

Risk Assessment and Risk Management Plan

Final Version

DIR 020/2002

Commercial release of Roundup Ready[®] 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 cannot 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 stakeholders including the public. The RARMP forms the basis of her decision whether or not to issue a licence.

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 Gene Technology Regulator is responsible for the evaluation of all applications for contained research and early stage trial work with GMOs in Australia. However, once a GMO reaches later stage development or commercial application, other product approval authorities also have a role. For example Food Standards Australia New Zealand (FSANZ) sets the standards for safety and labelling of foods for human consumption. Approvals may be sought for imported GM foodstuffs, prior to seeking approval from the Regulator to grow the crop in Australia.

Similarly, the Agricultural Pesticides and Veterinary Medicines Authority (APVMA) is responsible for assessing the safety and ensuring the efficacy of all agricultural chemicals and veterinary medicines on a whole of sector basis. Insecticidal GM crops must be registered by the APVMA as well as licensed for release by to the environment by the Regulator, and the

use of registered herbicides on GMOs (such as Roundup Ready[®] herbicide on Roundup Ready[®] canola) normally requires the approval of an extension of use to the registration.

The Regulator is required to seek input from both FSANZ and the APVMA during the preparation of the RARMP, as well as the Therapeutic Goods Administration which regulate pharmaceuticals and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) which regulates the use of industrial chemicals.

All of these agencies are required to advise the Regulator if they approve a product that is, or was produced by, a GMO in order for her to maintain a public record, on the OGTR website at www.ogtr.gov.au, of all dealings undertaken with GMOs in Australia.

The application

In June 2002, Monsanto Australia Ltd (Monsanto) applied for a licence (application number DIR 020/2002) for the commercial release of genetically modified (GM) canola (*Brassica napus*) into the environment.

The GM canola that Monsanto sought approval for is Roundup Ready[®] canola derived from transformation event GT73. Roundup Ready[®] canola is tolerant to the herbicide glyphosate.

Glyphosate is a broad-spectrum herbicide and is the active constituent of a range of proprietary herbicides, including Roundup[®], registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Glyphosate has been registered for use in non-selective (general) weed control in broadacre agriculture, horticulture and non-cropped areas including industrial areas and roadsides and is a widely used chemical in all these situations.

Conventional canola is sensitive to glyphosate, so the herbicide cannot be used for weed control in canola crops. Glyphosate can however be applied to Roundup Ready[®] canola without killing it, because of the introduced herbicide tolerance genes.

Glyphosate is registered under the trade name 'Roundup Ready[®]' herbicide by Monsanto' for use on Roundup Ready[®] cotton in Australia, but has not previously been registered for use on Roundup Ready[®] canola.

The APVMA has recently approved an extension of use on the registration of Roundup Ready[®] herbicide to enable its application 'over the top' of Roundup Ready[®] canola crops to control post-emergent weeds (*ie.* once the crop has been planted and germinated). Appendices 4 and 6 of the RARMP contain further details.

Monsanto's application to the Gene Technology Regulator proposed commercial cultivation of Roundup Ready[®] canola in all current and future canola growing regions of Australia without specifying any containment measures.

Subject to approval, Monsanto anticipated a steady increase in the area sown to Roundup Ready[®] canola over a number of years across the canola growing regions of Australia, with the rate of increase being determined by market acceptance, State Government agreement and seed and variety availability.

Monsanto stated its intention to continue to work closely with the grains industry and State and Territory Governments to manage the introduction of Roundup Ready[®] canola.

Roundup Ready® canola from this release is intended for use as oil in human food, or in animal feed, in the same way as conventional (non-GM) canola. Roundup Ready® canola has been approved for growing and human consumption in Japan, Canada and the USA. It is approved for food use in Europe and an application is pending for environmental release. Roundup Ready® canola has been trialed previously in Australia under limited and controlled conditions, and oil derived from Roundup Ready® canola has been approved by Food Standards Australia New Zealand (FSANZ) for use in human food in Australia. Chapter 1 of the RARMP provides further details.

