Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

8 August 2006

EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN
for
APPLICATION NO. DIR 062/2005
from
BAYER CROPSCIENCE PTY LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release (DIR) of herbicide tolerant genetically modified (GM) cotton into the Australian environment, in respect of application DIR 062/2005 from Bayer CropScience Pty Ltd (Bayer).

The DIR 062/2005 licence permits the commercial release of the GM cotton on an unrestricted basis in all areas of Australia. It should be noted that cultivation of this GMO may require additional approvals under State or Territory legislation that restrict the commercial release of GM crops on marketing grounds.

The *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations) govern the process undertaken by the Regulator before a decision is made on the whether or not to issue a licence. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in consultation with a wide range of experts, agencies and authorities and the public.

More information on the process required for the comprehensive 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/ir/process.htm>.

THE APPLICATION

Bayer applied for a licence to release a herbicide tolerant GM cotton, Liberty Link® Cotton, into the environment. Bayer is seeking approval for unrestricted, commercial scale planting of the GM cotton in all current cotton growing areas and potential future areas with environmental conditions suitable for cotton cultivation in Australia.

The GM cotton has only one introduced gene, the herbicide tolerance gene (*bar*), isolated from a common soil bacterium, *Streptomyces hygroscopicus*. The *bar* gene expresses a protein that provides tolerance to glufosinate ammonium, the active ingredient in the herbicide Liberty®, and enables the herbicide to be applied for weed control in the GM cotton crop. Otherwise, the GM cotton has the same water and climatic requirements as non-GM and commercially released GM cotton lines, and provides an alternative in crop weed control method to GM cottons that are tolerant to the herbicide glyphosate.

The GM cotton proposed for release has been approved previously (described as Liberty® or LLCotton25) for limited and controlled releases under DIR licences 015/2002, 038/2003 and 056/2004.

The applicant requests approval for commercial scale cultivation without containment measures, and the use of the GM cotton plants and their by-products in the same manner as non-GM or other commercially approved GM cotton. This would include conventional breeding with elite non-GM cotton cultivars to produce seed optimised for use under Australian conditions, sale of seed for commercial planting, use in human food and stockfeed, sale of lint, export of seed and unrestricted transport. Bayer has developed a training package and technical manual that will form part of the company's agreement with retailers and growers to purchase and handle Liberty Link® Cotton.

Under Australia's integrated framework for the regulation of genetically modified organisms, regulatory decisions are coordinated as far as possible. Bayer has received approval from Food Standards Australia New Zealand for the use of oil and linters derived from the Liberty Link® Cotton in food (FSANZ report A533). In addition, the Australian Pesticides and Veterinary Medicines Authority is currently assessing an application from Bayer to register Liberty® 150 Herbicide for the control of various weeds in Liberty Link® Cotton.

RISK ASSESSMENT

Background

The risk assessment first considered what harm to the health and safety of people or the environment could arise as a result of gene technology, and how it could happen, during the proposed release of the GM cotton into the environment (**hazard identification** refer to Chapter 2 for more information).

The risks to people and the environment from the proposed commercial release were assessed in comparison to non-GM cotton and GM cotton lines previously approved for commercial release by the Regulator, in the context of the intended agronomic management practices, and the environmental conditions in the regions proposed for the release.

Hazards are particular sets of circumstances (**events**) that might give rise to adverse outcomes (ie cause harm). When an event was considered to have some chance of causing harm, it was identified as posing a risk that required further assessment.

Each event associated with an **identified risk** was then assessed to determine the seriousness of harm (**consequence** - ranging from marginal to major) and the chance of harm (**likelihood** - ranging from highly unlikely to highly likely). The level of risk (ranging from negligible to high) was then estimated using a Risk Estimate Matrix (refer to Chapter 2 for more information).

Hazard identification

Of the 28 events compiled during the hazard identification process, three were selected for further assessment. The potential adverse outcome to the environment associated with these events was weediness. The remaining 25 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 weediness

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

- Expression of the herbicide tolerance gene (*bar*) increasing spread and persistence of the GM cotton plants through tolerance to glufosinate ammonium (event 1)

- Expression of the herbicide tolerance gene (*bar)* in non-GM *Gossypium hirsutum* or *G. barbadense* cotton plants increasing spread and persistence through providing glufosinate ammonium tolerance (event 2)

- Expression of the herbicide tolerance gene (*bar*) with introduced genes in other commercially approved GM cotton lines increasing spread and persistence through providing glufosinate ammonium tolerance as well as glyphosate tolerance and/or reduced insect attack on the plants (event 3).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for all three events is **negligible**.

RISK MANAGEMENT

The level of risk to health and safety of people or the environment for the three events that were assessed was estimated as **negligible**. The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. Therefore, no risk treatment measures are imposed.

The licence, detailed in Chapter 5 of the RARMP, 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 Liberty Link® Cotton poses **negligible** risks to the health and safety of people and the environment as a result of gene technology.

The risk management plan concludes that the negligible risks do not require specific risk treatment measures. Licence conditions that have been imposed relate to ongoing licence holder suitability; auditing and monitoring provisions; reporting requirements, including a compliance plan, annual report and other relevant information; and a suitable detection methodology.