



**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT
AND RISK MANAGEMENT PLAN**
for
APPLICATION NO. DIR 063/2005
from
HEXIMA LTD

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of a genetically modified (GM) cotton line with enhanced fungal resistance into the Australian environment, in respect of application DIR 063/2005 from Hexima Ltd (Hexima).

The DIR 063/2005 licence permits the release of one GM cotton line on a limited scale and under controlled conditions.

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 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, authorities and the public.

More information on the comprehensive assessment required for 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

Hexima applied for a licence to release a GM cotton line with enhanced resistance to certain disease causing fungi into the environment¹. The release is proposed to take place at two sites in the shire of Pittsworth, Queensland (QLD) and one site in the shire of Narrabri or Moree Plains, New South Wales (NSW) on a maximum total area of one hectare during each of the three summer cotton growing seasons of 2006/07, 2007/08 and 2008/09.

The GM cotton line contains the plant defensin gene, *nad1*, derived from ornamental tobacco (*Nicotiana glauca*). This gene encodes a defensin protein, NAD1, which inhibits the growth of fungi, including three major fungal pathogens that cause fusarium wilt, verticillium wilt and black root rot in cotton. Plant defensins occur naturally in many horticultural and crop plants such as dahlia, tomato, peas and wheat. Their expression can be stimulated by a range of environmental factors, including disease.

¹ Hexima initially requested approval for the release of three GM lines but subsequently amended the application to one only.

The GM cotton line also contains a bacterial gene (*nptII*, conferring resistance to the antibiotic kanamycin) that was used to select successfully modified plants during initial research and development work in the laboratory.

The purpose of the trial is to conduct early stage ('proof of concept') research to assess the extent of enhanced resistance to three fungal diseases and the agronomic performance of the GM cotton line under field conditions; to measure the expression levels of the introduced plant defensin gene and to test for adverse impacts on selected beneficial soil microorganisms. Lint fibres may be tested for their quality characteristics. Seed will also be collected for further studies and possible future releases (subject to additional applications and assessment processes). No products from the release will be used for human food or animal feed.

Hexima proposed a number of measures to limit the spread and persistence of the GMO and the introduced genetic material that were considered during the evaluation of the application.

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 line into the environment (**hazard identification**, refer to Chapter 2 for more information).

The risks to people and the environment from the proposed limited and controlled release were assessed in comparison to non-GM cotton, 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 24 events compiled during the hazard identification process, two were selected for further assessment. The potential adverse outcome to the environment associated with these events was: toxicity for, or growth-inhibition of, invertebrates and/or non-target microorganisms. The remaining 22 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, or growth inhibition of, invertebrates and/or non-target microorganisms

Two events were considered that might cause toxicity for, or growth inhibition in, invertebrates and/or non-target microorganisms as a result of the release of the GM cotton line:

- Direct or indirect ingestion of the introduced protein (NAD1) by invertebrates
- Exposure of non-target microorganisms to the introduced protein (NAD1).

The risk assessment considered the consequence and likelihood of harm that might result from each of the above events. The estimate of risk for each event 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 level of risk to the health and safety of people or the environment was assessed for two events. The risk estimates for the adverse outcome associated with both events were **negligible**.

The *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, containment and disposal measures have been imposed to restrict the release in locations, size and duration to those requested by the applicant, as these were an important part of establishing the context for assessing the risks.

The licence conditions require the applicant to limit the duration of the release to three summer cotton growing seasons of 2006/07, 2007/08 and 2008/09 on a maximum total area of one hectare at up to three sites; prevent the use of the GMO, or materials from the GMO, in food and animal feed; maintain physical isolation of the release sites; and conduct post-harvest monitoring to ensure all GM plants are destroyed².

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of a GM cotton line with enhanced fungal resistance into the shires of Pittsworth, QLD, Narrabri and Moree Plains, NSW, poses **negligible** risks to the health and safety of people and the environment.

The risk management plan concludes that these negligible risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the locations, size and duration requested by the applicant.

² The licence and conditions for DIR 063/2005 are available on the OGTR website (<http://www.ogtr.gov.au/gmorec/ir.htm#table>, following the path to DIR 063/2005).