



Australian Government

Department of Health
Office of the Gene Technology Regulator

8 August 2006

**TECHNICAL 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 decided to issue a licence (DIR 062/2005) to Bayer CropScience Pty Ltd (Bayer) for dealings involving the intentional, commercial scale release of herbicide tolerant genetically modified (GM) cotton into the Australian environment.

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), the Gene Technology Regulations 2001 (the Regulations) and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Regulator before making a decision whether or not to issue a licence to deal with a GMO.

The Regulator's *Risk Analysis Framework* explains the approach used to evaluate licence applications and to develop the Risk Assessment and Risk Management Plans (RARMPs) that form the basis of her decisions¹.

The RARMP for DIR 062/2005 has been finalised in accordance with the gene technology legislation. Matters raised in the consultation process regarding risks to the health and safety of people or the environment from the dealings proposed by the applicant were taken into

¹ More information on the assessment of licence applications and copies of the *Risk Analysis Framework* are 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>> and <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>> respectively.

account by the Regulator in deciding to issue a licence and the conditions that have been imposed.

Consistent with Australia's integrated regulatory framework for gene technology, the Regulator has also liaised closely with other regulatory agencies that have been considering applications relating to this release, namely Food Standard Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA), to avoid duplication and enable coordinated decision making.

SECTION 1 APPLICATION

Title:	Commercial release of herbicide tolerant Liberty Link® Cotton for use in the Australian cropping system*
Applicant:	Bayer CropScience Pty Ltd
Common name of the parent organism:	Cotton
Scientific name of the parent organism:	<i>Gossypium hirsutum</i> L.
Modified trait(s):	Herbicide tolerance
Identity of the gene(s) responsible for the modified trait(s):	<i>bar</i> gene from the bacterium <i>Streptomyces hygroscopicus</i>
Proposed location(s):	Unrestricted planting in current and potential cotton growing areas
Proposed release size:	Phased introduction over 3 years to commercial scale planting, as well as transport and stockfeed use anywhere in Australia.
Proposed time of release:	Ongoing from August 2006

*The title of the licence application submitted by Bayer is *Commercial release of the herbicide tolerant cotton event LLCotton25 (Gossypium hirsutum) for use in the Australian cropping system*

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 gene encodes the phosphinothricin acetyltransferase (PAT) protein. The PAT protein provides tolerance to glufosinate ammonium, the active ingredient in the herbicide Liberty®. This enables the herbicide to be applied for weed control in the GM cotton crop and provides an additional option for incorporation into integrated weed management strategies.

More detailed information on the GMOs, the introduced genes and their products is provided in Chapter 1.

The GM cotton proposed for release has previously been approved (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 to produce varieties suitable 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 anywhere in Australia.

The company anticipates a phased introduction over three years, involving large scale grower evaluations and seed increases, and the development of additional lines adapted for particular regional conditions. The rate of uptake will be determined by market acceptance, and seed and variety availability. Bayer expects the most substantial adoption of the GM cotton to occur initially in the existing cotton growing regions of New South Wales (NSW) and Queensland (QLD), followed by uptake in other areas where environmental conditions are suitable for cotton cultivation. Potential future cotton growing regions, as identified by the applicant, include additional parts of NSW and QLD, some areas of the Northern Territory (NT) and northern Western Australia (WA), and in South Australia (SA) and Victoria (VIC) close to the NSW border (discussed further in Chapter 1). Small scale use for demonstrations and educational purposes is also proposed outside these areas.

Bayer has developed a Reseller and Agronomist Training and Accreditation package and a Technical and Crop Management Plan to optimise and maintain the use of its technology. These will form part of the company's agreement with retailers and growers to purchase and handle Liberty Link[®] Cotton.

