



Office of the Gene Technology Regulator

EXECUTIVE SUMMARY

The Risk Assessment and Risk Management Plan for
Application No. DIR 023/2002 from
Monsanto Australia Ltd

*(Continued commercial release of GM herbicide tolerant and
herbicide tolerant/insecticidal cotton)*

THE REGULATION OF GENETICALLY MODIFIED ORGANISMS

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 stakeholders.

THE APPLICATION

Monsanto Australia Ltd (Monsanto) applied for a licence (application number DIR 023/2002) for the continued commercial release of genetically modified (GM) herbicide tolerant Roundup Ready[®] cotton and herbicide tolerant/insecticidal Roundup Ready[®]/INGARD[®] cotton into the environment, for cultivation in the cotton growing regions of New South Wales and Queensland south of latitude 22° South.

Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton were approved for general (commercial) release in 2000 (GR-9) and INGARD[®] cotton in 1996 (GR-3), based on advice from the Genetic Manipulation Advisory Committee (GMAC) which oversaw the previous voluntary system. Section 190 of the Act includes arrangements for such dealings to be 'deemed' as licensed for two years from the commencement of the Act on 21 June 2001, therefore expiring on 21 June 2003. The issuing of a licence in respect of application DIR 023/2002 will allow the continued commercial release of these genetically modified cottons beyond 21 June 2003. Continued commercial release of INGARD[®] cotton was approved under licence number DIR 022/2002.

Roundup Ready[®] cotton (GM event 1445) contains a gene that confers tolerance to glyphosate, the active ingredient of the herbicide Roundup[®]. Conventional cotton is susceptible to glyphosate damage. The use of Roundup Ready[®] cotton allows the application of glyphosate for the control of weeds that emerge early in the crop (up to the four-leaf growth stage). INGARD[®] cotton (GM event 531) contains a gene that encodes a highly specific lepidopteran insect toxin. Roundup Ready[®]/INGARD[®] cotton was produced by conventional breeding of Roundup Ready[®] cotton with INGARD[®] cotton, and expresses both the herbicide tolerance and insecticidal properties. Both Roundup Ready[®] cotton and

Roundup Ready®/INGARD® cotton contain bacterial genes conferring resistance to antibiotics that were used solely as selectable markers in the initial laboratory stages of developing the GM cottons.

It is intended that GM cotton plants and their by-products, including cottonseed, be used in the same manner as non-GM cotton, including for human food and stockfeed. Cottonseed is processed for oil that is used in a variety of foods, and for cotton linters (short fibres that do not contain genetic material or protein) that are used as a cellulose base in some foods. Food Standards Australia New Zealand (FSANZ, formerly the Australia New Zealand Food Authority, ANZFA) has already approved the use of oil and linters from Roundup Ready® cotton and INGARD® cotton in human food. Cottonseed from Roundup Ready® and Roundup Ready®/INGARD® cotton has also been used as stockfeed, including in northern Australia, since their commercial release in 2000.

The Australian Pesticides and Veterinary Medicines Authority (APVMA, formerly National Registration Authority for Agricultural and Veterinary Chemicals, NRA) is responsible for approving use patterns of GM cotton carrying insecticidal genes (including INGARD® cotton, Roundup Ready®/INGARD® cotton, Bollgard II® cotton and Roundup Ready®/Bollgard II® cotton), due to these plants' ability to produce an insecticidal substance. The APVMA currently limits planting of these GM cottons to 30% of the cotton crop in any region, to guard against the emergence of resistant insects. The APVMA is also responsible for setting conditions on the use of Roundup Ready® herbicide on Roundup Ready® cotton crops, including conditions relating to herbicide resistance management.

Monsanto proposes to phase-out Roundup Ready/INGARD® cotton over the next 2 cotton growing seasons while the GM herbicide tolerant/insecticidal Roundup Ready/Bollgard II® cotton (approved for commercial release under licence number DIR 012/2002) is phased-in over the same period.

