Australian Government
Department of Health
Office of the Gene Technology Regulator

Risk Assessment and Risk Management Plan
DIR 021/2002
Commercial release of
genetically modified (InVigor® hybrid) canola

EXECUTIVE SUMMARY

Introduction

The *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations) set out requirements which the Gene Technology Regulator (the Regulator) must follow when considering an application for a licence to intentionally release a genetically modified organism (GMO) into the environment.

For a licence to be issued, the Regulator must be satisfied that the release will not pose any risks to human health and safety or the environment that can not be managed. To this end, Section 51 of the Act requires the Regulator to prepare a risk assessment and risk management plan (RARMP) for each licence application, in consultation with a wide range of expert groups and key stakeholders, including the public.

The Regulator has taken into account all matters relevant to the protection of human health and safety and the environment that were raised during the consultation process in finalising the RARMP for application number DIR 021/2002. Information on the submissions received and how they were taken into account is contained in Chapter 2 and Appendix 10.

Licence decision

On 25 July 2003 the Regulator issued a licence to Bayer CropScience Pty Ltd (Bayer) approving the commercial release of genetically modified (GM) InVigor® hybrid canola, including lines T45, Topas19/2, MS1, RF1, RF2, RF3 and MS8.

The application

Bayer applied for a licence (application number DIR 021/2002) for the commercial release of seven (7) similar GM 'lines'[1] of canola: T45, Topas19/2, MS1, RF1, RF2, RF3 and MS8. Lines MS1, MS8, RF1, RF2 and RF3, and hybrids derived from MS x RF crosses, are covered by the registered trade name InVigor® canola.

Hybrid seed from the lines RF3 and MS8 would be marketed as InVigor® in Australia. Although Bayer does not intend to commercialise the other five lines in Australia at this time,

[1] The term 'line' has been used throughout this risk assessment. 'Line' is used to denote canola with a specific genetic modification derived from a single transformation event.

the applicant sought approval for all seven GM canola lines to achieve consistency with existing overseas regulatory approvals.

Table 1 summarises the modifications that are present in the seven Bayer GM canola lines proposed for release.

Table 1: Genetic modifications in the seven GM canola lines

Line	Glufosinate ammonium tolerance	Hybrid breeding system (InVigor®)	Antibiotic resistance
T45	*Pat*	–	–
Topas 19/2	*Pat*	–	*nptII*
MS1	*Bar*	*barnase*	*nptII*
RF1 and RF2	*Bar*	*barstar*	*nptII*
MS8	*Bar*	*barnase*	–
RF3	*Bar*	*barstar*	–

The GM canola from the proposed release would be used as oil in human food, or in animal feed, in the same way as conventional (non-GM) canola.

All seven lines are approved for growing and human consumption in the USA and Canada, and oil derived from all seven canola lines has been approved for use in human food in Australia. (ANZFA 2001a).

The hybrid canola seed which Bayer seeks to commercialise in Australia as InVigor® canola is produced with a novel hybrid generation system. This system is based on two genetically modified 'parent' lines of canola: a male sterile (MS) line that contains a male sterility gene (*barnase*), and a fertility restorer (RF) line containing a fertility restorer gene (*barstar*).

The development of the pollen-producing parts of canola flowers (anthers) is suppressed in MS plants. Crossing an MS line with an RF line overrides the suppression and makes the progeny fertile. The progeny are expected to have enhanced agronomic performance, otherwise known as 'hybrid vigour' (see Appendix 1 for more information).

Naturally occurring male sterile plants are routinely used in conventional (non-GM) breeding systems as a means to control breeding and produce more vigorous plant offspring.

All seven GM canola lines include a gene that confers tolerance to the herbicide glufosinate ammonium. The herbicide tolerance serves as a dominant marker for the introduced traits during breeding and hybrid seed production. It also enables glufosinate ammonium to be used for the control of weeds in the GM canola crop.

The Australian Pesticides and Veterinary Medicines Authority (APVMA), formerly known as the National Registration Authority (NRA), has granted Bayer registration of glufosinate ammonium for use on InVigor® canola under the trade name Liberty®. The APVMA has registered Liberty® for use only InVigor® canola crops, not for weed control in other crops. Glufosinate ammonium is not registered for use in any other broad-acre cropping in Australia. However, glufosinate ammonium is also registered as Basta® for weed control in horticultural crops and Finale® for weed control in non-crop agricultural areas, commercial and industrial areas and rights-of-way. Appendix 4 contains further details.

Four of the GM canola lines contain a gene that provides a 'marker' for antibiotic resistance in plants. This gene is used to identify and select modified plants during the development stage. Bayer does not intend to commercialise any of these lines.