Roundup Ready® canola has been genetically modified to be tolerant to the herbicide glyphosate by the introduction of two genes, the *CP4 EPSPS* gene from the bacterium *Agrobacterium* sp. strain CP4 and the *goxv247* gene from the bacterium *Ochrobactrum anthropi*. The *CP4 EPSPS* gene encodes the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) and the *goxv247* gene encodes the enzyme glyphosate oxidoreductase (GOX).

Glyphosate kills plants by inhibiting the endogenous plant EPSPS enzyme that is involved in an important biochemical pathway for synthesis of aromatic amino acids. The pathway is not present in mammalian, avian or aquatic animals which explains the herbicide's selective action on plants. The enzyme produced by the *CP4 EPSPS* gene has a higher tolerance to the action of glyphosate than the plant's equivalent protein. Roundup Ready® canola is tolerant to glyphosate because the GOX enzyme detoxifies the glyphosate herbicide and the *CP4 EPSPS* gene has a high tolerance to glyphosate.

Under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC), Monsanto conducted five limited and controlled releases (PR77 and extensions) of Roundup Ready® canola in Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia.

In addition, the Regulator has previously assessed an application for the limited and controlled release of Roundup Ready® canola, and authorised further field trials in Victoria, South Australia, New South Wales and Western Australia under Licence No. DIR 011/2001.

There have been no reports of adverse effects on human health or the environment resulting from any of the releases associated with these trials.

Some information supplied by Monsanto in response to requests by the Regulator has been declared 'Confidential Commercial Information' under section 185 of the Act. In accordance with section 184 of the Act this information was not available to the general public. However it *was* available to the expert groups and authorities that are required to be consulted on the preparation of the RARMP and the APVMA.

The information included detailed technical information on molecular characterisation of Roundup Ready® canola, and draft versions of documents relating to Monsanto's stewardship strategy for Roundup Ready® canola.

The draft documents could not be completed until regulatory approvals were received from the Regulator and the APVMA, and the final licence and registration conditions known and incorporated. Following approval by the Australian Pesticides and Veterinary Medicines Authority, many of these documents *eg.* Roundup Ready® canola Crop Management Plan, Resistance Management Plan and Tech Topics technical notes, will be available from Monsanto at www.monsanto.com.au/canola/roundupCanola.htm or by contacting Monsanto directly.

The risk assessment and evaluation process

Licence application DIR 020/2002 from Monsanto was evaluated and a RARMP was prepared, in accordance with the Act and the Regulations, using the Risk Analysis Framework. This framework was developed as part of the establishment of the new regulatory arrangements in consultation with the public, key State, Territory and Australian government stakeholders, and the Gene Technology Technical Advisory Committee, and is available at www.ogtr.gov.au/pdf/public/raffinal.pdf.

Details of the process that the Regulator must follow, including the prescribed consultation process, and the matters that must be considered in preparing a RARMP and licence, are set out in Appendix 9 of the RARMP. The complete, finalised RARMP can be obtained from the Office of the Gene Technology Regulator's (OGTR's) website at www.ogtr.gov.au or by contacting the Office on 1800 181 030.

The risk assessment considered information contained in the application (including information required by the Act and the Regulations on the GMO, the parent organism, and the proposed dealings and on potential impacts on human health and safety and the environment). The assessment also considered submissions received from expert groups and authorities consulted on the application as prescribed by the Act, invited advice from the public and the most current scientific knowledge.

As mentioned above, an extension of use to allow Roundup Ready[®] herbicide (a formulation of glyphosate) to be used for post emergent weed control in Roundup Ready[®] canola crops in Australia has been approved by the APVMA. 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, as well as herbicide efficacy and herbicide resistance management requirements.

