



Summary of Licence Application DIR 145

Introduction

An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Application number	DIR 145
Applicant:	Monsanto Australia Limited
Project Title:	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 XtendFlex™ and XtendFlex™ cotton) ¹
Parent organism:	Cotton (<i>Gossypium hirsutum</i> L.)
Introduced genes and modified traits:	Three insect resistance genes <ul style="list-style-type: none">• <i>vip3Aa19</i> gene from <i>Bacillus thuringiensis</i> (Bt)• <i>cry1Ac</i> gene from Bt• <i>cry2Ab2</i> gene from Bt Three herbicide tolerance genes <ul style="list-style-type: none">• <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4 for glyphosate tolerance• <i>dmo</i> gene from <i>Stenotophomonas maltophilia</i> for dicamba tolerance• <i>bar</i> gene from <i>Streptomyces hygroscopicus</i> for glufosinate tolerance Four selectable marker genes <ul style="list-style-type: none">• <i>aph4</i> from <i>Escherichia coli</i> for resistance to hygromycin B• <i>nptII</i> from <i>E. coli</i> for resistance to kanamycin and neomycin• <i>aad</i> from <i>E. coli</i> for resistance to aminoglycoside antibiotics• <i>uidA</i> from <i>E. coli</i> (visual reporter gene)
Proposed release dates:	Ongoing from date of approval
Proposed locations:	Australia wide

The proposed dealings

Monsanto Australia Limited (Monsanto) proposes the commercial release of two types of genetically modified (GM) cotton. XtendFlex™ cotton contains three genes that confer tolerance to the herbicides glyphosate, glufosinate and dicamba. Bollgard® 3 XtendFlex™ cotton contains the same three introduced genes for herbicide tolerance and three introduced genes that confer insect resistance and marker genes that were used for the selection of plants during the early stages of research.

XtendFlex™ was produced by conventional breeding of two parental GM cottons. Bollgard® 3 XtendFlex™ was produced by conventional breeding of four GM parental cottons, including the two used to produce XtendFlex™.

¹ The application title submitted by Monsanto Australia Limited was “Licence Application to the OGTR for the general release of *Gossypium hirsutum* genetically modified for insect resistance and herbicide tolerance in Australia”

The aim of the proposal is to introduce the GM cottons into the Australian cropping system. If a licence is issued, the GM cottons and their derived products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from the parent GM cottons. These approvals include food made from any offspring produced through conventional breeding, and therefore no further approvals are required for the XtendFlex™ and Bollgard® 3 XtendFlex™ cottons.

Parent organism

The parent organism is cotton (*Gossypium hirsutum*), which is exotic to Australia and is grown as an agricultural crop in New South Wales and southern and central Queensland, and on a trial basis in northern Queensland, northern Western Australia and the Northern Territory. More than 98% of the Australian cotton crop is genetically modified for the traits of insect resistance, herbicide tolerance or both.

The genetic modifications and their effects

Bollgard® 3 XtendFlex™ contains introduced *vip3Aa19*, *cry1Ac*, *cry2Ab*, *cp4 epsps*, *bar* and *dmo* genes. The *cry1Ac*, *cry2Ab2* and *vip3Aa19* genes are derived from the common soil bacterium *Bacillus thuringiensis*, and encode insecticidal proteins for control of insect pests. The inclusion of three different insecticidal genes is designed to reduce the chance of insects developing resistance to any of the encoded protein toxins.

Both XtendFlex™ and Bollgard® 3 XtendFlex™ cottons contain three herbicide tolerance genes. The *cp4 epsps* (two copies) is derived from the bacterium *Agrobacterium* sp. strain CP4 which confers tolerance to the herbicide glyphosate. The *bar* gene is derived from the bacterium *Streptomyces hygroscopicus* and confers tolerance to the herbicide glufosinate. The *dmo* gene from the bacterium *Stenotrophomonas maltophilia* confers tolerance to the herbicide dicamba.

Bollgard® 3 XtendFlex™ also contains the *aph4 (hpt)*, *nptII* and *aad* genes which confer antibiotic resistance and the *uidA* gene which produces a colour reaction. These genes were derived from *Escherichia coli* and were used as markers in the early stages of plant transformation to select for GM plants.

