

## Questions & Answers on licence application DIR 124 – commercial release of genetically modified cotton

### What is this application for?

Monsanto Australia Ltd is seeking approval for the commercial release of two types of genetically modified (GM) cotton: Bollgard<sup>®</sup> III cotton, modified for insect resistance; and Bollgard<sup>®</sup> III x Roundup Ready Flex<sup>®</sup> cotton, modified for both insect resistance and herbicide tolerance.

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.

The GM cottons and their products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) 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. Cultivation of GM insect resistant cotton varieties needs to comply with an approved insect resistance management plan and any other relevant conditions that may be imposed by the APVMA.

### How has the GM cotton been modified?

Bollgard<sup>®</sup> III cotton contains the genes *cry1Ac*, *cry2Ab* and *vip3A*, derived from a common soil bacterium (Bt), which produce proteins toxic to certain insects. Bollgard<sup>®</sup> III x Roundup Ready Flex<sup>®</sup> cotton contains these insect resistance genes and two copies of the *cp4 epsps* gene from another soil bacterium, which confer tolerance to the herbicide glyphosate. These GM cottons have been produced by conventional breeding between other GM cottons: Bollgard<sup>®</sup> II and Roundup Ready Flex<sup>®</sup> cottons, both of which are approved for commercial release throughout Australia, and VIP3A cotton (also known as COT 102 cotton), which has been grown in Australian field trials.

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

Almost all cotton currently grown in Australia is genetically modified. Over 80% of the Australian cotton crop is either Bollgard<sup>®</sup> II cotton or Bollgard<sup>®</sup> II x Roundup Ready Flex<sup>®</sup> cotton. These existing commercial GM cottons contain two introduced insecticidal genes, whereas the Bollgard<sup>®</sup> III and Bollgard<sup>®</sup> III x Roundup Ready Flex<sup>®</sup> cottons proposed for release contain one additional introduced insecticidal gene. Combining three different insecticidal genes is expected to reduce the chance of insect pests developing resistance.

### How can I comment on this application?

You are invited to submit your comments on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) that has been prepared for application DIR 124. The full consultation RARMP and a Summary are available on the OGTR website (under “What’s New”) or via the Freecall number below. Your advice would be appreciated on any risks to **the health and safety of people** or to **the environment** that may be posed by the proposed release. Please note that the consultation period closes on **14 May 2014** and written submissions are required by that date.

### What are the next steps in the evaluation process?

Submissions raising matters relating to protecting the health and safety of people or the environment will be taken into account in finalising the RARMP, which will then inform the Regulator’s decision on whether or not to issue a licence.

**The Office of the Gene Technology Regulator**  
**Tel: 1800 181 030      E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**  
**Website: <http://www.ogtr.gov.au>**