The Gene Technology Regulator's risk assessment evaluated potential hazards that might be posed by the release of the GM canola based on the combined consideration of the likelihood of the hazard occurring and the likely impact if the hazard were realised. These hazards were considered and evaluated previously for the same GM canola under the Roundup Ready[®] canola field trial application DIR 011/2002, but were reassessed to determine whether the proposed scale of the release posed any additional risks.

Through this process, potential hazards to human health and safety or the environment that may be posed by the release of the GM Roundup Ready[®] canola were investigated. They were evaluated on the basis of the likelihood of the hazard occurring and the likely impact of the hazard, if it were to be realised. The identified potential hazards relate to:

- **Toxicity or allergenicity to humans:** could Roundup Ready[®] canola be more toxic or allergenic than conventional canola, as a result of the novel gene products or because of unintended effects ?
- **Toxicity to other organisms:** could Roundup Ready[®] canola be harmful to other organisms including mammals (other than humans), livestock, wildlife, insects and microorganisms as a result of the novel gene products or because of unintended effects ?
- **Weediness:** could Roundup Ready[®] canola be harmful to the environment because of inherent weediness or increased potential for weediness ?
- **Gene transfer:** could the new genes introduced into Roundup Ready[®] canola transfer to conventional canola crops, closely related *Brassica* weeds, related

brassicaceous weeds or other organisms, with any adverse consequences for the environment ?

- **Herbicide Resistance:** as glyphosate is a widely used herbicide in Australia, both in agricultural and other situations, could weeds develop resistance to herbicide if the Roundup Ready[®] canola crop-herbicide combination is used inappropriately?
- **Change in herbicide use patterns:** what is the impact of using herbicides other than glyphosate to control Roundup Ready[®] canola volunteers ?

The consultation version of the RARMP was released for public comment on 2 October 2003. Although the Act specifies a minimum consultation of 30 days, the Regulator extended the period to eight weeks *ie.* until 28 November 2003.

Public consultation is an essential component of Australia's gene technology regulatory scheme that helps ensure that issues can be raised, hazards identified and risks investigated to determine whether or not they can be managed. Input from the public, interested organisations and government agencies on this application has provided particularly valuable feedback. The issues raised are discussed further in Chapter 2 and Appendix 10.

Comments on the RARMP for Roundup Ready[®] canola were wide ranging – from philosophical objections to gene technology generally, through to support for this canola variety in particular. Submissions ranged in length and substance from short one-sentence comments through to detailed papers covering many pages.

All of these submissions were analysed by OGTR. Many of the issues raised had been considered during the development of the consultation version of the RARMP. However, the consultation comments highlighted areas that required further explanation and we have sought to do this as part of this licence decision package.

Economic, trade and marketing considerations

There has been considerable speculation in the media and other forums, as well as in some submissions from the public, about the possible impact of the uptake of GM canola on conventional agriculture and upon Australia's 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 evaluation of risks to human health and safety and the environment. This was to prevent the possibility of economic considerations, such as cost-benefit analyses, market access and agricultural trade implications, from 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-benefit 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 Monsanto's Roundup Ready[®] canola to individual farmers, or on market impacts for the agricultural industry.

However, the Regulator and other government agencies are aware of the level of concern about, and the need for information on, marketing issues in particular. A number of submissions expressed disappointment that the Regulator could not consider potential economic and marketing impacts. It was therefore considered appropriate to highlight a number of government and industry initiatives (independent of this assessment) which do

focus on the assessment of economic and marketability considerations in relation to the adoption of GM canola by the Australian agriculture industry.