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), Bayer (formerly AgrEvo, Aventis CropScience) conducted 14 field trials (PR62, PR63 and extensions) with all seven GM canola lines in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia. In addition, the Regulator

issued a licence on 30 July 2002 to Bayer (DIR010/2002) to conduct a limited and controlled release of the same GM canola lines at 30 trial sites, totalling 106 hectares, in New South Wales, Victoria and South Australia for the summer and winter growing seasons in the three years from 2002-03. There have been no reports of adverse effects on human health or the environment resulting from any of these releases.

Some detailed technical information on precise gene constructs and molecular characterisation data included in Bayer's original application and subsequent material supplied in response to OGTR requests has been declared 'Confidential Commercial Information'. In accordance with section 184 of the Act this technical information is not available to the general public. However the information was available to the expert groups which are required to be consulted on the preparation of the RARMP.

The evaluation process

Licence application DIR 021/2002 from Bayer has been evaluated, and a risk assessment and risk management plan (RARMP) prepared, in accordance with the Act and the Regulations, using a Risk Analysis Framework. This framework was developed by the Regulator in consultation with the public and key local, State, Territory and Commonwealth government stakeholders and the Gene Technology Technical Advisory Committee.

Details of the process that the Regulator must follow, including the prescribed consultation process on the application, and the matters that must be considered in preparing a RARMP, are set out in Appendix 9. The complete, finalised RARMP can be obtained from the OGTR or from the OGTR's web site.

The risk assessment considered information contained in the application (including information required by the Act and the Regulations on the GMO, the parent organism, the proposed dealings and potential impacts on human health and safety and the environment), submissions received during consultation and current scientific knowledge.

As mentioned above, the use of Liberty® herbicide (a formulation of glufosinate ammonium) has been registered by the APVMA for use on InVigor® canola crops in Australia. As part of the assessment of this use, the APVMA considered potential human health and environmental effects, for example arising through occupational exposure or residues. The APVMA also considered a number of issues that are outside the scope of the Gene Technology Regulator's assessment, such as the efficacy of the herbicide and herbicide resistance management.

Through the risk assessment process, potential hazards to human health and safety or the environment that may be posed by the commercial release of the Bayer canola were identified. These were evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard, were it to be realised. These hazards were considered and evaluated previously for limited and controlled trials with the same GM canola under licence application DIR 010/2001. They were reassessed for this release to determine whether the proposed commercial scale, and the removal of specific licence conditions for containment measures to limit the movement of the GMOs and the introduced genes, posed any additional risks. The identified potential hazards relate to:

- ***toxicity and allergenicity for humans*:** could the GM canola lines be more toxic or allergenic than non-GM canola as a result of the novel gene products or because of unintended effects?
- ***toxicity and allergenicity for other organisms*:** could the GM canola lines be harmful to other organisms including mammals (other than humans), livestock, wildlife, other insects and microorganisms as a result of the novel gene products or because of unintended effects?

- ***weediness*:** could the genetic modifications be harmful to the environment by increasing the potential for the GM canola lines to establish as problem weeds?
- ***transfer of introduced genes to other organisms*:** could there be adverse consequences from possible transfer of the new genes in the GM canola lines to non-GM canola crops, closely related *Brassica* weeds, other brassicaceous weeds, or to other organisms?
- ***herbicide resistance*:** could weeds develop resistance to herbicide if the InVigor®-Liberty® crop-herbicide combination is used inappropriately?

Considerations outside the scope of the assessment

There has been considerable speculation in the media and other forums, as well as in some submissions, about the possible impact of the uptake of GM canola on non-GM farmers and upon international export markets.

Feedback from extensive stakeholder consultation during the development of the *Gene Technology Act 2000* made it clear that the community wanted the regulatory system to focus exclusively on the protection of human health and safety and the environment. This is to prevent the possibility of economic considerations such as cost-benefit analyses, market access and agricultural trade implications compromising the regulatory system's focus upon the scientific evaluation of risks and the protection of human health and safety and the environment. As a result, economic and cost-benfit considerations were expressly excluded from the scope of the assessments conducted under the Act.

Therefore, this RARMP does not draw any conclusions about the possible costs or benefits of the Bayer canola to individual farmers, or on market impacts for the agricultural industry.

