptII</i>) from <i>E. coli</i> (antibiotic resistance for selection during initial development)

¹ The title of the licence application submitted by Bayer is “Commercial release of InVigor® x TruFlex™ Roundup Ready® (*Brassica napus*) for use in the Australian cropping system”.

Proposed locations	Australia-wide, in all canola growing areas
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 GMOs 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 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; increased spread and persistence leading to 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 and 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 limited capacity of the GM canola to spread and persist in undisturbed natural habitats. In addition, food made from the GM canola is 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.