Available documentation such issues includes:

- the ABARE report *Market Access Issues for GM Products – Implications for Australia* available from www.abareonlineshop.com/product.asp?prodid=12559
- the Australian Bureau of Agricultural & Resource Economics (ABARE) report *Australian Grains Industry 2003-GM Canola. What are its economics under Australian conditions?* available from www.abareonlineshop.com/product.asp?prodid=12526
- the Productivity Commission report *Modelling Possible Impacts of GM Crops on Australian Trade* available at www.pc.gov.au/research/staffres/gmcrops/index.html
- the (industry-based) Gene Technology Grains Committee's *Canola Industry Stewardship Protocols for Coexistence of Production Systems and Supply Chains*. The Gene Technology Grains Committee protocols are available at www.avcare.org.au/default.asp?V_DOC_ID=887

A number of other informative papers are available from the Australian Government Department of Agriculture, Fisheries and Forestry at www.daff.gov.au/agbiotech.

Further information on industry and government initiatives is provided in Appendix 7 of the RARMP.

Conclusions of the risk assessment

Following rigorous assessment, the Regulator considers that the risks posed by the proposed commercial release of Roundup Ready[®] canola to human health, safety and the environment are no greater than those posed by conventional (non-GM) canola. Accordingly, the Regulator has decided to issue a licence in respect of the Monsanto application DIR 020/2002, which contains only minimal oversight conditions. The assessment of each potential hazard identified above is summarised under a separate heading below.

Toxicity or allergenicity to humans

Roundup Ready[®] canola is not likely to prove more toxic or allergenic to humans than conventional canola in either food or non-food uses. Studies show that the introduced proteins are not toxic, are rapidly degraded by mammalian digestive systems and do not share significant sequence homology with known protein toxins or allergens. Feeding studies with Roundup Ready[®] canola seed or meal demonstrate no anti-nutritional effects of the genetic modification. The composition of Roundup Ready[®] canola and the level of naturally occurring toxicants do not significantly differ from conventional canola. The major metabolites of glyphosate are not toxic. In addition, the introduced proteins are expressed at low levels in the GM plants and are already commonly encountered by humans in nature. Oil from the Roundup Ready[®] canola, which contains no detectable levels of genetic material or protein, is the only component of the canola that will be consumed by humans and has been approved for use in food by FSANZ.

Toxicity to other organisms

Roundup Ready[®] canola is not likely to prove more toxic to other organisms than conventional canola. As outlined above, a number of studies, including toxicity and feeding studies in a range of organisms, have shown no increased toxicity to other organisms.

Therefore the risks are considered negligible and it is not considered necessary to impose any management conditions in relation to potential toxicity to other organisms.

Weediness

The risk that Roundup Ready® canola will be more invasive or persistent than conventional (non-GM) canola in Australia is negligible.

The growth characteristics and agronomic performance of Roundup Ready® canola are within the range of conventional canola.

Canola can occur as an agricultural weed, particularly as plants (known as volunteers) that germinate after harvest from fallen seed. However, because it is a highly domesticated crop, canola does not establish or persist well in undisturbed, natural habitats.

The introduction of tolerance to the herbicide glyphosate will not provide any selective advantage over conventional canola except where glyphosate is used.

Roundup Ready® canola is only tolerant to glyphosate and its susceptibility to other herbicides is no different to conventional canola. Therefore, Roundup Ready® canola can be effectively managed and controlled using alternative herbicides and other (non-chemical) weed control practices that can be applied to conventional canola.

Glyphosate is widely used for weed control (including canola volunteers) in Australia in broad-acre agriculture, horticulture and other situations. The APVMA has approved an extension of the registration of Roundup Ready® by Monsanto for post-emergent weed control in Roundup Ready® canola crops (*ie.* once the crop has been planted and the seed has germinated).

The emergence of volunteer plants subsequent to the cultivation of a crop, and their control or removal prior to the next season's planting, is an integral part of normal agricultural practice that is not in any way restricted or peculiar to either canola or GM crops. Therefore, adoption of Roundup Ready® canola will mean that farmers will need to make choices and potentially modify their farming practices. This may result in increased complexity in implementing alternative weed management strategies, as well as other economic considerations. It will not pose any greater risks to human health and safety or the environment than conventional canola. Therefore no risk management conditions are proposed in relation to weediness.