Method of genetic modification

The two GM cottons were generated using conventional breeding of the four parental lines. The parental lines were produced using *Agrobacterium*-mediated transformation or a combination of biolistic and *Agrobacterium*-mediated transformation. These transformation methods have been widely used in Australia and overseas for introducing genes into plants. More detailed information on methods of genetic modification can be found in the document *Methods of plant genetic modification* available from the [Risk Assessment References](#) page on the OGTR website.

Previous releases of the same or similar GMOs

XtendFlex™ and Bollgard® 3 XtendFlex™ cottons have been approved for field trial in Australia under licence DIR 120.

XtendFlex™ has been approved for cultivation in Japan and for food and feed in Japan and Mexico.

Three of the parental GM cottons, individually and in combination, have been approved for commercial release throughout Australia:

- Bollgard II™ under DIR 012/2002
- Bollgard II™, Roundup Ready™ Flex™; Bollgard II™x Roundup Ready™ Flex™ under DIR 059/2005 and DIR 066/2006
- Bollgard® 3 and Bollgard® 3 Roundup Ready™ Flex™ under DIR 124

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

Assessment and consultation process for this DIR application

The Act and the Gene Technology Regulations 2001 set out requirements for considering licence applications, including matters that the Regulator must take into account before deciding whether or not to issue a licence.

Since this application is for commercial purposes, the Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of a Risk Assessment and Risk Management Plan (RARMP). This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, any local council that the Regulator considers appropriate and the Environment Minister.

While the Regulator is not required to seek public comment at this stage, copies of the application are available on request from the OGTR. Please quote application number DIR 145.

In a second round of consultation, the Regulator will seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and will inform the Regulator's decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in September 2016**. 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. The RARMP and other related documents will be available on the OGTR website or from the OGTR.

More information on Australia's national scheme for regulation of gene technology and the assessment process can be found at the [OGTR website](#).

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 Email: ogtr@health.gov.au

[OGTR website](http://www.ogtr.gov.au) www.ogtr.gov.au

Questions & Answers on licence application DIR 145 – commercial release of genetically modified cotton

What is this application for?

Monsanto Australia Limited (Monsanto) is seeking approval for commercial cultivation of two types of genetically modified (GM) cotton. XtendFlex™ cotton has been modified for herbicide tolerance and Bollgard® 3 XtendFlex™ cotton has been modified for both insect resistance and tolerance to the same three herbicides.

How has the GM cotton been modified?

XtendFlex™ cotton contains three genes that confer tolerance to the herbicides glyphosate, glufosinate and dicamba. Bollgard® 3 XtendFlex™ cotton contains the same three introduced genes for herbicide tolerance, three introduced genes that confer insect resistance and marker genes that were used in the selection of plants during the early stages of research.

The genes that confer insect resistance produce proteins that are toxic to certain pest insects. They are derived from a common soil bacterium.

The genes that confer herbicide tolerance are derived from common bacteria.

The selectable marker genes are derived from a gut bacterium. Three of these confer antibiotic resistance and one produces a colour reaction.

Bollgard® 3 XtendFlex™ and XtendFlex™ cottons were produced by conventional breeding between up to four parental GM cottons. Three of the parental cottons have been approved for commercial release. The fourth has been approved for field trials in Australia.

What is the purpose of the release?

The purpose of the proposed release is to allow commercial production of these types of GM cotton in all cotton growing areas of Australia. The GM cottons and their products would enter general commerce, including use in human food and animal feed.

The introduced insecticidal genes in the GM cotton are intended to control insect pests of cotton crops. Combining three different insecticidal genes is expected to reduce the chance of insect pests developing resistance to the insecticidal proteins.

The introduction of three herbicide tolerance genes would enable farmers to use glyphosate, glufosinate, or dicamba herbicides as options for weed control when growing GM cotton crops.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised taking into account submissions received, and inform the Regulator's decision whether or not to issue a licence.

Are other regulatory approvals required?

Food Standards Australia New Zealand (FSANZ) is responsible for food safety. FSANZ has approved the use of food derived from each of the parent GM cottons. No further approvals are required from FSANZ for the GM cottons proposed for release.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for agricultural chemicals, including herbicides and insecticidal products, in Australia. The GM cottons meet the definition of an agricultural chemical product due to their insecticidal properties and are therefore subject to regulation by the APVMA. Application of herbicide to the GM cottons is also subject to approval by the APVMA.

How can I comment on this application?

The comprehensive RARMP for this application is expected to be released for public comment in **September 2016**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 145. A summary of the application is available on the OGTR website (under '[What's New](#)') or by contacting the OGTR.