



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

2 June 2005

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN FOR APPLICATION DIR 057/2004**

THE DECISION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of genetically modified (GM) herbicide tolerant hybrid Indian mustard (*Brassica juncea*) into the environment, in respect of application DIR 057/2004 from Bayer CropScience Pty Ltd (Bayer).

The licence allows Bayer to conduct a limited and controlled field trial during each of the winter and summer seasons of 2005 to 2008, at four sites on a maximum of four hectares (ha) per site (maximum total of 16 ha per season), in up to 17 shires in New South Wales, Victoria and South Australia.

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 and the environment that can not be managed. As part of the evaluation process, 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 stakeholders.

Under Section 52 of the Act, the Regulator is required to seek comment on the RARMP from those consulted in its preparation and to invite submissions from the public. Matters raised relating to the protection of human health and safety or the environment are taken into account in finalising the RARMP, which then forms the basis of the Regulator's decision on whether, or not, to issue a licence and if so, what conditions to impose.

The Act is designed to operate in a cooperative legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise. As well as enhancing coordinated decision making, this arrangement avoids duplication. The OGTR liaises closely with other regulators to ensure the identification, evaluation and management of risks that may be associated with the development and use of gene technology.

THE APPLICATION

Bayer CropScience (Bayer) applied for a licence (application number DIR 057/2004) for the intentional release of herbicide tolerant, hybrid GM Indian mustard (*Brassica juncea*), under limited and controlled conditions. The release may take place on up to a total of 96 ha over three years during the winter and summer growing seasons of 2005-

08. Sites will be chosen from 17 shires in Victoria, South Australia and New South Wales.

The aim of the trial is to conduct early stage research to evaluate the agronomic performance of up to 70 different GM Indian mustard lines, including comparison with conventional Indian mustard and GM and conventional canola (*B. napus*), to assess the effectiveness of the herbicide tolerance trait in the field, and to produce seed from lines selected for ongoing evaluation trials planned for overseas and possibly also Australia (subject to further approvals).

The GM Indian mustard lines were developed in laboratories and greenhouses in Europe by crossing GM herbicide tolerant, hybrid *B. napus* (approved for limited and controlled release under licence number DIR 032/2002) with conventional *B. juncea*, followed by multiple backcrosses with the conventional *B. juncea* parent.

The GM Indian mustard lines therefore contain the same herbicide tolerance gene and *barnase* and *barstar* genes as the GMOs in licence DIR 032/2002. The last two genes comprise Bayer's novel hybrid breeding system that emulates the natural phenomenon of hybrid vigour. This enables crossing of the male sterile (MS) (*barnase* gene) lines with the fertility restorer (RF) (*barstar* gene) lines to produce fertile hybrid plants and seeds.

The GM Indian mustard does not contain any antibiotic resistance marker genes.

In accordance with the provisions of section 185 of the *Gene Technology Act 2000*, Bayer sought and received approval for details of the herbicide tolerance gene, gene constructs including plasmid maps, precise arrangement of the regulatory sequences and data on molecular characterisation to be declared Confidential Commercial Information (CCI). While the Regulator was satisfied that the public interest in the release does not outweigh the prejudice that disclosure would cause the applicant, the CCI was made available to the various prescribed expert groups that were consulted on the preparation of the RARMP for this application.

Bayer proposed a range of containment and inspection measures (detailed in chapter 1), based on the measures applied to release of GM canola authorised under DIR 032/2002, to limit the possible dissemination and persistence of the GM Indian mustard. The proposed measures were considered during the risk assessment of the application and in the preparation of the risk management plan.

There has been no previous release in Australia of the GM Indian mustard to be trialled in this application.

THE EVALUATION PROCESS

A risk assessment and risk management plan (RARMP) in relation to licence application DIR 057/2004 has been prepared in accordance with the Act, the Regulations and the Regulator's *Risk Analysis Framework*. The framework was originally developed in consultation with the public, State, Territory and Australian government agencies, key stakeholders and the Gene Technology Technical Advisory Committee. It has recently been revised in consultation with the same stakeholders in order to more fully explain the OGTR's risk analysis process and is available at <http://www.ogtr.gov.au/pdf/public/raffinal2.1.pdf>.

