



February 2018

Summary of the Risk Assessment and Risk Management Plan for Licence Application DIR 157

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of insect resistant genetically modified (GM) cotton 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 157
Applicant	Syngenta Australia Pty Ltd (Syngenta)
Project title	Commercial release of cotton genetically modified for insect resistance (COT102)
Parent organism	<i>Gossypium hirsutum</i> L. (cotton)
Introduced gene and modified trait	One insect resistance gene: <ul style="list-style-type: none">• <i>vip3Aa19</i> gene from <i>Bacillus thuringiensis</i> (Bt) One selectable marker gene: <ul style="list-style-type: none">• <i>aph4</i> from <i>Escherichia coli</i> for resistance to hygromycin B
Proposed locations	Australia-wide
Primary purpose	Commercial release of the GM cotton

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.

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 cotton; potential for increased weediness of the GM cotton 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 or toxic to other desirable organisms; proteins similar to the introduced proteins are widespread in the environment; the GM cotton was licenced for field trials in Australia between 2002 and 2010, with no reported adverse or unexpected effects; and the GM cotton has limited capacity to survive in natural habitats. In addition, food made from the GM cotton 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 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.