Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

16 August 2013

Issue of licence DIR 118 to Monsanto Australia Ltd for the commercial release of GM pima cotton

On 19 April 2013, Gene Technology Regulator (the Regulator) invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 118 from Monsanto Australia Ltd (Monsanto).

The Regulator has issued a licence in respect of application DIR 118, authorising the commercial release of pima cotton (a species of cultivated cotton) that has been genetically modified (GM) for herbicide tolerance.

The release is authorised to take place throughout Australia. The GM cotton and products derived from the GM cotton would enter general commerce, including use in human food and animal feed. Note that cultivation of GM cotton may also be subject to other requirements in some Australian States and Territories for marketing reasons.

The decision to issue the licence was made after extensive 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 relevant local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

Issues relating to the health and safety of people and the protection of the environment raised during the consultation process were considered in the context of current scientific information in reaching the conclusions set out in the finalised RARMP and in making the 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 that there is ongoing oversight of the release.

Appendices A and B of the RARMP summarise the advice that was 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 the document. One submission was received from the public on the consultation RARMP, and the issues raised are summarised in Appendix C of the RARMP.

A Summary and the complete finalised RARMP, together with a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 118 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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