Australian Government
Department of Health
Office of the Gene Technology Regulator

22 March 2016

Issue of licence DIR 138 to Bayer CropScience Pty Ltd for the commercial release of GM canola

On 20 November 2015, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 138 from Bayer CropScience Pty Ltd.

The Regulator has now issued a licence in response to application DIR 138, authorising the commercial release of canola genetically modified for dual herbicide tolerance and to facilitate production of the GMOs.

The release is authorised to take place throughout Australia. The GM canola and products derived from the GM canola 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 canola. Note that cultivation of GM canola 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.

Issues raised during the consultation process that related to the health and safety of people and the protection of the environment 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 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 the document. Eleven 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 on-line from the DIR 138 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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