

QUESTIONS & ANSWERS ON LICENCE DIR 062/2005: COMMERCIAL RELEASE OF GENETICALLY MODIFIED COTTON

What is this licence for?

Bayer CropScience Pty Ltd (Bayer) has obtained approval to commercially release genetically modified (GM) cotton (known as Liberty Link[®] Cotton) on an unrestricted basis in Australia. This includes breeding, cultivation, transport, storage, supply and sale of Liberty Link[®] Cotton and its products anywhere in Australia.

How has the cotton been modified?

Liberty Link[®] Cotton (formerly known as Liberty[®] cotton or LLCotton25) has been modified by the introduction of a herbicide tolerance gene that enables GM cotton plants to be sprayed with glufosinate ammonium to kill weeds without damaging the crop. Glufosinate ammonium is the active constituent of the herbicides Liberty[®], Basta[®] and Finale[®].

What controls have been imposed for this release?

Risks to human health and safety and the environment from the commercial release of Liberty Link[®] Cotton were determined to be negligible. Therefore, no specific containment measures have been imposed. The licence imposes a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring provisions, and reporting requirements which include an obligation to report any unintended effects.

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.

Is Liberty Link[®] Cotton different from other commercially approved GM cottons?

Yes. Other GM cottons currently approved for commercial release contain insect resistance genes (that are resistant to the major caterpillar insect pests of cotton) and/or a herbicide tolerance gene (that confers tolerance to the herbicide glyphosate). However, the Liberty Link[®] Cotton only contains a gene that confers tolerance to a different herbicide, glufosinate ammonium. The similarities, differences and potential interactions between Liberty Link[®] Cotton and these other GM cottons have been examined in detail during the assessment of this application.

Where will the GM cotton be grown?

Bayer anticipates a phased transition to commercial scale production over a 3 year period. Initially, the most substantial plantings are expected to occur in the existing cotton growing regions of New South Wales (NSW) and Queensland (QLD), followed by uptake in other areas where environmental conditions are suitable for cotton cultivation. Potential future cotton growing regions include additional parts of NSW and QLD, some areas of the Northern Territory and northern Western Australia, and in South Australia and Victoria close to the NSW border. A map of current cotton growing shires in Australia can be accessed via the OGTR website: www.ogtr.gov.au/pdf/public/cotmaplga.pdf. The rate of adoption will be determined by market acceptance, and the availability of seed and suitable varieties.

Has this GM cotton been trialled in Australia?

Yes. Three limited and controlled releases of the same herbicide tolerant GM cotton have been approved under the current regulatory system: DIR 015/2002 and DIR 038/2003 undertaken by CSIRO, and DIR 056/2004 currently being undertaken by Bayer. Two field trials were conducted under the previous voluntary system. Additional GM cottons containing either the

same herbicide tolerance gene, or a similar gene, combined with insecticidal and/or antibiotic resistance marker genes, have been (DIR 016/2002 and DIR 040/2003), or are currently being (DIR 036/2003 and DIR 044/2003), trialled in Australia. There have been no reports of adverse effects on human health or the environment resulting from any of these releases.

Are other regulatory approvals required?

The OGTR operates in an integrated regulatory framework with other regulatory authorities that have complementary responsibility and specialist expertise. The applicant will require approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to apply glufosinate ammonium to Liberty Link[®] Cotton for weed control. Food Standards Australia New Zealand (FSANZ) has approved the use of oil and linters derived from Liberty Link[®] Cotton in human food. Cultivation of this GMO may require additional approvals under State or Territory legislation that restrict the commercial release of GM crops on marketing grounds.

Has this GM cotton been commercially approved in other countries?

Yes. Liberty Link[®] Cotton has been approved for commercial scale, unrestricted environmental release and for food use in the USA, Japan and Korea.

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.