Prior to commercial release of Roundup Ready® cotton, 23 limited and controlled releases involving Roundup Ready® cotton and 12 involving Roundup Ready®/INGARD® cotton were conducted under the former voluntary system overseen by GMAC. There have been no reports of adverse effects on human health or the environment resulting from any of these releases, nor have there been any such reports since INGARD® and Roundup Ready® cotton were released commercially in 1996 and 2000 respectively.

THE EVALUATION PROCESS

Licence application DIR 023/2002 from Monsanto 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 State, Territory and Commonwealth 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 on the application, and the matters that must be considered in preparing a RARMP, are set out in Appendix 8 of the RARMP. The complete RARMP can be obtained from the OGTR or from the OGTR's web site at www.ogtr.gov.au.

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

As mentioned above, the use of Roundup Ready[®] herbicide (a formulation of glyphosate) on Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton crops in Australia is registered by the APVMA. As part of their assessment of this use, the APVMA consider potential human health and environmental effects, for example arising through occupational exposure or residues. Thus risks associated with the use of glyphosate are not generally considered in the risk assessment of these GM cottons.

Through this process, potential hazards to human health and safety or the environment that may be posed by release of Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton were identified. These have been evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard, were it to be realised. The identified potential hazards relate to:

- **toxicity and allergenicity for humans:** could Roundup Ready[®] cotton or Roundup Ready[®]/INGARD[®] cotton be more toxic or allergenic than non-GM cotton, as a result of the novel gene products or because of unforeseen or unintended effects?
- **toxicity for non-target organisms:** could Roundup Ready[®] cotton or Roundup Ready[®]/INGARD[®] cotton be harmful to non-target organisms as a result of the novel gene products or because of unforeseen or unintended effects?
- **weediness:** could Roundup Ready[®] cotton or Roundup Ready[®]/INGARD[®] cotton be harmful to the environment because of inherent weediness or increased potential for weediness?
- **transfer of introduced genes to other organisms:** could the new genes introduced into the cottons transfer to non-GM cotton crops, feral or native cottons, or to other organisms, with adverse consequences?
- **insecticide and herbicide resistance:** could target insects develop resistance to the insecticidal protein produced by the introduced insecticidal gene in Roundup Ready[®]/INGARD[®] cotton. Similarly, could weeds develop resistance to herbicide if the Roundup Ready[®] crop-herbicide combination is used inappropriately?

CONCLUSIONS OF THE RISK ASSESSMENT

The Regulator considers that no risks to human health and safety, or to the Australian environment, will result from the continued commercial release of Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton, that are greater than the very low risks posed by non-GM cotton. The assessment of each potential hazard identified above is summarised under a separate heading below.

Toxicity or allergenicity to humans

Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton are unlikely to prove more toxic or allergenic to humans than conventional cotton. As noted above, FSANZ has previously approved the use in food of oil and linters from Roundup Ready[®] cotton and INGARD[®] cotton, concluding that products from these GM cottons are as safe as are those from non-GM cotton. Therefore it is not considered necessary to impose any management conditions in relation to potential toxicity or allergenicity.

Toxicity to non-target organisms

Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton are unlikely to prove more toxic to non-target organisms than conventional cotton. The introduced proteins have been

found to be non-toxic to non-target organisms, and these GM cottons have been used as stock feed with no reports of adverse effects. Therefore it is not considered necessary to impose any management conditions in relation to potential non-target toxicity.

Weediness

The risk of Roundup Ready[®] cotton or Roundup Ready[®]/INGARD[®] cotton establishing as a weed in cotton-growing areas of Australia south of latitude 22° South is very low, and not likely to be greater than that of conventional cotton. The germination and/or persistence of non-GM and GM cotton in southern Australia are effectively limited by the prevailing conditions of soil moisture, soil nutrients, plant competition and frosts. Therefore it is not considered necessary to impose any conditions to manage the risk of weediness in southern Australia.

Although Monsanto only seeks approval to grow Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton south of latitude 22° South, cottonseed from these GM cottons may be transported north for use as stockfeed. Limited experimental data suggests that INGARD[®] cotton may have the potential to be more weedy than non-GM cotton in certain habitats in northern Australia. However INGARD[®] cottonseed has been used as stockfeed in northern Australia since its commercial release in 1996, and Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cottonseed since 2000, with no indication that these cottons have become problematic weeds, or more prevalent than conventional cotton.

