Australian Government
Department of Health
Office of the Gene Technology Regulator

24 October 2014

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 129

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for a limited and controlled 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 field trial poses negligible risks to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Application number	DIR 129
Applicant:	Sugar Research Australia Limited (SRA)
Project Title:	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Parent organism:	Sugarcane (*Saccharum spp.* Hybrid)
Introduced genes[1] and modified traits:	• one gene from a plant species (herbicide tolerance) and • three variants of a gene from a bacterium (herbicide tolerance)
Proposed release dates:	November 2015 – November 2021
Proposed locations:	Seven[2] sites in the local government areas of Bundaberg, Mackay, Burdekin, Moreton Bay and Cairns (Queensland)
Proposed release size:	30 hectares per season
Primary purpose:	To evaluate the field performance of GM herbicide tolerant sugarcane and to conduct breeding to develop commercially useful GM herbicide tolerant sugarcane clones.

Risk assessment

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

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 are characterised in relation to

[1] The identities of these genes have been declared Confidential Commercial Information (CCI) under section 185 of the Act.
[2] The applicant requested an additional site in the Bundaberg LGA during consultation.

both the seriousness and likelihood of harm, taking into account information in the application (including proposed limits and controls), relevant previous approvals and current scientific/technical knowledge, and advice received from a wide range of experts, agencies and authorities consulted on the RARMP. Both the short and long term potential harms are considered.

Credible pathways to potential harm that were considered included: unintended exposure to the GM plant material; increased spread and persistence of the GM sugarcane relative to unmodified plants; and transfer of the introduced genetic material to non GM sugarcane, or other sexually compatible plants. Potential harms associated with these pathways included toxicity to people and other animals, allergic reactions in people and environmental harms associated with weediness.

The principal reasons for the conclusion of negligible risks are that the introduced genetic modifications are unlikely to cause harm to human health or safety or to the environment, the introduced genes are similar to those already existing in the environment, and furthermore, the imposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure.

Risk management plan

The risk management plan concludes that risks posed by the proposed dealings can be managed so as to protect people and the environment by imposing conditions on 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, evaluates controls and limits proposed by the applicant, 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, as this is a limited and controlled release, the licence includes limits on the size, locations and duration of the release, as well as controls including containment provisions at the trial sites; prohibiting the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's guidelines; and conducting post-harvest monitoring at the trial sites to ensure all GMOs are destroyed.