Australian Government
Department of Health
Office of the Gene Technology Regulator

June 2018

Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 158

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) safflower 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 158
Applicant	GO Resources Pty Ltd (GO Resources)
Project title	Commercial release of safflower genetically modified for high oleic acid composition[1]
Parent organism	*Carthamus tinctorius* L. (safflower)
Introduced gene and modified trait	**Two gene fragments involved in altered fatty acid composition:** • Fragment of *CtFATB* (palmitoyl-ACP-thioesterase), derived from safflower • Fragment of *CtFAD2.2* (Δ12 desaturase), derived from safflower **One selectable marker gene:** • *Hph* (hygromycin phosphotransferase), from *Streptomyces* sp., antibiotic resistance gene
Proposed locations	Australia-wide
Primary purpose	Commercial release of the GM safflower

[1] The title of the application submitted by GO Resources is "Commercial release of *Carthamus tinctorius* L. genetically modified for high oleic acid composition".

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 safflower; potential for increased weediness of the GM safflower 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 genetic modifications are not considered to produce compounds that are toxic or allergenic to people or toxic to other desirable organisms; genes similar to the introduced gene constructs are widespread in the environment; the GM safflower was licenced for field trials in Australia from 2013, with no reported adverse or unexpected effects; and the GM safflower has limited capacity to survive in natural habitats.

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.