

QUESTIONS & ANSWERS ON LICENCE DIR 066/2006 FOR COMMERCIAL RELEASE OF GENETICALLY MODIFIED COTTON

What is this licence for?

Monsanto Australia Ltd (Monsanto) has obtained approval to commercially release, without specific containment conditions, five herbicide tolerant and/or insect resistant genetically modified (GM) cotton lines in northern Australia, *north* of latitude 22° South (22°S).

When will commercial release occur?

Monsanto has indicated that large scale commercial production is not planned at this stage, and will not occur until a range of industry, community and infrastructure issues have been resolved. In the first instance, the company anticipates conducting plant breeding, agronomic trials and seed production in areas that may prove suitable for cotton growing in the future.

Have these GM cottons previously been released in Australia?

Yes. All five GM cotton lines have been approved for commercial release in southern Australia, *south* of latitude 22°S. Various GM cotton varieties have been grown on a commercial scale in Australia since 1996, and these GM cotton lines currently constitute 90% of Australia's total cotton crop. In addition, numerous field trials with the same lines have also been conducted under limited and controlled conditions in northern Australia. There have been no reports of adverse effects on public health or the environment resulting from any of these releases.

Have any restrictions been placed on this release?

The Risk Assessment and Risk Management Plan (RARMP) for this licence concluded that the proposed release posed negligible risks to people and the environment. Therefore, no specific containment measures have been imposed. However, the licence does contain a number of general conditions, including a range of reporting requirements that will enable the Regulator to maintain oversight of the release.

Will this GM cotton behave differently from non-GM cotton?

The GM cotton lines approved for release have the same water, soil type, nutrient and climatic requirements as non-GM cotton. Therefore, any expansion of cotton production in northern Australia using these GM lines would only happen in regions suitable for growing *any* cotton. All crops (GM or non-GM) will be affected by changes to climate and environmental conditions.

Why does this licence only apply to northern Australia?

Unrestricted release of insect resistant GM cotton has not been allowed *north* of latitude 22°S until now. More information was needed to determine whether insect resistant GM cotton was more likely than non-GM cotton to become a weed in northern Australia and the results from relevant research studies have only recently become available.

Will these GM cottons become weeds?

Non-GM cotton does not have characteristics typical of weeds (such as rapid growth, short life cycle, and large numbers of seeds that disperse widely and persist in the soil) and it is not considered a serious weed in Australia or anywhere else in the world.

Research conducted over several years has shown that caterpillar pests (to which three of the GM cotton lines are resistant) are *not* the major factor limiting the establishment or persistence of cotton. In addition, while the herbicide tolerance trait (present in three of the GM cotton lines) is useful for in crop weed control on-farm, it does not confer an advantage off-farm. Cotton in northern Australia was found to be mainly limited by water and nutrient availability, plant competition and insects such as grasshoppers. Therefore, the genetic modifications will *not* make these GM cotton lines more 'weedy'.

Why have previous attempts to cultivate cotton in northern Australia failed?

Attempts over the past 100 years to grow cotton commercially in northern Australia were unsuccessful due to a combination of factors. These include planting at the wrong times, unsuitable cotton varieties,

poor choice of soils, plant diseases, inappropriate insect pest management practices and irrigation techniques, as well as inadequate infrastructure and transport costs that made the industry unviable.

It is now known that the main factors influencing cotton growth include temperature during growing seasons, timing of rainfall and suitability of soil. Based on this information, the Australian Cotton Cooperative Research Centre has identified approximately 200,000 ha of potential irrigation areas in WA, NT and QLD that could be suitable for cotton cultivation over the next 10 years. A link to this study is available on the OGTR website (see contact details below).

What impact will these cottons have on animals and insects?

The licence permits GM cotton seed and plant material to continue to be used for animal feed. The introduced proteins do not display characteristics common to known food allergens or toxins and they are quickly degraded during animal digestion in the same way as non-GM proteins.

The proteins produced by the insect resistant cotton lines are only toxic to the targeted caterpillar pests (lepidoptera). A large number of insect species have been tested for sensitivity to these proteins. These studies showed that growing Bollgard II[®] cotton plants has no different effect on non-target invertebrate organisms than non-GM cotton, whereas the sprays required for non-insect resistant cottons adversely affect a broad range of invertebrates.

How have the GM cotton lines been modified?

One GM cotton line (*Bollgard II*[®]) was modified by introducing two genes derived from a common soil bacterium which produce insect resistance proteins that are highly specific and toxic to the caterpillars of the two major insect pests of cotton.

Two of the GM cotton lines (*Roundup Ready*[®] and *Roundup Ready Flex*[®]) were modified by introducing one or two copies respectively of a gene (also derived from a common soil bacterium) which produces a protein that provides tolerance to glyphosate, the active constituent in Roundup Ready[®] Herbicide. The presence of the protein enables these GM cotton lines to be sprayed with glyphosate to kill weeds without damaging the cotton plants.

The remaining two lines were produced by conventional crossing of *Bollgard II*[®] with each of the herbicide tolerant lines.

Some of the GM cotton lines also contain marker genes and a reporter gene (*uidA*) which were used to develop GM plants in the laboratory.

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.

Food Standards Australia and New Zealand (FSANZ) has previously approved food (oil and linters) derived from Bollgard II[®] cotton, Roundup Ready[®] cotton and Roundup Ready Flex[®] cotton. No additional FSANZ approvals are required for the combined varieties.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has registered Roundup Ready[®] Herbicide for use on Roundup Ready[®], Roundup Ready Flex[®] and Roundup Ready Flex[®]/Bollgard II[®] cottons. The APVMA has also registered the use of the insecticidal proteins in GM Bollgard II[®] cotton as insecticidal products for New South Wales (NSW) and Queensland (QLD) south of 22°S. The APVMA is scheduled to make a decision on Monsanto's application to vary the label for Bollgard II[®] to remove restrictions on planting north of 22°S in the near future.

How can I obtain more information?

A number of documents relating to this decision are available on the OGTR website (www.ogtr.gov.au under "What's New") or via Freecall 1800 181 030. These documents include the comprehensive 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 a copy of the Licence.