



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

20 December 2016

**Issue of licence DIR 145 to Monsanto Australia Limited for  
the commercial release of GM cotton**

On 31 August 2016, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 145 from Monsanto Australia Ltd.

The Regulator has now issued a licence in response to application DIR 145, authorising the commercial release of cotton genetically modified for insect resistance and herbicide tolerance (known as XtendFlex™ and Bollgard® 3 XtendFlex™).

The release is authorised to take place throughout Australia. The GM cotton and products derived from the GM cotton may enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has approved the use in food of material derived from this GM cotton. Note that cultivation of GM cotton is subject to restrictions in some Australian States and Territories for marketing reasons.

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 commercial release poses negligible risks to people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

Appendices A and B of the RARMP summarise the advice received from prescribed experts, agencies and authorities, and indicate how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document. Seven submissions were received from the public on the consultation RARMP and the issues raised, and their consideration, are summarised in Appendix C of the RARMP.

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 online from the [DIR 145](#) page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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