SECTION 2 RISK ASSESSMENT

The risk assessment considered information contained in the application, previous GM cotton assessments, current scientific knowledge, and issues relating to risks to human health and safety and the environment raised in submissions received during consultation with a wide range of prescribed experts, agencies and authorities on the application, including all local government authorities in Australia (summarised in Appendix B), and on the RARMP (see Appendix D).

Similarly, advice received from the public on the application and from consultation on the RARMP and how it was considered is summarised in Appendices C and E, respectively.

The risk assessment first considered what harm to the health and safety of people or the environment could arise due to gene technology, and how it could happen during this release of GMOs into the environment (hazard identification), in comparison to non-GM and commercially released GM cotton and in the context of the proposed release area.

A hazard (source of potential harm) may be an event, substance or organism (OGTR 2005). The hazard identification process resulted in the compilation of a list of 28 events that describe sets of circumstances (events) by which the proposed release could potentially give rise to adverse outcomes.

A risk is identified when a hazard is considered to have some chance of causing harm to people and/or the environment. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process. The events that are considered to have the potential to lead to adverse outcomes are assessed further to determine the seriousness of harm (consequence) that could result and how likely it is that the harm would occur. The level of risk is then estimated using the *Risk Estimate Matrix* (see below and Chapter 2).

		RISK ESTIMATE			
		Low	Moderate	High	High
LIKELIHOOD	Highly likely	Low	Moderate	High	High
	Likely	Negligible	Low	High	High
	Unlikely	Negligible	Low	Moderate	High
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	Minor	Intermediate	Major
		CONSEQUENCES			

Risk Estimate Matrix: A *negligible* risk is considered to be insubstantial with no present need to invoke actions for mitigation. A *low* risk is considered to be minimal but may invoke actions for mitigation beyond normal practices. A *moderate* risk is considered to be of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective. A *high* risk is considered to be unacceptable unless actions for mitigation are highly feasible and effective.

Three of the 28 events characterised in the hazard identification process for the proposed release were identified as requiring further assessment. The potential adverse outcome associated with these events was increased spread and persistence (weediness). This identified risk was assessed in comparison to the parent organism and other GM cotton lines previously approved for commercial release, in the context of the intended agronomic management practices, and the environmental conditions in the regions where the proposed release might occur.

The consequence and likelihood assessments used to derive risk estimates for these three events are summarised in Table 1 (the detailed risk assessments are in Chapter 3). More information on the remaining 25 events that were considered not to give rise to an identified risk is provided in Chapter 2.

If a risk is estimated to be higher than negligible, risk treatment measures may be required to protect the health and safety of people or the environment.

Table 1 Summary table for the risk assessment

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Event 1</p> <p>Expression of the <i>bar</i> gene increasing spread and persistence of the GM cotton plants through tolerance to glufosinate ammonium</p>	<p>Marginal</p> <ul style="list-style-type: none"> • Glufosinate ammonium is not effective for the control of established cotton volunteers. • In the presence of glufosinate ammonium, the small competitive advantage of the GM cotton is offset by abiotic and biotic factors (such as water availability, temperature, soil type and nutrients) that limit the spread and persistence of all cotton in Australia. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Glufosinate ammonium is not a widely used herbicide for the control of cotton volunteers as other methods are more commonly used, such as mechanical means or, if still at the seedling stage, by the use of alternative herbicides. • The chance of volunteer GM plants arising from unintended seed dispersal (eg transportation, use as stockfeed, via animals or flooding) finding suitable ecological niches and establishing as weeds would be no greater than for non-GM and commercially approved GM cotton lines. 	<p>Negligible</p>	<p>No</p>
<p>Event 2</p> <p>Expression of the <i>bar</i> gene in other <i>G. hirsutum</i> or <i>G. barbadense</i> cotton plants (not including commercially released GM cotton lines) providing glufosinate ammonium tolerance</p>	<p>Marginal</p> <ul style="list-style-type: none"> • Glufosinate ammonium is not effective for the control of established cotton volunteers. • In the presence of glufosinate ammonium, the small competitive advantage of the GM cotton is offset by abiotic and biotic factors (such as water availability, temperature, soil type and nutrients) that limit the spread and persistence of all cotton in Australia. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • Cotton is primarily self-pollinating and gene transfer to other cotton plants is only expected to occur in close proximity and at low frequencies. • The requirement to apply insecticides to herbicide tolerant GM cotton will further reduce the chance of gene transfer via insects. • Glufosinate ammonium is not a widely used herbicide for the control of cotton volunteers as other methods are more commonly used, such as mechanical means or, if still at the seedling stage, alternative herbicides. 	<p>Negligible</p>	<p>No</p>

