Australian Government
Department of Health
Office of the Gene Technology Regulator

23 January 2017

Issue of licence DIR 147 to Monsanto Australia Limited for the limited and controlled release of GM cotton

On 22 November 2016, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 147 from Monsanto Australia Limited.

The Regulator has now issued a licence in response to application DIR 147, authorising the limited and controlled release (field trial) of cotton genetically modified (GM) for insect resistance and herbicide tolerance. The GMOs proposed for release are a GM cotton with a modified gene for protection against certain bugs, aphids and thrips; and combinations of this GM cotton with previously authorised insect resistant and/or herbicide tolerant cottons.

The trial is proposed to take place in cotton growing areas of Australia from March 2017 to July 2021 in New South Wales, Queensland, Northern Territory, Victoria and Western Australia. The proposal is to plant up to 50 sites per year with a maximum combined area of 50 ha in 2017, 100 ha in 2018, and 250 ha per year in 2019 and 2020. The maximum planting size of individual trial sites is proposed to be 2 ha in 2017, 10 ha in 2018, and 50 ha per year in 2019 and 2020. The GM cotton would not be used in human food or animal feed.

The Regulator's decision to issue the licence was made after consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

The Regulator considered all submissions provided during the consultation process that related to the health and safety of people or the protection of the environment. The comments were considered in the context of current scientific information and used in finalising the RARMP. The finalised RARMP informed the Regulator's decision to issue the licence.

The finalised RARMP concludes that this limited and controlled release poses negligible risks to people and the environment and does not require specific risk treatment measures. However, licence conditions have been imposed to restrict spread and persistence of the GMOs and their genetic material in the environment and to limit the release in size, location and duration, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the advice received from prescribed experts, agencies and authorities, and indicates how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document. No submissions were received from the public.

The finalised RARMP, together with a summary of the RARMP, a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 147 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

Office of the Gene Technology Regulator **MDP 54 GPO Box 9848 CANBERRA ACT 2601**
Telephone: 1800 181 030 E-mail: ogtr@health.gov.au OGTR website (www.ogtr.gov.au)