

QUESTIONS & ANSWERS ON LICENCE DECISION DIR 091 FOR COMMERCIAL RELEASE OF GENETICALLY MODIFIED COTTON

What is this licence for?

Dow AgroSciences Australia Ltd (Dow) has received approval for the commercial release of one line of genetically modified (GM) cotton into the Australian environment.

What is the purpose of the release?

The purpose of the proposed release is the ongoing commercial release of the GM insect resistant cotton known as WideStrike™ Insect Protection cotton. The applicant intends that the commercial release occurs in all cotton growing areas of Australia south of latitude 22° South, and that plant material from the GM cotton be used in the same manner as plant material from non-GM cotton and from other commercially approved GM cottons and enter general commerce.

How has the GM cotton been modified?

The GM cotton contains two genes, derived from a soil bacterium, that have been shown to increase resistance to insect pests. Similar genes are widespread in the environment. The GM cotton also contains a herbicide tolerance gene, which was used to identify transformed plants during the initial development of GM plants in the laboratory. This gene is also from a common soil bacterium. However, the applicant is not proposing that the herbicide be used on the GM plants.

What controls have been imposed?

The licence is for an ongoing commercial release. Nonetheless, specific licence conditions have been imposed by the Regulator to help mitigate the low risk of the spread and persistence of WideStrike™ cotton in northern Australia. The GM cotton is authorised to be planted only south of latitude 22° South, and north of this latitude GM cotton seed must:

- ◆ be transported in covered vehicles
- ◆ only fed to livestock inside stockyards, feedlots or dairies.

General conditions are also imposed to ensure there is ongoing oversight of the release. In particular, post-release review requirements require the licence holder to collect and provide further information related to the progress of the authorised dealings.

Are other regulatory approvals required?

Australia's gene technology regulatory system operates as an integrated legislative framework involving the Regulator and other regulatory agencies that avoids duplication and enhances coordinated decision making. Other agencies that also regulate GMOs or GM products include Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine and Inspection Service (AQIS). Dealings conducted under a licence issued by the Regulator may also be subject to regulation by one or more of these agencies.

FSANZ is responsible for human food safety assessment, including GM food. FSANZ has approved the use of linters and cotton seed oil from WideStrike™ cotton for use in human food. The APVMA has regulatory responsibility for the supply of agricultural chemicals, including herbicides and insecticidal products, in Australia. As WideStrike™ cotton meets the definition of an agricultural chemical product under the *Agricultural and Veterinary Chemicals Code Act 1994*, it is also subject to regulation by the APVMA, which is currently assessing an application from Dow for WideStrike™ cotton. An AQIS permit has been granted to allow the importation of seed.

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 Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan, an Executive Summary, a Technical Summary and a copy of the full licence.