Gene Transfer

When analysing the risk of gene transfer, it is important to distinguish between hybridisation and introgression. Hybridisation is the crossing of two different plants of the same or different species, resulting in the production of hybrid progeny. Introgression is the incorporation of the new gene into successive generations of the hybrid population. Hybridisation only occurs in a single subsequent generation of plants whereas introgression is ongoing. Therefore introgression is more likely to pose an environmental consequence.

To other canola

In a commercial situation, outcrossing between canola varieties is inevitable, but the overall frequency of out-crossing will be very low decreasing significantly at distances of over 5-10 metres. Gene transfer to other canola is most likely in close proximity to Roundup Ready® canola.

Even if gene transfer to other canola did occur, it would pose no greater risks other than the negligible risks posed by Roundup Ready® canola itself, or require management. As explained above, transfer of the herbicide tolerance genes will not confer a selective

advantage in the absence of glyphosate and will not make plants more invasive or persistent. Roundup Ready® canola is only tolerant to glyphosate and it is as susceptible to other herbicides as conventional canola, and glyphosate tolerant volunteers can be controlled with other herbicides and management practices.

The emergence of glyphosate tolerant volunteers where Roundup Ready® canola has not previously been sown will mean that farmers must make choices about methods of weed control, after considering farm practice and economic issues.

Gene transfer to other canola will not pose any greater risks to human health and safety or the environment than conventional canola.

To closely related Brassica species

The likelihood of some gene transfer from Roundup Ready® canola to the closely related weedy *Brassica* species *B. rapa* and *B. juncea* is high, but less than for the transfer to canola (*B. napus*) and decreases rapidly with distance from the crop. Because of the lower incidence of these species, especially *B. juncea*, and the reduced 'fitness' of any progeny *eg.* vigour, fertility *etc.*, the overall frequency of introgression would also be lower. Gene transfer to *B. oleracea* would be unlikely, as hybrids are not readily formed.

B. rapa, *B. juncea* and *B. oleracea* are all principally weeds of agricultural cropping or disturbed habitats, but not of undisturbed natural habitats. Glyphosate tolerant hybrids would be most likely to arise within or adjacent to Roundup Ready® canola crops, where glyphosate would not be used for weed control post-harvest because it would not control Roundup Ready® canola volunteers. In such situations, measures taken to control Roundup Ready® canola would also eliminate any glyphosate tolerant *Brassica* species.

In disturbed habitats such as roadsides, glyphosate tolerant *Brassica* species can be controlled by all other herbicide and non-chemical methods currently used to control them. Glyphosate is widely used for non-selective weed control in Australia, including the control of brassicaceous weeds. Glyphosate is not the herbicide of choice for the control of all broadleaf weeds, and therefore other herbicides are often incorporated with glyphosate (tank mixing or 'spiking') in situations where there is a mixed weed spectrum or enhanced knockdown of difficult to control weeds is required.

If gene transfer from Roundup Ready® canola *B. rapa*, *B. juncea* and *B. oleracea* did occur, it would not make them more invasive or persistent. While transfer of the glyphosate tolerance trait to related species would not result in an adverse impact on the environment, it would have implications for the choice of herbicide(s) in situations where glyphosate is the principal strategy for control of these plants.

Taking into account the relative weediness, persistence and distribution of the related *Brassica* species, the risk of gene transfer from Roundup Ready® canola in a commercial situation resulting in adverse environmental impacts is considered to be very low for *B. rapa* and negligible for *B. juncea* and *B. oleracea*.

To sexually compatible brassicaceous weeds

Gene transfer from Roundup Ready® canola to the less closely related brassicaceous weed species would be restricted to *Raphanus raphanistrum*, *Hirschfeldia incana* and *Sinapis arvensis*. The overall frequency of outcrossing is expected to be extremely low, and the likelihood of introgression in any resulting hybrid plants is considered to be very low because of genome incompatibility and the severely reduced 'fitness' of any progeny.

