



APPLICATION FOR LICENCE FOR COMMERCIAL RELEASE OF GMO INTO THE ENVIRONMENT: Application No. DIR 066/2006

SUMMARY INFORMATION

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| Project Title: | Commercial release of GM herbicide tolerant and/or insect resistant cottons north of latitude 22° South ¹ |
| 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 and/or insect resistance |
| Identity of the gene(s) responsible for the modified trait(s): | <ul style="list-style-type: none">• <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4 (herbicide tolerance)• <i>cry1Ac</i> and <i>cry2Ab</i> genes from the bacterium <i>Bacillus thuringiensis</i> (insecticidal)• <i>nptII</i> gene from the bacterial Tn5 transposon (antibiotic resistance)• <i>uidA</i> gene from <i>Escherichia coli</i> (reporter gene) |
| Proposed Location(s) | North of latitude 22° South in areas suitable for cotton growing |
| Proposed Release Size: | Plant breeding/agronomic/seed production trials and if feasible, commercial scale planting in the future |
| Proposed Time of Release | Ongoing from date of approval |

¹The title of the licence application submitted by Monsanto was *Licence Application covering use of Bollgard II (MON 15985), Roundup Ready Flex (MON 88913) and Roundup Ready (MON 1445) technology in cotton in areas north of latitude 22° South.*

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), an Australian Government 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 licence².

The application and the proposed dealings

The OGTR has received an application from Monsanto Australia Ltd (Monsanto) for a licence to commercially release the following genetically modified (GM) cotton lines, without specific containment measures, north of latitude 22° South:

- insect resistant Bollgard II[®] cotton (also known as MON15985)
- herbicide tolerant Roundup Ready[®] cotton (also known as MON1445)
- herbicide tolerant Roundup Ready Flex[®] cotton (also known as MON88913)
- herbicide tolerant/insect resistant Roundup Ready[®]/Bollgard II[®] cotton (also known as MON1445/MON15985)
- herbicide tolerant/insect resistant Roundup Ready Flex[®]/Bollgard II[®] cotton (also known as MON88913/MON15985).

Monsanto intends to conduct plant breeding/agronomic/seed production trials and cultivate the GM cottons in areas suitable for cotton growing in northern Australia. Monsanto indicates that commercial scale plantings are not planned at this stage as a range of industry, community and infrastructure issues would need to be resolved before commercial cotton production could take place in northern Australia.

Monsanto intends to use GM cotton plants and their products in the same manner as conventional cotton and GM cottons commercially approved south of latitude 22° South, including use in human food and stockfeed, transportation and sale of lint.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia. Roundup Ready[®] Herbicide is currently registered for use on Roundup Ready[®] cotton. An application for the registration of its use on Roundup Ready Flex[®] cotton is currently being assessed.

The APVMA registered the use of the insecticidal proteins as produced by the insecticidal genes (*cryIAc* and *cry2Ab*) in GM Bollgard II[®] cotton as insecticidal products for New South Wales (NSW) and Queensland (Qld) south of latitude 22° South in 2003. Any plantings north of latitude 22° South would also require APVMA approval. Further information about the APVMA can be obtained from www.apvma.gov.au.

Cotton seed oil and cotton linters (short fibres from the seed surface that do not contain any genetic material) from Bollgard II[®] cotton, Roundup Ready[®] cotton and Roundup Ready Flex[®] cotton have previously been approved by Food Standards Australia New Zealand (FSANZ) for use in human food.

Previous releases of the GMOs and other GM cottons

There have been many releases of these GM cottons other GM cottons under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (GMAC) and the current regulatory system.

Numerous field trials with Roundup Ready[®], Bollgard II[®] and Roundup Ready[®]/Bollgard II[®] cotton were conducted under the voluntary system. Under the current regulatory system the GM cottons proposed for release have previously been approved for commercial release south of latitude 22° South (under DIRs 012/2002, 023/2002 and 059/2005) and for field trials north of latitude 22° South (under DIRs 006/2001, 009/2001, 012/2002, 035/2003 and 055/2004).

² More information on the comprehensive assessment required for licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030) or at <http://www.ogtr.gov.au/ir/process.htm>. Further information on the evaluation process is contained in the Regulator's *Risk Analysis Framework* (OGTR, 2005), <http://www.ogtr.gov.au/pdf/raffinal2.2pdf>.

There have been no reports of adverse effects on human health and safety or the environment resulting from 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 southern and central Qld, and on a trial basis in northern Qld, WA and the NT.

