

Office of the Gene Technology Regulator

APPLICATION FOR LICENCE FOR INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT: Application No. DIR 0023/2002

SUMMARY INFORMATION

Project Title:	Commercial release of herbicide tolerant (Roundup Ready [®]) and herbicide tolerant/insect resistant (Roundup Ready [®] /INGARD [®]) cotton*
Applicant:	Monsanto Australia Ltd PO Box 6051 Melbourne, VIC 8008
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Herbicide tolerance (Roundup [®] herbicide) Herbicide tolerance/Insect resistance (Roundup [®] herbicide/Bt protein) Antibiotic resistance
Identity of the gene(s) responsible for the modified trait(s):	<ul style="list-style-type: none">• CP4 EPSPS gene from <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)• cryIAC gene from the bacterium <i>Bacillus thuringiensis</i> (insecticidal)• nptII gene from bacterial Tn5 transposon (antibiotic resistance)
Proposed Release Location	Cotton growing regions of New South Wales (NSW) and Queensland (Qld) south of latitude 22° South (see Appendix for possible release sites)
Proposed Release Size:	As required by the Australian cotton industry. A size limit is imposed on the Roundup Ready [®] /INGARD [®] cotton planting area as part of the Insecticide Resistance Management Strategy for INGARD [®] cotton regulated by the NRA.
Proposed Release Date:	First cotton growing season after issuing of the licence (August 2003) and ongoing thereafter.

* Approval of this application would enable the continued commercial-scale release of the GMO that was authorised to proceed under the previous voluntary system and a 'deemed' licence, which expires in June 2003, issued when the new regulatory system came into effect.

Introduction

The *Gene Technology Act 2000* (the Act) took effect on 21 June 2001. The Act, supported by the *Gene Technology Regulations 2001*, an inter-governmental agreement and corresponding legislation that is being enacted in each State and Territory, underpins Australia's nationally consistent regulatory system for gene technology. Its objective is to protect the health and safety of people, and

the environment, by identifying risks posed by or as a result of gene technology, and managing those risks by regulating certain dealings with genetically modified organisms (GMOs).

The Act establishes a statutory officer, the Gene Technology Regulator (the Regulator), to administer the legislation and make decisions under the legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), a Commonwealth regulatory agency located within the Health and Ageing portfolio.

The legislation sets out the requirements for considering applications for licences for dealings with GMOs and the matters that the Regulator must take into account before deciding whether, or not, to issue a licence.

The application and the proposed dealings

In accordance with section 190 of the Act, a 'deemed' licence (GR-9) for the general (commercial) release of Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton was issued to Monsanto Australia Ltd (Monsanto) before the commencement of the Act on 21 June 2001, based on the approval issued under the previous voluntary system administered by the Genetic Manipulation Advisory Committee (GMAC). The deemed licence is effective during the transition period, i.e. 2 years from the commencement of the Act. Therefore, the deemed approval for commercial cultivation of Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton will expire in June 2003.

The OGTR has received a licence application from Monsanto for the intentional release of Roundup Ready[®] and Roundup Ready[®]/INGARD[®] cotton into the environment in the cotton growing regions of NSW and Qld south of latitude 22° South. Approval would enable the continued commercial release of the genetically modified cotton. Monsanto also proposes the phasing-out of Roundup Ready[®]/INGARD[®] cotton over the next three years while Roundup Ready[®]/Bollgard II[®] cotton (which was approved for commercial release in September 2002; DIR 012/2002) is phased-in over the same period.

Roundup Ready[®] cotton contains a gene that provides tolerance to glyphosate, the active ingredient of the herbicide Roundup[®]. Conventional cotton is susceptible to glyphosate. The use of Roundup Ready[®] cotton allows the application of Roundup[®] for the control of weeds that emerge in the crop. Roundup Ready[®]/INGARD[®] cotton was produced by conventional breeding of Roundup Ready[®] cotton with INGARD[®] cotton. The Roundup Ready[®]/INGARD[®] cotton inherits an insecticidal gene from INGARD[®] cotton that produces a protein toxic to lepidopteran caterpillar pests.

It is intended that GM cotton plants and their by-products, including cottonseed, be used in the same manner as conventional cotton, including for human food and stockfeed. Cottonseed is processed for oil that is used in a variety of food products and for cotton linters (a type of fibre that does not contain any genetic material) that are used as a cellulose base for several consumer food products. Food Standards Australia New Zealand, FSANZ, (formerly the Australia New Zealand Food Authority, ANZFA) has approved the use of oil and linters from Roundup Ready[®], INGARD[®] and Bollgard II[®] cotton in human food.