The revised framework introduces a *Risk Estimate Matrix* (see below) that is used to assess the combination of likelihood and consequence that leads to an estimate of risks to human health and safety and/or the environment that may be posed by dealings with a GMO.

RISK ESTIMATE MATRIX					
LIKELIHOOD	Highly likely	Low	Moderate	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	Minor	Intermediate	Major
CONSEQUENCES					

Legend: A *negligible* risk is considered to be insubstantial with no present need to invoke actions for mitigation. A *low* risk is considered to be minimal but may invoke actions for mitigation beyond normal practices. A *moderate* risk is considered to be of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective. A *high* risk is considered to be unacceptable unless actions for mitigation are highly feasible and effective.

Details of the process that the Regulator must follow, including the prescribed consultation process on the application, and the matters that she must consider in preparing a RARMP, are set out in detail in Appendix 6 of the RARMP. The complete RARMP and a set of 'Questions and Answers' on the decision on this application can be obtained from the OGTR by contacting the Office on 1800 181 030 or from the OGTR's website at www.ogtr.gov.au.

The risk assessment considered information contained in the application (comprising: information required by the Act and the Regulations on the GMO; on the parent organism; the proposed dealings, including proposed containment conditions; and potential impacts on human health and safety and the environment), current scientific knowledge, and submissions received during consultation with expert groups and authorities and the public (issues raised in submissions are summarised in Chapter 2 and Appendix 7 of the RARMP). The Regulator has also obtained valuable input from additional independent experts on the cultivation and characteristics of *B. juncea*.

Through this process, potential hazards to human health and safety or the environment that may be posed by the release of the GM Indian mustard lines were identified. These have been evaluated to determine whether risks might arise, based on the likelihood of each hazard occurring and the likely impact of each hazard, were they to be realised.

The identified potential hazards relate to:

- **toxicity and allergenicity to humans and other organisms:** could these GM Indian mustard plants be more toxic or allergenic than non-GM Indian mustard plants to humans or harmful to other organisms as a result of the novel gene products or because of unintended effects resulting from the introduced genetic elements?
- **weediness:** could the genetic modifications be harmful to the environment by increasing the potential for these Indian mustard plants to establish as problematic weeds? and

- **transfer of introduced genes to other organisms:** could there be adverse consequences from potential transfer of the introduced genes/genetic elements to non-GM Indian mustard plants, naturalised Indian mustard or weedy relatives, or to other organisms?

CONCLUSIONS OF THE RISK ASSESSMENT

The Regulator has concluded that the limited and controlled release of GM Indian mustard on a maximum of 16 ha per season (summer and winter) from 2005 to 2008 does not pose significant risks to human health and safety and the environment.

The risk assessment of each potential hazard identified above is summarised under a separate heading below.

Toxicity or allergenicity to humans and other organisms

As this is part of an early stage research trial, acute toxicity tests have not been conducted on the GM Indian mustard to date. However, none of the genetic materials introduced into the GM Indian mustard is derived from or similar to a known toxin or allergen. The genetic modifications result in herbicide tolerance and enable the production of fertile hybrid plants/seeds. This is not expected to have any impact on the toxicity or allergenicity compared to non-GM Indian mustard. Exposure of humans to the GM Indian mustard will be minimised because the trial is controlled and limited in scale and duration.

Allergies to conventional Indian mustard seed occur in the general population. Indian mustard contains the toxicants erucic acid and glucosinolates. The proteins added to the GM Indian mustard as a consequence of the modification are widespread in the environment. The level of occupational exposure to the introduced proteins through working with the GM Indian mustard is likely to be low. There have been no reports of toxic or allergenic effects from previous releases of other GMOs containing the herbicide tolerance gene.

