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

2 December 2011

NOTIFICATION OF DECISION

Issue of licence DIR 108 to Bayer CropScience Pty Ltd for the commercial release of GM canola

On 23 August 2011, 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 108 from Bayer CropScience Pty Ltd (Bayer).

The Regulator has now made a decision to issue a licence in respect of application DIR 108, authorising the commercial release of canola that have been genetically modified (GM) for herbicide tolerance and a hybrid breeding system (InVigor® x Roundup Ready® canola).

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. 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 local councils, as required by the *Gene Technology Act 2000* and corresponding State and Territory laws.

Issues relating to the health and safety of people and the protection of the environment raised during the consultation process were weighed against the body 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 submissions that were 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. Nine submissions were received from the public on the consultation RARMP and the issues raised are summarised in Appendix C of the RARMP.

The Executive Summary, Technical Summary and 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 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 OGTR Website