Although it is considered that there is a low risk of Roundup Ready[®]/INGARD[®] cotton becoming weedy in specific habitats in northern Australia, conditions have been imposed to limit and monitor for the spread and persistence of these GM cottons in northern Australia.

Transfer of introduced genes to other organisms

Some gene transfer from Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton to other cultivated cotton is likely but the overall frequency of out-crossing is very low. If this occurs, it would not pose any risks additional to those posed by the GM cotton itself. The conventional farming practice of using certified (pure) seed every season minimises the presence of the new genes in non-GM crops.

The potential for transfer of the introduced genes to native cotton species is negligible, because of genetic incompatibility with all native species and, for many, geographic isolation.

The potential for gene transfer to feral (naturalised) cotton is low because of geographic isolation of known feral populations in Western Australia and the Northern Territory from areas of NSW and Queensland in which Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton will be grown. Although herbarium records suggest that feral cotton populations may also occur in Queensland, there is a relative lack of detailed information on the location of such populations. Licence DIR 022/2002, issued for the continued commercial release of INGARD[®] cotton, requires Monsanto to document the location of these populations, if they exist, in Queensland and determine their distance from cotton production locations, to assess whether additional controls are required.

The likelihood of transfer of the introduced genes to other organisms is negligible, but even if such transfer occurred it would be unlikely to pose any hazard to human health and safety or the environment. Therefore it is not considered necessary to impose any management conditions in relation to gene transfer.

Insecticide and herbicide resistance

The risk of the targeted insects developing resistance to the insecticidal protein in the long term is high, however this risk is being managed by the APVMA through oversight of an insecticide resistance management plan in connection to the use of INGARD[®] cotton.

There is also potential for development of herbicide-resistant weeds if the Roundup Ready[®] crop-herbicide combination is used inappropriately. This risk is also being managed by the APVMA, through conditions placed on the use of Roundup Ready[®] herbicide on Roundup Ready[®] cotton crops. Therefore no additional management conditions have been imposed in relation to insecticide and herbicide resistance.

THE RISK MANAGEMENT PLAN (KEY LICENCE CONDITIONS)

As part of the evaluation process for this licence application, a risk management plan has been developed to address the identified risks (refer to Conclusion of the Risk Assessment, above). This plan is given effect by the licence conditions imposed. The key licence conditions are outlined below.

Toxicity or allergenicity to humans

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

Toxicity to non-target organisms

Based on the risk assessment, no management conditions have been imposed in relation to non-target toxicity.

Weediness

Based on the risk assessment, no management conditions have been imposed in relation to weediness in southern Australia. However, in order to complete the environmental monitoring program required in relation to the original commercial release of Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton in 2000, the licence requires:

- continuation of monitoring for volunteer cotton in non-agricultural situations within the cotton growing areas of New South Wales and Queensland for an additional growing season.

Also based on the risk assessment, conditions have been imposed to limit the spread and persistence of GM cotton in northern Australia, and to further assess the potential for weediness of these GM cottons in northern Australia. The licence includes conditions that require:

- the use of covered vehicles for transport of GM cotton seed north of latitude 22° South;
- the licence holder to develop, in consultation with the OGTR, a strategy to communicate the importance of control of cotton plants to recipients of GM cotton seed north of latitude 22° South; and
- the licence holder to conduct an annual survey of the incidence of volunteer cotton in areas where GM cotton seed is used as stock feed, and the effectiveness of the communication strategy required above.

Transfer of introduced genes to other organisms

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

Insecticide and herbicide resistance

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

General conditions

Any licence issued by the Regulator also contains a number of general conditions, which are also relevant to risk management. These include, for example, identification of the persons or classes of person covered by the licence and informing the Regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

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.

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 (www.ogtr.gov.au), or by calling 1800 181 030 (please quote application number DIR 023/2002).