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

**What does this licence allow?**

Monsanto Australia Ltd has received approval for the commercial release of two types of genetically modified (GM) cotton known as XtendFlex™ cotton, modified for herbicide tolerance and Bollgard® 3 XtendFlex™ cotton, modified for both insect resistance and herbicide tolerance.

### What other regulatory approvals are required?

The GM cottons and their products can enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has approved the use in food of material derived from these GM cottons. The GM cottons would also be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which assesses all herbicides and insecticidal products used in Australia and sets their conditions of use. Monsanto will need to seek approval from the APVMA for the use of Bollgard 3® XtendFlex™ to control insects in cotton crops and for the use of the herbicides to which the crops are tolerant, in GM cotton crops.

**Where will this cotton be grown?**

The GM cotton may be grown anywhere in Australia, subject to restrictions in some Australian States and Territories for marketing reasons. The main cotton growing areas of Australia are in central to northern New South Wales and southern to central Queensland. Cotton is also grown on a trial basis in north western Victoria, northern Queensland and northern Western Australia.

**How has the GM cotton been modified?**

Xtend Flex™ cotton contains three introduced genes for herbicide tolerance: one gene confers tolerance to the herbicide glyphosate, a second gene confers tolerance to glufosinate herbicides and the third gene confers tolerance to dicamba. Thus, farmers can use one or all of these herbicides for weed control without damaging their cotton crop. All three genes were sourced from common bacterial species, found in the environment.

In addition to the three herbicide tolerance genes, Bollgard® 3 Xtend Flex™ cotton contains three bacterial genes that confer insect resistance. The genes encode proteins that are toxic to specific pest insects that cause major yield losses in cotton crops. Combining three different insecticidal genes is expected to reduce the chance of insect pests developing resistance.

The GM cottons also contain four introduced selectable marker genes derived from a common bacterium. Three of the genes confer antibiotic resistance and the fourth allows colour selection. They were used to select the plants during laboratory development of the GM cottons and do not have any function when plants are grown in the field.

**How is this GM cotton different from existing commercial GM cotton?**

Almost all cotton currently grown in Australia is genetically modified. Over 90 % of the Australian cotton crop is either Bollgard® II cotton or Bollgard® II Roundup Ready Flex® cotton. Those cottons contain two introduced insecticidal genes. In the 2016/17 season Bollgard® 3 and Bollgard® 3 Roundup Ready Flex® cottons are available for wide scale planting in Australia. Bollgard® 3 and Bollgard® 3 Roundup Ready Flex® cotton contain the three insecticidal genes also present in Bollgard® 3 XtendFlex™ cotton. Combining three different insecticidal genes is expected to reduce the chance of insect pests developing resistance. Bollgard® II Roundup Ready Flex® and Bollgard® 3 Roundup Ready Flex® cottons contain one type of herbicide tolerance gene, while XtendFlex™ and Bollgard® 3 XtendFlex™ cottons contain the same herbicide tolerance gene and two other herbicide tolerance genes. Other insect resistant and herbicide tolerant cottons have also been approved by the Regulator but these are not currently widely grown.

**What controls have been imposed for this GM cotton?**

The licence is for an ongoing commercial release. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that this release of GM cotton poses negligiblerisks to the health and safety of people or the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the release.

**Want more information?**

A number of documents relating to this decision are available on the [DIR 145 page](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR145) of the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, a summary of the RARMP and the licence.

**The Office of the Gene Technology Regulator**

**Tel: 1800 181 030 E-mail: ogtr@health.gov.au**

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