As the applicant seeks approval for commercial release of the GM cotton in all Australian cotton growing regions south of latitude 22° South, no limitations on transportation or storage are proposed (see below for further explanation).

Previous releases of the GMO

Roundup Ready[®] cotton and Roundup Ready[®]/INGARD[®] cotton was approved for general (commercial) release in 2000 (GR-9), by the Minister for Health and Aged Care, on the basis of advice from GMAC. INGARD[®] cotton had previously been approved for general (commercial) release in 1996 (GR-3), by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), also on the basis of advice from GMAC. General releases were restricted to the

cotton growing regions of NSW and Qld south of latitude 22° South because of concerns about the potential weediness of the cotton in tropical areas, as well as the potential for out-crossing to feral and native cotton species in these areas.

Prior to commercial release, numerous limited and controlled releases of Roundup Ready® and Roundup Ready®/INGARD® cotton were conducted under the voluntary system overseen by GMAC, as listed below:

Roundup Ready® - 23 limited and controlled releases undertaken by;

- CSIRO Division of Plant Industry (PR-55, PR-55X, PR-55X2, PR-55X3 and PR-55X5 and PR-55X6),
- Deltapine Australia Pty Ltd (PR-32, PR-52, PR-52X, PR-52X2, PR-52X3, PR-71, PR-71X, PR-71X2, PR-83, PR-83X, PR-83X3, PR-140, PR-140X and PR-143),
- Monsanto (PR-83X2 and PR-83X4) and
- Cotton Seed Distributors Pty Ltd (PR 55-X4).

INGARD® - 44 limited and controlled releases undertaken by;

- Queensland Department of Primary Industries (PR-141),
- Deltapine Australia Pty Ltd (PR-17, PR-31, PR-33, PR-34, PR-47, PR-47X, PR-47X2, PR-47X3, PR-47X4, PR-50, PR-50X, PR-51, PR-51X, PR-51X2, PR-51X3 and PR-51X5, PR-98, PR-98X, PR-112X, PR-112X2),
- CSIRO Division of Plant Industry (PR-20, PR-36, PR-36X, PR-36X2, PR-36X3, PR-36X4, PR-36X6, PR-38, PR-38X, PR-44, PR-44X, PR-44X2, PR-56, PR-89, PR-89X, PR-89X2, PR-131, PR-131X2 and PR-138),
- Cotton Seed Distributors Pty Ltd (PR-36X5) and
- Western Australian Department of Agriculture (PR-87, PR-87X, PR-87X2 and PR-144).

INGARD®/Roundup Ready® - 12 limited and controlled releases undertaken by;

- Deltapine Pty Ltd (PR-83, PR-83X, PR-83X3, PR-109, PR-109X, PR-140, PR-140X and PR-143),
- CSIRO Division of Plant Industry (PR-94) and
- Cotton Seed Distributors Pty Ltd (PR94X, PR-94X2 and PR-94X3).

On 28 March 2002 the Regulator issued a licence to the Western Australian Department of Agriculture for a limited and controlled release of INGARD® cotton (licence number DIR 008/2002) in Western Australia under the new regulatory system.

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

Parent organism

The parent organism is cultivated cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is grown as an agricultural crop in NSW and QLD and on a trial basis in Western Australia and the Northern Territory.

Genetic modification and its effect

Roundup Ready® cotton contains a herbicide tolerance gene, *CP4 EPSPS*, derived from a bacterium, *Agrobacterium* sp. strain CP4. This gene encodes an enzyme that is naturally tolerant of glyphosate, the active ingredient in Roundup® herbicide.

Roundup Ready® cotton plants also contain antibiotic resistance genes, *npt II* and *aad* derived from bacteria. The *nptIII* gene encodes for resistance to the antibiotics kanamycin and neomycin. It was

used as a selectable marker in the initial laboratory stages to select cotton plants containing the *CP4 EPSPS* gene. The *aad* gene encodes for spectinomycin and streptomycin resistance. It was used in the laboratory prior to the production of the genetically modified plants to select for bacteria containing the modified DNA. The *aad* gene is not expressed in the GM cotton plants because the promoter that is required for its expression is not active in plants.

Roundup Ready[®]/INGARD[®] cotton plants are produced through the conventional breeding of Roundup Ready[®] cotton and INGARD[®] cotton. Roundup Ready[®]/INGARD[®] cotton plants also contain an insecticidal gene *cryIAC*, derived from a common soil bacterium, *Bacillus thuringiensis* (Bt). This gene produces a protein that is toxic to lepidopteran caterpillars, including the two key *Helicoverpa* pests of cotton.

