Australian Government
Department of Health
Office of the Gene Technology Regulator

21 November 2014

Issue of licence DIR 127 to Monsanto Australia Ltd for the commercial release of GM canola

On 24 July 2014, the Gene Technology Regulator (the Regulator) invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 127 from Monsanto Australia Ltd (Monsanto).

The Regulator has now issued a licence in respect of application DIR 127, authorising the commercial release of canola that has been genetically modified (GM) for herbicide tolerance.

The release is authorised to take place throughout Australia. The GM canola and products derived from the GM canola would 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 canola. Note that cultivation of GM canola 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. Seventeen submissions were 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 127 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 Facsimile: 02 6271 4202 E-mail: ogtr@health.gov.au
Website: http://www.ogtr.gov.au