Exposure of other organisms including aquatic organisms will also be minimised by the limited scale of the release and conditions such as a monitoring zone and inclusion of a pollen trap and isolation zone of 400 m or, in the absence of a pollen trap, an isolation zone of 1000 m.

The applicant does not intend to use any products or materials from the GM Indian mustard in human food or stock feed, thus limiting potential exposure. Food Standards Australia New Zealand (FSANZ) is responsible for human food safety assessment, and FSANZ approval would be needed before products from GM Indian mustard could be used in human food.

The risk estimates for GM Indian mustard for toxicity or allergenicity to humans and other organisms have been assessed as low and licence conditions imposed limit unintended exposure to the GMOs (refer to key licence conditions below).

Weediness

Indian mustard is closely related to canola and grows in a similar way. However, it is more tolerant of heat and water stress, the seed pods are less prone to shatter and it provides a stronger yield boost to wheat crops than canola when it is grown immediately prior to wheat in crop rotation in some circumstances.

Conventional Indian mustard is not considered a noxious weed or a weed of national significance in either undisturbed habitats or agricultural and disturbed habitats. Evidence from areas in southern NSW and Victoria in which Indian mustard crops are

grown indicates that it occurs less frequently in disturbed areas, such as roadsides, than canola does where it is grown.

The genetic modifications are unlikely to enhance the weediness of the GM Indian mustard compared to non-GM Indian mustard, particularly as the release is limited and controlled. The presence of the herbicide tolerance gene will only have a selective advantage in the presence of that herbicide. The GM Indian mustard remains susceptible to other herbicides and can be controlled using alternative herbicides and non-chemical management methods currently used to control conventional Indian mustard.

The risk estimate of the GM Indian mustard establishing as a weed in the release areas is considered to be low due to both the limited scale of the release and containment measures imposed by the licence. Conditions have been imposed to minimise the spread and persistence of the GMOs in the environment, including the use of a monitoring zone, an isolation zone, distance from other *Brassica* crops and post-harvest monitoring of the site (refer to key licence conditions below).

Transfer of introduced genes

Indian mustard is primarily self-pollinating (approximately 75%) with rates of out-crossing to other cultivated Indian mustard plants of approximately 18% recorded in adjacent rows. The risk estimate of gene transfer from the GM Indian mustard to other *Brassica* plants (including Indian mustard crops and naturalised Indian mustard) and to related species within the genus *Brassica*, particularly *B. napus* (canola), has been assessed as low. Licence conditions imposed minimise the risk of transfer of the introduced genes to plants outside the release site, including a range of measures to limit pollen movement, monitoring and isolation zones (refer to key licence conditions below).

The risk estimate of transfer of the introduced genes to other organisms has been assessed as negligible because of genetic incompatibility. Even if such transfer occurred, the consequences to human health and safety and the environment are also likely to be negligible.

THE RISK MANAGEMENT PLAN (KEY LICENCE CONDITIONS)

As part of the evaluation process for this licence application, a risk management plan was developed to address the risks identified in the risk assessment process. A number of containment measures proposed by the applicant to minimise exposure to the GMOs and the spread and persistence of the GMOs and introduced genetic materials in the environment were also considered.

The key licence conditions imposed by the Regulator to protect human health and safety and the environment are outlined below. Chapter 2 of the RARMP provides a tabulated summary of the risk assessment conclusions and the corresponding management measures. Full details of the licence conditions are provided in Appendix 5.

Toxicity or allergenicity to humans and other organisms

Licence conditions have been imposed requiring the applicant to:

- prevent the GMOs and products derived from the GMOs entering the human food supply;
- prevent GMO materials being used as stockfeed;
- limit the scale and duration of the release;

- limit exposure to humans and other animals;
- destroy all GMO and other plant material not required for possible future trials or research;
- securely transport and store the GMO and other plant material and seeds; and
- report any adverse effects to the Regulator.