Short regulatory sequences that control expression of the genes are also present in the genetically modified cotton. These sequences are derived from the cauliflower mosaic virus, figwort mosaic virus, *Agrobacterium tumefaciens* and soybean. Although a number of these organisms are plant pathogens, the regulatory sequences comprise only a small part of their total genome and are not in themselves capable of causing disease.

Method of gene transfer

Roundup Ready[®] cotton is generated by inserting the *CP4 EPSPS*, *nptII* and *aad* genes into cotton on a plasmid vector carried by *A. tumefaciens* (a bacterium). INGARD[®] cotton is developed by inserting the *cryIAC*, *nptII* and *aad* genes using the same method. The plasmid vector is 'disarmed' since it lacks the genes that encode the tumorigenic functions of *A. tumefaciens*.

Consultation on draft Risk Assessment and Risk Management Plan

The Regulator has made an initial assessment as to whether the proposed release may pose significant risks to human health or the environment, in accordance with section 49 of the Act. **The Regulator has decided that the proposed release does not pose a significant risk to human health or the environment for the following reasons:**

- there has been extensive experience with the release of this GMO at commercial scale with no reported adverse effects on human health and safety or the environment; and
- the potential risk of toxicity, allergenicity, pathogenicity weediness and out-crossing to native cottons and other plant species has been demonstrated to be very low south of latitude 22° South.

This means that the Regulator is **not required to seek public comment** on the assessment of this proposal until the risk assessment and risk management plan has been prepared.

As required by section 50 of the Act, the Regulator is preparing a risk assessment and risk management plan in relation to the licence application and will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Commonwealth agencies, the Environment Minister, the Gene Technology Technical Advisory Committee and appropriate local councils.

As required by section 52 of the Act, the Regulator will again consult with these prescribed agencies and authorities in finalising the risk assessment and risk management plan that is expected to be issued in **early 2003**. The public will also be invited to provide comment on the risk assessment and risk management plan over a 30 day consultation period, via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. Summaries and copies of the risk assessment and risk management plan will be available from the OGTR, or on the OGTR website.

Issues to be considered by the Regulator

In making a decision on whether to issue a licence for the proposed release, the Regulator is required to consider applications and submissions within the context of the object of the Act, which focuses upon **protecting the health and safety of people and the environment**.

Please note that issues such as food labelling, the use and safety of insecticides and herbicides, marketability and trade implications do NOT fall within the scope of the evaluations conducted under the Act as these are the responsibility of other agencies and authorities.

Further information about food safety assessments and food labelling, and the use and safety of insecticides and herbicides are available from FSANZ and the NRA, respectively:

Food Standards Australia New Zealand
PO Box 7186
Canberra Mail Centre ACT 2610
Phone: (02) 6271 2222
Fax: (02) 6271 2278
E-mail: info@foodstandards.gov.au
<http://www.foodstandards.gov.au>

National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
KINGSTON ACT 2604
Phone: (02) 6272 5158
Fax: (02) 6272 4753
Email: nra.contact@nra.gov.au
<http://www.nra.gov.au>

Issues such as marketability and trade implications posed by the commercialisation of GM crops in Australia are being actively considered by the Commonwealth, State and Territory Governments (both individually and through forums such as the Primary Industries Ministerial Council and its Plant Industries Committee), by the Department of Agriculture, Fisheries and Forestry Australia through its Supply Chain Management for Genetically Modified Products Project, and by industry through groups such as the Gene Technology Grains Committee.

If you have any questions about the application or the assessment process, please contact the OGTR at:

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Appendix

Possible release shires for Licence application DIR 023/2002

NSW	QLD
Balranald	Aramac
Barraba	Balonne
Berrigan	Banana
Bingara	Bauhinia
Bland	Belyando
Bogan	Broadsound
Bourke	Bungil
Brewarrina	Cambooya
Broken Hill	Chinchilla
Carrathool	Clifton
Central Darling	Dalby
Cobar	Duaringa
Conargo	Emerald
Coolah	Fitzroy
Coonabarabran	Flinders
Coonamble	Gatton
Deniliquin	Inglewood
Dubbo	Jondaryan
Forbes	Kingaroy
Griffith	Milmerran
Gunnedah	Monto
Hay	Murilla
Jerilderie	Murweh
Lachlan	Peak Downs
Manilla	Pittsworth
Moree Plains	Quilpie
Murray	Richmond
Murrumbidgee	Rosalie
Narrabri	Tara
Narromine	Taroom
Parkes	Toowoomba
Parry	Waggamba
Quirindi	Wambo
Tamworth	Warroo
Urana	Warwick
Wakool	Wondai
Walgett	
Warren	
Wellington	
Wentworth	
Yallaroi	