



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

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2 December 2011

**TECHNICAL 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 Gene Technology Regulator (the Regulator) before making a decision whether 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 public<sup>1</sup>.

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

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<sup>1</sup> 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>>.

All GM InVigor® x Roundup Ready® canola proposed for commercial release contains genes conferring tolerance to the herbicides glufosinate ammonium and glyphosate. In addition, some of the GM canolas proposed for release contain genes conferring a hybrid breeding system and/or an antibiotic resistance gene, depending on the specific GM InVigor® parent line<sup>2</sup>.

Glyphosate tolerance is conferred by expression of the *goxv247* gene (a modified version of the *gox* gene obtained from the soil bacterium *Ochrobactrum anthropi* strain LBAA) and the *cp4 epsps* gene obtained from the soil bacterium *Agrobacterium tumefaciens* strain CP4. The *goxv247* gene encodes glyphosate oxidoreductase, an enzyme capable of degrading glyphosate into non-toxic metabolites. The *cp4 epsps* gene encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme. EPSPS enzymes participate in a biosynthetic pathway found in both plants and microorganisms that is required for the synthesis of some essential amino acids. Most plant EPSPS enzymes are inhibited by glyphosate, which results in plant death due to the lack of essential amino acids. However, CP4 EPSPS has a much lower affinity for glyphosate than related plant EPSPS enzymes and can continue to function in the presence of glyphosate.

Glufosinate ammonium herbicide tolerance is conferred by expression of the *pat* gene obtained from *Streptomyces viridochromogenes* or the *bar* gene obtained from *Streptomyces hygroscopicus*. Both genes encode functionally equivalent phosphinothricin acetyltransferase enzymes that alter the structure of the active component in glufosinate ammonium herbicides, rendering the herbicide inactive.

Some of the GM canolas proposed for release contain the *barnase* and/or *barstar* genes obtained from the soil bacterium *Bacillus amyloliquefaciens*. *Barnase* encodes a ribonuclease enzyme (BARNASE), and *barstar* encodes a specific inhibitor of the BARNASE enzyme. BARNASE is produced specifically in the anthers of GM flowers and prevents pollen production, resulting in male-sterility. Production of BARSTAR in the same cells inhibits BARNASE activity to restore fertility of the flower.

Some of the GM canolas also contain the *nptII* gene obtained from the bacterium *Escherichia coli*. The *nptII* gene encodes the enzyme neomycin phosphotransferase II which confers resistance to kanamycin and structurally related antibiotics. During development of the GM canola, this marker gene enabled selection of genetically modified plant tissues.

Short regulatory sequences necessary to control expression of the novel genes are present in GM InVigor® x Roundup Ready® canola. These sequences have been derived from: the common soil bacterium *A. tumefaciens*; the plant species *Arabidopsis thaliana* (thale cress), *Nicotiana tabacum* (tobacco) and *Pisum sativum* (pea); and the plant viral pathogens Cauliflower Mosaic Virus and Figwort Mosaic Virus. Although *A. tumefaciens*, Cauliflower Mosaic Virus and Figwort Mosaic Virus are plant pathogens, the regulatory sequences comprise only a small part of their total genome, and are not in themselves capable of causing disease.

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.

## **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,

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<sup>2</sup>The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

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.

A reference document, *The Biology of Brassica napus (canola)*, was produced to inform the risk assessment process for licence applications involving GM canola plants. The document is available from the OGTR or from the website <<http://www.ogtr.gov.au>>.

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. The principal reasons for this include:

- the GM canola has been produced by conventional breeding of GM canola lines that have previously been assessed and authorised for commercial release in Australia
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or evidence of harm from them
- limited capacity of the GM canola to spread and persist in undisturbed natural habitats.

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.

### ***Other regulatory considerations***

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including FSANZ, the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Quarantine and Inspection Service (AQIS)<sup>3</sup>.

FSANZ is responsible for human food safety assessment, including GM food. 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.

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 AQIS permit would be required to allow the importation of seed.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

### ***Suitability of the applicant***

The Regulator has assessed the suitability of Bayer CropScience Pty Ltd to hold a DIR licence as required by the Act. Bayer is considered suitable as the Regulator is satisfied that no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

### ***Conclusions of the consultation 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, licence conditions have been imposed to ensure that there is ongoing oversight of the release.

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<sup>3</sup> More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.