However, there are a number of industry and government initiatives (independent of this assessment) which do focus on economic and marketability considerations in relation to the adoption of GM canola by the Australian agriculture industry. These include:

- indicative principles of the Commonwealth, State and Territory governments' Plant Industries Committee (circulated as *Guidelines for Industry Stewardship Programs and Crop Management Plans for the Management of Genetically Modified Crops in Australian Farming Systems*)
- the (industry-based) Gene Technology Grains Committee's *Canola Industry Stewardship Protocols for Coexistence of Production Systems and Supply Chains*.
- the Productivity Commission report *Modelling Possible Impacts of GM Crops on Australian Trade*.
- the Australian Bureau of Agricultural & Resource Economics (ABARE) report *Australian Grains Industry 2003-GM Canola. What are its economics under Australian conditions ?* available from http://www.abareonlineshop.com/product.asp?prodid=12526

Bayer also submitted a draft version of the *InVigor® Canola Crop Management Plan* as part of its application. All of the above documents were analysed in detail for any information of relevance to the assessment. They are summarised in Appendix 7.

Conclusions of the risk assessment

The Regulator considers that the risks to human health and safety, or to the Australian environment, from the commercial release of any of Bayer's seven GM canola lines are no greater than those posed by non-GM canola ie they are as safe as conventional canola. The assessment of each identified potential hazard is summarised under a separate heading below.

Toxicity or allergenicity to humans and other organisms

The GM canola lines are very unlikely to prove more toxic or allergenic to humans or other organisms than conventional canola. Therefore the risks are considered negligible and it is not considered necessary to impose any management conditions in relation to potential toxicity or allergenicity. As noted above, FSANZ has previously approved the use in food of oil from the seven GM canola lines, concluding that products from these GM canolas are as safe as are those from non-GM canola.

Weediness

The risk of the genetic modifications making this GM canola more invasive or persistent than conventional canola in Australia is negligible

The growth characteristics and agronomic performance of the seven GM canola lines are within the range of conventional canola. The hybrid vigour displayed in InVigor® canola hybrids is not a function of the genetic modification, results from the breeding of the two genetically distinct parents. The growth characteristics and agronomic performance of InVigor® canola hybrids are within the range of conventional canola hybrids.

The introduced genes do not confer a selective advantage in the absence of the herbicide glufosinate ammonium. Glufosinate ammonium is not registered for use in any broad-acre agriculture except on Bayer's GM InVigor® canola. It is used in viticulture and horticulture but is rarely used in non-agricultural areas.

Therefore it is not considered necessary to impose any conditions to manage the risk of weediness.

Transfer of introduced genes to other organisms

The introduced genes do not confer any selective advantage in the absence of the herbicide glufosinate ammonium. The hybrid vigour displayed in InVigor® canola hybrids is not a function of the genetic modification that can be transferred as a single trait, but is a result of the breeding of the two genetically distinct parents.

The likelihood of some gene transfer from the GM canola to other cultivated canola is high but diminishes rapidly away from close proximity to the crop, hence the overall frequency of out-crossing will be low. If gene transfer to other canola did occur, as explained above, no competitive environmental advantage is conferred. It remains susceptible to the control measures currently used on conventional (non-GM) canola and can be managed in the same way. Therefore, transfer of introduced genes to other canola crops poses negligible risk and does not require the imposition of specific management conditions.

The likelihood of some transfer of the introduced genes to the closely related weedy *Brassica* species *B. rapa* and *B. juncea* is high, though less than for conventional (non-GM) canola. And, due to the lower incidence of these species and the reduced 'fitness' of any progeny *eg.* vigour, fertility *etc*, the overall frequency and persistence will be considerably lower. If gene transfer to *B. rapa* or *B. juncea* did occur, it would not confer a selective advantage in the absence of the herbicide glufosinate ammonium. Gene transfer to *B. rapa* poses a very low risk while the risk posed by gene transfer to *B. juncea* would be negligible. Outcrossing to *B. oleracea* would be unlikely and the risks posed by this would be negligible. Gene transfer to any of these three species would not require any specific management conditions under the *Gene Technology Act 2000*.

The likelihood of transfer of the introduced genes from the GM canola to the less closely related brassicaceous weed species *Raphanus raphanistrum, Hirschfeldia incana* and *Sinapis*

arvensis is very low, because of genome incompatibility and the severely reduced fitness of any progeny. The overall frequency of outcrossing will be very low. Although these species are weeds of both agricultual and disturbed habitats, they are not considered invasive weeds of undisturbed environments. Even if the glufosinate ammonium tolerance trait was transferred to these species it would not pose any additional risks for the control of these weeds (glufosinate ammonium is known to be ineffective for the control of *R. raphanistrum*). Therefore it is concluded that gene transfer to *R. raphanistrum*, *H. incana* and *S. arvensis* poses a very low risk, and no additional management practices would be needed to control any transgenic hybrids, if they occur, and management strategies would be the same as for other brassicaceous weeds.