Genetic modification and its effect

Genetic modifications in the GM cottons proposed for commercial release are given below:

| GM Cottons | Introduced Gene | Function | Source |
|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| MON15985 (Bollgard II®) | <i>cry1Ac</i> , <i>cry2Ab</i> <i>uidA</i> <i>nptII</i> <i>aad</i> | Insect resistance Reporter Antibiotic resistance marker Antibiotic resistance marker | <i>Bacillus thuringiensis</i> <i>Escherichia coli</i> <i>E. coli</i> , Tn5 <i>E. coli</i> , Tn7 |
| MON 1445 (Roundup Ready®) | <i>cp4 epsps</i> <i>nptII</i> <i>aad</i> | Herbicide tolerance Antibiotic resistance marker Antibiotic resistance marker | <i>Agrobacterium</i> sp. CP4 strain <i>E. coli</i> , Tn5 <i>E. coli</i> , Tn7 |
| MON 88913 (Roundup Ready Flex®) | <i>cp4 epsps</i> | Herbicide tolerance | <i>Agrobacterium</i> sp. CP4 strain |
| MON15985/ MON 1445 (Roundup Ready®/Bollgard II®) | <i>cry1Ac</i> , <i>cry2Ab</i> <i>cp4 epsps</i> <i>uidA</i> <i>nptII</i> <i>aad</i> | Insect resistance Herbicide tolerance Reporter Antibiotic resistance marker Antibiotic resistance marker | <i>B. thuringiensis</i> <i>Agrobacterium</i> sp. CP4 strain <i>E. coli</i> <i>E. coli</i> , Tn5 <i>E. coli</i> , Tn7 |
| MON 88913/ MON15985 (Roundup Ready Flex®/Bollgard II®) | <i>cry1Ac</i> , <i>cry2Ab</i> <i>cp4 epsps</i> <i>uidA</i> <i>nptII</i> <i>aad</i> | Insect resistance Herbicide tolerance Reporter Antibiotic resistance marker Antibiotic resistance marker | <i>B. thuringiensis</i> <i>Agrobacterium</i> sp. CP4 strain <i>E. coli</i> <i>E. coli</i> , Tn5 <i>E. coli</i> , Tn7 |

The two insect resistance genes in Bollgard II® cotton produce insect resistant proteins that are highly specific and toxic to the major insect pests of cotton.

The herbicide tolerance gene in Roundup Ready® cotton produces a protein that provides tolerance to glyphosate, the active constituent in Roundup Ready® Herbicide, up to the 4-leaf stage of growth to kill weeds without damaging the cotton plants.

Expression of two copies of the same herbicide tolerance gene in Roundup Ready Flex® cotton confers tolerance to glyphosate throughout the growing season.

Some of the GM cottons also contain antibiotic resistance marker genes (*nptII* and *aad*) and a reporter gene (*uidA*) which helped identify and select modified bacteria, plant tissue or plants during the development of the GMOs in the laboratory.

Regulatory sequences

The GM cottons also contain short regulatory sequences derived from plant pathogens (cauliflower mosaic virus, figwort mosaic virus, *Agrobacterium tumefaciens*) and from the plants, *Glycine max* (soybean), *Pisum sativum* (pea) and *Arabidopsis thaliana*. Although the first three of these organisms are plant pathogens, these sequences are not capable of causing disease.

Method of genetic modification

Bollgard II® cotton was generated by particle bombardment of the *cry2Ab* and *uidA* genes into the GM INGARD® cotton (containing the *cry1Ac*, *nptII* and *aad* genes). This technique involves coating the DNA consisting of the *cry2Ab* and *uidA* genes onto very small particles which were 'shot' into cotton plant tissue, followed by selection of plants that contained single, functional copies of the genes.

Roundup Ready[®] cotton and Roundup Ready Flex[®] cotton were produced by the introduction of either one or two copies of the *cp4 epsps* gene and associated regulatory sequences into cotton plant tissue via a plasmid vector carried by *Agrobacterium tumefaciens*. The vector is 'disarmed' since it lacks the genes that encode the tumour-inducing functions of *A. tumefaciens*.

Roundup Ready[®]/Bollgard II[®] cotton and Roundup Ready Flex[®]/Bollgard II[®] cotton were generated through conventional crossing of GM Bollgard II[®] cotton with GM Roundup Ready[®] cotton or Roundup Ready Flex[®] cotton, respectively.

Consultation on preparation of the 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 and safety 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 and safety or the environment.**

This means that the Regulator **is not required to seek public comment** on the assessment of this proposal until after a risk assessment and risk management plan (RARMP) has been prepared. However, in preparing the RARMP, the Regulator will seek input from a wide range of key stakeholders and expert groups comprising State and Territory Governments, relevant Australian Government agencies, the Minister for the Environment and Heritage, the Gene Technology Technical Advisory Committee and appropriate local councils, as required by section 50 of the Act. In accordance with section 52 of the Act, the Regulator will again consult with these prescribed experts, agencies and authorities as well as the public in finalising the RARMP that will then form the basis of her decision whether to issue a licence.

At this stage, the consultation version of the RARMP is expected to be issued for an extended eight week consultation period in **July 2006**. The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. Summaries and copies of the RARMP will be available from the OGTR, or on the OGTR website. In the interim, copies of the application are available on request from the OGTR. Please quote application number DIR 066/2006.

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 agricultural chemicals, 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.

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

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