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

22 December 2010

NOTIFICATION OF DECISION

Issue of licence DIR 105 to Monsanto for a limited and controlled release of GM canola

On 15 October 2010, the Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 105 from Monsanto Australia Ltd.

The Gene Technology Regulator has now made a decision to issue a licence in respect of application DIR 105, authorising the limited and controlled release of a canola line that has been genetically modified (GM) for herbicide tolerance.

The release is authorised to take place over four years, from March 2011 to December 2014, with up to 2 sites in the first year, 8 sites in the second and third years, and 20 sites in the fourth year. Sites will be a maximum area of 4 ha in the first year and 10 ha in subsequent years, and will be located in 46 possible local government areas (LGAs) in New South Wales, 28 possible areas in Victoria and 53 possible LGAs in Western Australia. None of the GM canola plants are permitted for use in human food or animal feed.

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 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 limited and controlled release poses negligible risks to people and the environment. Licence conditions have been imposed to restrict spread and persistence of the GMOs and their genetic material in the environment and to limit the release in size, locations and duration, as these were important considerations in the evaluation process.

Appendix A of the RARMP summarises the submissions that were received from prescribed experts, agencies and authorities, and indicates where issues raised relating to risks to human health and safety or the environment were considered in the document. Thirty-one submissions were received from members of the public, and the issues raised are summarised in Appendix B 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.

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