



25 November 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND
RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 091
FROM
DOW AGROSCIENCES**

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of licence application (DIR 091) from Dow AgroSciences Australia Ltd (Dow) for a commercial release of genetically modified (GM) cotton.

The *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision on whether or not to issue a licence to deal with a GMO. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public¹.

The application

Dow has applied for a licence for dealings involving the intentional release of GM WideStrike™ Insect Protection (WideStrike™) cotton. The applicant proposed that the commercial release would allow WideStrike™ cotton to be grown 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 other commercially approved GM cotton(s), and enter general commerce.

WideStrike™ cotton has been genetically modified for resistance to insects. The GM cotton contains two genes derived from a common soil bacterium. These genes confer resistance to a range of major lepidopteran caterpillar pests of cotton.

In addition to the genes for insect resistance, the GM cotton contains a selectable marker gene from a common soil bacterium. This gene confers tolerance to the herbicide glufosinate ammonium. During development of the GM cotton, this marker gene enabled identification and selection of plant tissues in which this herbicide tolerance gene was also present. Short regulatory sequences that control expression of the genes are also present in the GM cotton.

¹ More information on the process for assessment of licence applications to release a genetically modified organism (GMO) into the environment is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>

WideStrike™ cotton has been previously approved for field trials in Australia under licences DIR 040/2003 and DIR 044/2003 issued to Dow. There have been no reports of adverse effects on human health and safety or the environment resulting from these releases.

The GM cotton proposed for release meets the definition of an agricultural chemical product under the *Agricultural and Veterinary Chemicals Code Act 1994*, due to its production of insecticidal substances. Therefore, WideStrike™ GM cotton is also subject to regulation by the Australian Pesticide and Veterinary Medicines Authority (APVMA). The APVMA is currently assessing an application from Dow for WideStrike™ cotton. The applicant does not intend glufosinate ammonium to be used as an herbicide in the field and therefore does not intend to seek approval from APVMA for the use of this herbicide on WideStrike™ cotton.

The oil and cotton linters derived from this GM cotton have been approved by Food Standards Australia New Zealand (FSANZ) for use in human food².

Confidential Commercial Information

Some details, including the gene and protein sequences of the introduced synthetic genes and molecular characterisation of WideStrike™ cotton, have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

Risk assessment

The risk assessment took into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP and on the consultation RARMP.

A **hazard** identification process was used in the first instance to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Fourteen events were identified whereby the proposed dealings might give rise to harm to people or the environment. The risk assessment included consideration of whether or not expression of the introduced genes could result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM plants; or produce unintended changes in their biochemistry or physiology. The opportunity for gene flow to other organisms and its effects if it occurred were also assessed.

A **risk** is only identified when a hazard is considered to have some chance of causing harm. Events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The characterisation of the fourteen events in relation to both the magnitude and probability of harm, in the context of the large scale of the release proposed by the applicant, gave rise to three identified risks that required further assessment to determine their level of risk to people or the environment. The potential adverse

² Insect-protected, glufosinate ammonium-tolerant cotton line MXB-13, Dow AgroSciences, FSANZ Application [A518](#).

outcomes to the environment associated with these events were toxicity to non-target invertebrates and weediness. The remaining eleven events were not assessed further as they were considered not to give rise to an identified risk to human health and safety or the environment (refer to Chapter 2 for more information).

Risk of toxicity to non-target invertebrates

One event was considered that might cause toxicity to non-target invertebrates as a result of the release of the GM cotton line via direct or indirect ingestion of the insect resistance proteins by non-target invertebrates (Event 2, Identified Risk 1).

The risk assessment considered the consequence and likelihood of harm that might result from the above event. The estimate of the level of risk for this event is **low**.

Risk of weediness

Two events were considered that might result in the GM WideStrike™ cotton exhibiting greater weediness than the non-GM cotton or other GM cotton lines previously approved for commercial release.

- Expression of the introduced genes for insect resistance improving the survival of the GM cotton plants and leading to increased spread and persistence north of latitude 22° South (Event 7, Identified Risk 2).
- Expression of the introduced *cry* genes in other insect resistant GM cotton plants as a result of gene transfer leading to increased spread and persistence (Event 10, Identified Risk 3).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of the level of risk for Event 7 (Identified Risk 2) is **low** and Event 10 (Identified Risk 3) is **negligible**.

Risk management

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people and/or the environment.

The Regulator's *Risk Analysis Framework* (OGTR 2007) defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. The level of risk to human health and safety and the environment for twelve of the fourteen events assessed was estimated as negligible. For these events, no specific risk treatment measures are imposed.

The risk estimate for the two remaining events was low. A low risk is defined as a risk that is minimal but may evoke actions for mitigation beyond normal practices³. The Regulator has imposed specific licence conditions to treat the risk of spread and persistence of the GM cotton line in northern Australia. These include transport conditions and restrictions on where the seed from WideStrike™ cotton can be fed to animals.

The Regulator has also imposed licence conditions under post-release review (PRR) to ensure that there is ongoing oversight of the release and included provisions to require collection of information to verify the findings of the RARMP.

³ The risk assessment methodology used by the Regulator is outlined in more detail at [the OGTR website](#).

The licence also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.

Conclusions of the RARMP

The risk assessment concludes that this commercial release of WideStrike™ cotton to be grown in areas south of latitude 22° South, and the entry of products derived from the GM cotton into general commerce Australia wide, poses **negligible** risks to the health and safety of people, and **negligible** to **low** risks to the environment as a result of gene technology.

The risk management plan concludes that one of the low risks requires specific risk treatment measures. General licence conditions are imposed to ensure that there is ongoing oversight of the release.