



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

2 December 2011

**EXECUTIVE SUMMARY OF THE
RISK ASSESSMENT AND RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 108
FROM
BAYER CROPSCIENCE PTY LTD**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of application DIR 108 from Bayer CropScience Pty Ltd (Bayer). The licence authorises dealings involving the commercial release of genetically modified (GM) canola into the environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a genetically modified organism (GMO).

The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public¹.

The application

Bayer has applied for a licence for dealings involving the intentional release of GM InVigor® x Roundup Ready® canola. Bayer is seeking approval to release the GM canola in all commercial canola growing areas of 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.

GM InVigor® x Roundup Ready® canola was produced by conventional breeding between GM InVigor® canola and GM Roundup Ready® canola, which were individually approved

¹ More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

by the Regulator in 2003 for commercial release under licences DIR 021/2002 and DIR 020/2002, respectively.

The GM InVigor® x Roundup Ready® canola proposed for commercial release contains genes from common bacteria conferring tolerance to the herbicides glufosinate ammonium and glyphosate. In addition, some of the GM canolas proposed for release contain genes from common bacteria conferring a hybrid breeding system and/or an antibiotic resistance gene. The antibiotic resistance gene, which confers tolerance to the antibiotic kanamycin, was used to select genetically modified plants during their initial development in the laboratory.

GM InVigor® x Roundup Ready® canola has been previously approved for field trials in Australia under licences DIR 069/2006 and DIR 104 issued to Bayer.

Food Standards Australia New Zealand (FSANZ) has approved the use of food derived from GM InVigor® canola and GM Roundup Ready® canola for human consumption. These approvals also cover GM InVigor® x Roundup Ready® canola.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for the supply of agricultural chemicals, including herbicides, in Australia. Amendments to the labels of glufosinate ammonium and glyphosate herbicides would be required for them to be used on commercial scale plantings of InVigor® x Roundup Ready® canola.

An Australian Quarantine and Inspection Service (AQIS) permit would be required to allow the importation of seed.

Risk assessment

The risk assessment took into account information in the application, previous approvals, relevant scientific/technical knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP has also been considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios), and those that warrant detailed characterisation are determined. This process is described as risk identification.

Five risk scenarios were postulated, including consideration of whether or not expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms, or alter characteristics that may impact on the spread and persistence of the GM canola. The opportunity for gene flow to other organisms, and its effects if it were to occur, were also assessed.

A **risk** is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The characterisation of the five risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the large scale of the release proposed by the applicant and considering both the short and long term, did not identify any risks that could be greater than negligible. Therefore, they did not warrant further detailed assessment.

Risks to the health and safety of people, or the environment, from the proposed release of GM canola into the environment are assessed to be **negligible**.

Risk management plan

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks and considers general risk management measures. The risk management plan is given effect through the licence conditions.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. As the risks to the health and safety of people or the environment from the proposed dealings are assessed to be **negligible**, no specific risk treatment measures are imposed.

However, the Regulator has imposed licence conditions under post-release review (PRR) to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP.

The licence also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.

Conclusions of the RARMP

The risk assessment concluded that this commercial release of GM InVigor® x Roundup Ready® canola to be grown throughout Australia, and the entry of products derived from the GM canola into general commerce Australia-wide, poses **negligible** risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded that these **negligible** risks do not require specific risk treatment measures. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.