Even if gene transfer from Roundup Ready® canola to *R. raphanistrum*, *H. incana* and *S. arvensis* did occur over time, it would not make the hybrids more invasive or persistent.

Like the more closely related *Brassica* species, *R. raphanistrum*, *H. incana* and *S. arvensis* are all principally weeds of agricultural cropping or disturbed habitats, but not of undisturbed natural habitats. Glyphosate tolerant hybrids would be most likely to arise within or adjacent to Roundup Ready® canola crops where glyphosate would not be used for weed control post-harvest because it would not control Roundup Ready® canola volunteers.

Glyphosate is widely used for non-selective weed control in disturbed habitats in Australia, including the control of brassicaceous weeds. As for the related *Brassica* species, transfer of the glyphosate tolerance trait to these species would not result in an adverse impact on the environment but it would have implications for the choice of herbicide(s) in situations where glyphosate is the principal strategy for control of these plants. Glyphosate tolerant brassicaceous weeds would be effectively controlled by all other herbicide and non-chemical methods that are currently used to control them.

Taking into account the relative weediness, persistence and distribution of these species, the risk of gene transfer to any of these brassicaceous weeds in a commercial situation resulting in adverse impacts on human health and safety or the environment is considered to be very low.

To other brassicaceous species

Natural hybridisation between canola and other brassicaceous species has not been demonstrated and the risk of gene transfer from Roundup Ready® canola to other brassicaceous species is therefore considered negligible.

To other organisms

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 and the overall risk is considered negligible.

Herbicide Resistance

The Australian Pesticides and Veterinary Medicines Authority (APVMA) operates the national system that evaluates, registers and regulates agricultural and veterinary chemical products. Both the OGTR and the APVMA recognise the importance of assessing potential risks associated with the use of herbicides on genetically modified canola. In particular, over the past year, both agencies have been consulting with a range of key stakeholders to evaluate the issues that may arise from the proposed extended use of glyphosate as Roundup Ready® herbicide by Monsanto for weed control in Roundup Ready® canola crops.

The effectiveness of Roundup Ready® canola as a crop depends upon the use of Roundup Ready® herbicide (glyphosate) to control other competing plants and weeds. Because glyphosate has low toxicity to animals (including humans) and microbes, and minimal persistence in the environment, its use is favoured over other, less benign herbicides and may provide an environmental benefit. However, there is potential for development of herbicide-resistant weeds if glyphosate (including Roundup Ready® herbicide) is used (or overused) inappropriately.

Development of herbicide resistance leads to the reduction in options for chemical weed control. In the case of glyphosate resistance, this would mean the reduced usefulness and shortened lifespan of a relatively innocuous, effective and inexpensive agricultural tool. The Regulator is mindful of the importance of glyphosate to Australia in both the agricultural and non-agricultural environments and has worked closely with the APVMA to ensure mechanisms are in place to avoid further development of resistance.

This issue has been assessed by the APVMA and addressed by conditions of registration for the use of Roundup Ready® herbicide on Roundup Ready® canola crops. Accordingly, no specific conditions in relation to management of herbicide resistance are included in the Regulator's licence for Roundup Ready® canola.

The Regulator strongly endorses the range of measures being put in place by the APVMA and industry to minimise the development of herbicide resistance. These measures include:

- implementation of Monsanto's Roundup Ready® canola Resistance Management Plan;
- reporting of resistance incidents to the APVMA; and
- establishment of an industry/expert/government Herbicide Resistance Consultation Group.

Change in Herbicide Use Patterns

During the course of consultations, a number of stakeholders sought clarification on the impact that the introduction of Roundup Ready® canola might have on the herbicides used. It is important to note that mixtures of herbicides are commonly applied to achieve effective control where a range of weeds of differing sensitivity may be present.

