Australian Government
Department of Health
Office of the Gene Technology Regulator

21 November 2014

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 127

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of a genetically modified organism (GMO) into the environment. 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 licence.

The application

Application number	DIR 127
Applicant	Monsanto Australia Ltd (Monsanto)
Project title	Commercial release of canola genetically modified for herbicide tolerance (MON 88302) [1]
Parent organism	*Brassica napus* (canola)
Introduced gene and modified trait	5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) gene derived from the bacterium *Agrobacterium* sp. strain CP4 (herbicide tolerance)
Proposed locations	Australia-wide, in all canola growing areas
Primary purpose	Commercial release of the GM herbicide tolerant canola

This commercial release follows field trial work conducted under licence DIR 105.

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

[1] The title of the licence application submitted by Monsanto is "General release of *Brassica napus* genetically modified for herbicide tolerance (MON 88302) in Australia".

of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term are 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 GM canola has previously been grown under limited and controlled conditions in Australia since 2011 without adverse effects on human health or environment; the widespread presence of the same or similar proteins encoded by the introduced gene in the environment and lack of known toxicity or evidence of harm from them; and the limited capacity of the GM canola to spread and persist 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 concludes that risks from the proposed dealings, either in the short or long term, to the health and safety of people, or the environment, are negligible. No specific risk treatment measures are proposed.

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 under 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.