



QUESTIONS & ANSWERS ON LICENCE DIR 059/2005: COMMERCIAL RELEASE OF GENETICALLY MODIFIED COTTON

What is this licence for?

Monsanto Australia Limited (Monsanto) has obtained approval to commercially release two genetically modified (GM) cottons on an unrestricted basis south of latitude 22° South in Australia. The licence permits breeding, cultivation, transport, supply and sale of herbicide tolerant (Roundup Ready Flex[®] MON 88913 referred to here as *Roundup Ready Flex[®]*) GM cotton and herbicide tolerant/insect resistant (Roundup Ready Flex[®] /Bollgard II[®]) GM cotton and their products. The licence also permits the use of seed from the GM cotton plants as stockfeed in northern Australia, subject to licence conditions to limit spread and persistence of the GMOs.

Where will the commercial release occur?

The licence permits commercial scale planting of the GM cotton lines south of latitude 22° South without containment measures. Monsanto anticipates a phased introduction commencing with up to 20,000 hectares in spring 2006 in the current cotton growing areas of NSW and southern QLD. A map of these areas is available on the OGTR website (www.ogtr.gov.au/pdf/public/cotmaplga.pdf).

The company expects that these GM cotton lines will gradually replace its existing GM cotton lines (Roundup Ready[®] and Roundup Ready[®]/Bollgard II[®]). The genetic modification in Roundup Ready Flex[®] cotton does not affect the climatic and water requirements of the plants. Therefore, any expansion beyond the current cotton growing areas in southern Australia will only occur where environmental conditions are suitable for growing non-GM cotton. The timing and extent of any increased plantings will depend upon a number of factors such as grower acceptance and seed availability.

How has the GM cotton been modified?

The GM herbicide tolerant cotton contains two copies of a gene which was derived from a common soil bacterium. The protein produced by the inserted gene is very similar to a protein produced by a plant gene that is important for plant growth. The functioning of the plant protein is inhibited by glyphosate (the active ingredient in Roundup Ready[®] Herbicide) but the protein produced by the inserted genes in this new cotton still works when glyphosate is applied. This allows farmers to apply glyphosate to kill weeds in the crop without damaging the cotton plants.

The GM herbicide tolerant/insect resistant cotton was produced by crossing Roundup Ready Flex[®] with an insect resistant cotton (Bollgard II[®]). This added two genes that produce insecticidal proteins which provide protection from the major caterpillar pests of cotton. Bollgard II[®] cotton is already approved for commercial release south of latitude 22° South in Australia.

What is the difference between the existing Roundup Ready[®] cotton and this new Roundup Ready Flex[®] cotton?

Roundup Ready[®] cotton has only one copy of the glyphosate tolerance gene described above, whereas Roundup Ready Flex[®] has two.

Glyphosate can only be applied to Roundup Ready[®] cotton plants prior to flower formation, approximately 3-5 weeks after planting. If farmers are not be able to apply glyphosate in this period (*eg* if weather conditions are unsuitable) they must then resort to other more intensive methods of weed management (*eg* inter-row cultivation, hand weeding, or shielded/spot-spraying). Roundup Ready Flex[®] can be sprayed with glyphosate throughout the growing season providing farmers with greater flexibility in applying herbicide.

Will Roundup Ready Flex[®] cotton be more difficult to control than other cottons?

No. Glyphosate is not effective in controlling established conventional (non-GM) cotton or any of the current, commercially released GM cottons. If the herbicide is applied to mature cotton plants, they will be damaged but they will not usually be killed and can recover.

While Roundup Ready Flex[®] may make on-farm weed control easier and remove the need to use more intensive weed management practices, it will not have a survival advantage that would enhance the plants' weediness in the broader (off-farm) environment. Roundup Ready Flex[®] cotton is equally susceptible to the environmental factors (*eg* low soil moisture, frost, plant competition) and weed management practices that limit the spread of all other cottons.

Are other regulatory approvals required?

The OGTR operates in an integrated regulatory framework with other regulatory authorities that have complementary responsibility and specialist expertise. As well as avoiding duplication, this arrangement also enhances coordinated decision making. Monsanto has obtained approval from Food Standards Australia New Zealand (FSANZ) for the use of oil and linters from Roundup Ready Flex[®] cotton in human food (Bollgard II[®] cotton was approved previously.)

The company also requires approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to apply Roundup Ready[®] Herbicide to Roundup Ready Flex[®] and Roundup Ready Flex[®]/Bollgard II[®] cotton for weed control and the latter will also be subject to the insect resistance management strategies required for Bollgard II[®] cotton.

How will the new cotton affect the use of Roundup Ready[®] Herbicide?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates the use of all agricultural chemicals. The APVMA will consider any change to herbicide use associated with the introduction of this new GM cotton into the farming system during its assessment of Monsanto's parallel application to extend the current registration of Roundup Ready[®] Herbicide. The APVMA generally imposes conditions on the use of herbicides consistent with best practice in herbicide resistance management and integrated weed management (*eg* how many and at what stage of crop growth herbicide applications can be made).

Is this the first release of these GM cottons?

No. Two limited and controlled releases of Roundup Ready Flex[®] and Roundup Ready Flex[®]/Bollgard II[®] GM cotton lines have been approved under the current regulatory system in NSW, QLD, northern WA and the NT under DIR 035/2003 (up to 946 ha) and DIR 055/2004 (up to 1815 ha).

Two commercial release licences (for south of latitude 22° South) have been issued for GM cottons containing the same introduced genes: DIR 012/2002 (for Bollgard II[®] and Bollgard II[®]/Roundup Ready[®] cotton) and DIR 023/2002 (for Roundup Ready[®] and Roundup Ready[®]/Ingard[®] cotton). Prior to these commercial release approvals, numerous field trials were conducted under the requirements of both the current regulatory system and the previous voluntary system. These trials were conducted in NSW, QLD, WA and the NT.

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

Why is the release restricted to south of latitude 22° South?

Commercial release licences for GM cotton currently prohibit unrestricted cultivation above latitude 22° South pending the collection and consideration of further information about potential weediness of insect resistant cotton in the northern tropical areas of Australia.

What controls have been imposed for this release?

A range of licence conditions have been imposed to minimise the dissemination of GM cotton seed, and spread and persistence of GM cotton plants, in areas north of latitude 22° South.

These conditions include restrictions on transport (eg in covered vehicles only), restrictions on where stock may be fed the GM seed (only inside diaries, stock yards or feedlots) and a requirement for the licence holder to provide information about cotton volunteers and their control to end-users of cotton seed north of latitude 22° South.

Full details of the licence conditions are set out in the final version of the Risk Assessment and Risk Management Plan (RARMP) that was prepared for this application and formed the basis of the Regulator's decision to issue this licence.

Want more information?

A number of documents relating to this decision are available on the OGTR website (<<http://www.ogtr.gov.au>> under 'What's New') or via Freecall 1800 181 030. These documents include the complete RARMP (which contains a summary of the submissions received through the consultation process with prescribed experts, agencies and authorities and the public), an Executive Summary, a Technical Summary and the full Licence.

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