Wherever *unwanted* Roundup Ready® canola plants occur (*eg.* following harvest of a Roundup Ready® canola crop or a less likely scenario where glyphosate tolerant weeds develop as a result of gene transfer), methods *other* than glyphosate would have to be used for their eradication. These may include other herbicides or mechanical weed control.

Because glyphosate has low toxicity to animals (including humans) and microbes, and minimal persistence in the environment, its use may provide an environmental benefit over other, less benign herbicides that may be more toxic or persistent (*eg.* able to enter ground water).

The APVMA ensures that the use-pattern associated with these herbicides as specified by label conditions does not compromise the safety of users or the environment and has recently introduced a program for reporting any adverse effects associated with agricultural chemical use. The list of approved chemicals can be reviewed by the APVMA at any time. For example, the herbicide 2,4-D (one of the most commonly used herbicide mixers) and atrazine (the most widely used triazine herbicide) currently under review.

Nevertheless, over-reliance on individual herbicides encourages the development of resistance and there are many other herbicides registered by the APVMA that can be applied. Increasingly, growers are adopting integrated weed management to reduce their reliance on chemicals. This includes measures such as:

- active control of volunteers (both chemical and mechanical);
- informed selection and rotation of herbicides and crops ;
- maintenance of hygiene in seed, harvesting and transport; and
- implementation of good agronomic practice.

In addition to the above measures and those designed to minimise the development of herbicide resistance outlined previously, Monsanto and other industry bodies will be implementing a range of initiatives to promote sustainable agricultural practices generally and integrated weed management practices in particular (see Appendix 4 and 6 for further details). The OGTR and the APVMA are highly supportive of this trend and will continue to liaise to ensure the consistent identification and coordinated management of issues relating to herbicide use and GMOs.

Summary of the risk management plan

Risk of toxicity or allergenicity

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

Risk of weediness

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

Risk of gene transfer

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

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 the GMO or its novel genetic material.

Herbicide resistance

This issue has been assessed by the APVMA and addressed by conditions of registration for the use of Roundup Ready[®] herbicide on Roundup Ready[®] canola. Therefore no specific conditions in relation to management of herbicide resistance are included in the Regulator's licence for Roundup Ready[®] canola. The licence holder's obligation to comply with conditions imposed by the APVMA is noted in the licence.

Reporting conditions

The licence holder is required to provide an annual report on the commercial release. The Act requires all licence holders to inform the Regulator as soon as they become aware of any new information about risks to human health and safety or the environment, or of any unintended effects so that remedial action could be taken. The annual report also includes information on any adverse impacts on human health and safety or the environment caused by the GMO. In addition, Monsanto is required to report to the Regulator the amount of Roundup Ready[®] canola sold commercially or otherwise grown in each growing season for each State and Territory. Monsanto is also required to report annually and comply with other conditions required under the APVMA registration of Roundup Ready[®] herbicide.

Detailed information on the proposed licence conditions is available in the full RARMP document. The RARMP can be obtained from the Office of the Gene Technology Regulator (OGTR) website at www.ogtr.gov.au or by contacting the Office on 1800 181 030.

Industry management proposals

Draft Monsanto guidance documents and industry guidelines developed to assist all participants in the agricultural supply chain to achieve coexistence between different production systems (eg. GM/non-GM) were all considered in the course of the evaluation.

Monsanto's documents aim to achieve effective technology stewardship, and both they and the industry management guidelines focus on agricultural and handling practices which aim to enable separation of GM and conventional crops to the extent required by markets. 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 even in the absence of any supply chain management controls.

Although the evaluation demonstrates there are no risks from Monsanto's Roundup Ready[®] 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. A number of State and Territory Governments have introduced interim measures pending agreement on market access and supply chain segregation issues. The rate of take-up of Monsanto's Roundup Ready[®] canola will therefore be determined by State Government and industry consultations.

Although the Regulator has approved the commercial release on human health, safety and environmental grounds, the applicant still needs to obtain the requisite approval from such jurisdictions in order to grow Roundup Ready[®] canola.

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.