Event that may give rise to weediness	Consequence assessment	Likelihood assessment	Risk estimate	Does risk require treatment?
<p>Event 3</p> <p>Expression of the <i>bar</i> gene in combination with <i>cp4 epsps gene</i> and/or <i>cry1Ac</i> and <i>cry2Ab</i> genes providing dual herbicide tolerance and reducing lepidopteran herbivory</p>	<p>Minor</p> <ul style="list-style-type: none"> • Glufosinate ammonium and glyphosate is not effective for the control of established cotton volunteers. • In the presence of glufosinate ammonium, and glyphosate and/or lepidopteran herbivory, the small competitive advantage of any stacked GM cotton is offset by abiotic and biotic factors (such as water availability, temperature, soil type and nutrients) that limit the spread and persistence of all cotton in Australia. • The <i>bar</i> gene operates independently of the herbicide tolerant and insecticidal genes present in other GM cotton lines and there is no evidence of any interactions. 	<p>Highly unlikely</p> <ul style="list-style-type: none"> • The current commercially approved GM cotton lines are only authorised for unrestricted release in southern areas of Australia. Stacking is not expected to occur in northern areas of Australia as field trials with GM cotton in northern Australia are required to be conducted under limited and controlled conditions. • Cotton is primarily self-pollinating and gene transfer to other cotton plants is expected to occur in close proximity and at low frequencies. • The requirement to apply insecticides to herbicide tolerant GM cotton will further reduce the chance of gene transfer via insects. • Glufosinate ammonium and glyphosate are not used to control established cotton volunteers as other methods are more commonly used, such as mechanical means or, if still at the seedling stage, alternative herbicides. 	Negligible	No

SECTION 3 RISK MANAGEMENT

A risk management plan builds upon the risk assessment to consider whether any action is required to mitigate the identified risks, and what can be done to protect the health and safety of people and the environment.

The risk assessment considered three events that might lead to a risk to the environment. The risk estimates for the adverse outcome associated with all three events are **negligible** (ie insubstantial with no present need to invoke actions for their mitigation). Therefore, no risk treatment measures for identified risks were 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.

3.2 Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework (OGTR 2005). Other agencies that also regulate GMOs or GM products include FSANZ, APVMA, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Australian

Quarantine Inspection Service. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies².

FSANZ is responsible for human food safety assessment, including GM food. FSANZ has approved the use of food (oil and linters) derived from Liberty Link[®] Cotton (FSANZ report A533).

The use of herbicides containing glufosinate ammonium on the Liberty Link[®] Cotton is subject to regulation by the APVMA. Bayer has a research permit for use of glufosinate ammonium in current cotton trials involving this GMO, and the APVMA is currently assessing an application from Bayer to register Liberty[®] 150 Herbicide for the control of various weeds in Liberty Link[®] Cotton.

SECTION 4 CONCLUSIONS OF THE RARMP

The risk assessment concludes that this commercial release of herbicide tolerant GM 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.

² More information on Australia's integrated regulatory framework for gene technology is contained in the *Risk Analysis Framework* available from the Office of the Gene Technology Regulator (OGTR). Free call 1800 181 030 or at <<http://www.ogtr.gov.au/pdf/public/raffinal2.2.pdf>>.