The likelihood of gene transfer to any other brassicaceous species is considered negligible. Even if gene transfer to these species did occur, it would not pose any additional risks for the control of these weeds.

The likelihood of transfer of the introduced genes to other organisms is negligible, but even if such transfer did occur it would be unlikely to pose any hazard to human health and safety or to the environment.

Herbicide resistance

There is a potential for development of herbicide-resistant weeds if the InVigor® crop-Liberty® herbicide combination is used inappropriately. The APVMA has noted that the resistance management plan as contained in Bayer's *InVigor® Canola Crop Management Plan* is an essential part of managing herbicide resistance and will effective in managing the development of resistance to glufosinate ammonium. The APVMA requires that the plan be available to all users of Liberty® herbicide. The APVMA has regulatory responsibility and oversight for agricultural chemical use and have stipulated a number of conditions on the use of Liberty® herbicide on InVigor® canola crops. Therefore no herbicide resistance management conditions are required under the *Gene Technology Act 2000*.

Industry stewardship proposals

The Bayer *InVigor® Canola Crop Management Plan*, and industry guidelines developed to assist all participants in the agricultural supply chain achieve coexistence between different productions systems e.g. GM/non-GM, GM/organic, were considered in detail in the course of evaluating the application.

The industry stewardship proposals focus on good agricultural and handling practices. The stated aims of the proposals are to:

- enable separation of GM and non-GM crops to the extent required by markets;
- maximise the effective life of the technology; and
- contribute to agricultural sustainability.

The evaluation of this material concluded that there was no information that added to, or impacted on, the risks posed to human health and safety or the environment by the activities proposed in the application. The risk assessment process evaluated risks that might occur in the *absence* of any supply chain management controls or product stewardship measures.

InVigor® hybrid canola will be supplied through accredited resellers from 2004. Growers will be required to sign a grower agreement and will be trained to follow the Crop Management Plan (CMP). The stated aims of the CMP are to ensure awareness of the industry protocols for coexistence of GM and other canola and knowledge of the regulatory conditions placed on the seed and herbicide.

Although it is considered there are no risks from Bayer GM canola that require management to protect human health and safety or the environment, governments and the agricultural

industry are still assessing the impact of the commercial release of GM canola on trade and marketability.

The risk management plan (key licence conditions)

The Regulator considers that the proposed release does not pose risks to the health and safety of people or the environment in Australia that require management through specific licence conditions (refer to Conclusion of the Risk Assessment, above). Accordingly, the licence the Regulator has issued in respect of the Bayer application DIR 021/2002 contains only minimal oversight conditions. The key licence conditions are outlined below.

Toxicity or allergenicity to humans and other organisms

Based on the risk assessment, no management conditions have been imposed in relation to toxicity or allergenicity.

Weediness

Based on the risk assessment no management conditions have been imposed in relation to weediness.

Transfer of introduced genes to other organisms

Based on the risk assessment no management conditions have been imposed in relation to the transfer of introduced genes to other organisms.

The licence includes a condition that requires the applicant to provide the Regulator with a testing methodology that is able to reliably detect the presence of each of the GMOs or their genetic material.

Herbicide resistance

No conditions have been imposed in relation to the management of herbicide resistance, as this is the responsibility of the APVMA. The licence holder's obligation to comply with any conditions imposed by the APVMA is noted in the licence.

Reporting conditions

Bayer sought regulatory approval for seven GM canola lines, although it has indicated that only lines RF3 and MS8 will be commercialised in Australia as InVigor® canola. The licence includes a condition that Bayer report to the Regulator the amount of each GM canola line sold commercially or otherwise grown in each growing season for each State and Territory.

As part of the ongoing commitment to making information publicly available, the Regulator intends to report on the implementation of the InVigor® canola release after three years of commercial plantings. The Regulator has indicated that she will call for public input to the proposed report as part of the responsible oversight of the progress of this and other licences for genetically modified crops.

General conditions

Any licence issued by the Regulator contains a number of general conditions, which are also relevant to risk management. These include, an obligation to inform the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

The licence holder is also obliged to comply with all other relevant Commonwealth, State and Territory legislation.

Monitoring and enforcement of compliance by the OGTR

As well as the legislative capacity to enforce compliance with licence conditions, the Regulator has additional options for risk management. The Regulator can direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment.

In this regard, the reporting requirements imposed by the licence conditions will enable the Regulator to monitor and review the progress of all commercial releases of GM crops in Australia.

Further information

Detailed information on the evaluation of the application, including the licence conditions, is available in the risk assessment and risk management plan document for this application, which can be obtained from the website of the Office of the Gene Technology Regulator , or by calling 1800 181 030 (please quote application number DIR 021/2002).