Weediness

Licence conditions have been imposed requiring the applicant to:

- limit the scale and duration of the release;
- undertake light tillage in appropriate conditions (ie following rain or irrigation) to optimise germination of volunteers;
- securely transport and store the GMO and other plant material and seeds;
- clean both the release site after harvest and equipment used at the site; and
- monitor the release site and monitoring zone after harvest and destroy volunteers.

Transfer of introduced genes to other organisms

Licence conditions have been imposed which require the applicant to:

- limit the scale and duration of the release;
- surround the GM Indian mustard and any other plants grown on the site with a monitoring zone within the isolation zone;
- surround the GM Indian mustard and any other plants grown on the site with a monitoring zone (within the isolation zone), an isolation zone of either 400 m (with pollen trap) or 1 km (without pollen trap). No other Indian mustard or sexually compatible plants may be planted in the isolation zone. A 400 m isolation zone will also apply if 'selfing' bags or insect proof cages and/or tents are used;
- ensure the pollen trap of either Indian mustard (*B. juncea*) or non-GM canola (*B. napus*) or male sterile GM canola is 15 m wide;
- confine bees, if used, within cages or tents that are regularly inspected to maintain their integrity;
- kill or confine bees used at the location to the tents or cages until the end of flowering to ensure no viable pollen will be carried by the bees from the location once the hives are relocated;
- securely transport and store the GMO and other plant material and seeds;
- clean both the release site after harvest and equipment used at the site; and
- monitor the release site and monitoring zone after harvest and destroy volunteers.

General conditions

Any licence issued by the Regulator also contains a number of general conditions that are also relevant to risk management. These include, for example:

- identification of the persons or classes of persons covered by the licence;
- a requirement that the applicant allows access to the release site by the Regulator, or persons authorised by the Regulator, for the purpose of monitoring or auditing; and
- a requirement to inform the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

Research requirements for current release

The release represents early stage research to determine the performance of the GM Indian mustard in Australian field conditions, select the most suitable lines for further development and produce seed for possible future research.

The data available on expression and molecular characterisation of the introduced genes for the GM Indian mustard was collected in glasshouse conditions overseas. Although these showed no unintended effects on plant properties, genes inserted by genetic modification can have an influence on multiple, sometimes unrelated plant traits. Unintended effects of the inserted genes may result in changes to characteristics that affect toxicity or allergenicity to humans, toxicity to other organisms, or weediness.

Accordingly, licence conditions have been imposed that require the applicant, in consultation with the OGTR, to collect and provide to the Regulator the following data to validate the conclusions of the risk assessment:

- changes to agronomic characteristics that may affect the weediness potential of the GMO; and
- stability of the inserted genes in the GM Indian mustard over successive generations.

Identification of issues to be addressed for future releases

If the applicant were to apply for any future (particularly larger scale) releases, more information would be required including:

- molecular characterisation of the introduced genetic material and insertion in the genome;
- the levels of expression of the introduced genes in various tissues and seasonal variation under Australian field conditions;
- unintended effects of the genetic modification on toxicity;
- weediness potential of the GM Indian mustard, including seed dormancy and pollen viability data; and
- the level of pollen mediated gene flow between closely situated GM and non-GM Indian mustard and other closely related plants.

It should be noted that provision of the above data during the release is not required to ensure the management of risks to human health and safety and the environment from the release. This will be achieved by the risk management measures summarised in Chapter 2 (Table 2) and given effect by the licence conditions.

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. The OGTR also independently monitors releases that the Regulator has authorised. At least 20% of all field trial sites will be inspected each year, in accordance with a monitoring and compliance strategy based on risk profiling (which takes into account biological, seasonal, geographical and ecological risk factors) to determine whether licence holders are complying with the licence conditions, or whether there are any unforeseen problems.

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. This can be obtained from the website of the Office of the Gene Technology Regulator (www.ogtr.gov.au), or by calling 1800 181 030 (please quote application number DIR 057/2004).