



**EXECUTIVE SUMMARY**  
of  
**THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN**  
for  
**APPLICATION No. DIR 039/2003**

*(Field trial of genetically modified high oleic cotton)*

**THE REGULATION OF GENETICALLY MODIFIED ORGANISMS**

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) set out requirements which the Gene Technology Regulator (the Regulator) must follow when considering an application for a licence to intentionally release a genetically modified organism (GMO) into the environment.

For a licence to be issued, the Regulator must be satisfied that the release will not pose any risks to human health and safety and the environment that can not be managed. To this end, Section 51 of the Act requires the Regulator to prepare a risk assessment and risk management plan (RARMP) for each licence application, in consultation with a wide range of expert groups and stakeholders.

Under Section 52 of the Act, the Regulator is required to seek comment on the RARMP from those consulted in its preparation and to invite submissions from the public. Matters raised relating to the protection of human health and safety or the environment are taken into account in finalising the RARMP, which then forms the basis of the Regulator's decision on whether, or not, to issue a licence.

**THE APPLICATION**

CSIRO Plant Industry (CSIRO) has applied for a licence (application number DIR 039/2003) for the limited and controlled release of genetically modified (GM) high oleic (HO) acid cotton into the environment. CSIRO proposes to conduct the trial for one growing season (2003 – 2004) at the Australian Cotton Research Institute (ACRI) in the Shire of Narrabri, NSW, covering a total of 2 hectares.

CSIRO proposes to release two GM cotton lines intended to increase the level of monounsaturated oleic acid (C18:1) and decrease the level of polyunsaturated linolenic acid (C18:2) in cottonseed. Both GM HO cotton lines were genetically modified with two genes, a modified fatty acid desaturase gene (*ghFAD2-1*) from cotton and an antibiotic resistance gene (neomycin phosphotransferase type II, *nptII*) from *Escherichia coli*. Short regulatory sequences control the expression of the introduced genes. The modified fatty acid enzyme is linked to the regulatory elements of a soybean lectin gene (*lec1*) to provide seed-specific gene function.

The modified fatty acid desaturase gene is expected to prevent the function of cotton's own desaturase enzyme and reduce conversion of oleic acid to linoleic acid. In glasshouse trials, the ratios of fatty acids in GM HO cottonseed are altered and contain higher oleic acid levels, and lower linoleic and palmitic acids, than non-GM cottonseed. No novel fatty acid is expected to be produced by GM HO cotton. The *nptII* gene confers resistance to the antibiotics kanamycin and neomycin. This gene was used in the early laboratory stages to select plant cells containing the desired genetic modification.

CSIRO's stated aims for the proposed field trials are:

- to conduct agronomic evaluation of GM HO cotton under field conditions; and
- to store seed from the release for testing the maintenance of high oleic acid levels in cottonseed.

No seeds will be retained for future plantings, as the applicant does not intend to conduct any future trials with these lines. If the proof of concept work is successful the novel trait will be bred into non-GM cotton varieties that are more suitable for commercialisation (subject to further approvals).

After the lint, cottonseed oil is the most valuable product derived from cotton plants. Oil from cottonseed is widely used in food applications around the world, following processing to remove gossypol and other toxic or anti-nutritional compounds such as cyclopropenoid fatty acids. The high levels of polyunsaturated fatty acids present in non-GM cottonseed oil often necessitates additional processing through partial hydrogenation to obtain oil with higher stability and more resistance to oxidation (ie to avoid becoming rancid). However, hydrogenation results in fatty acid structural forms (*trans*, rather than the *cis* arrangement of hydrogen atoms more commonly found in nature) that may increase cholesterol levels upon consumption.

GM HO cottonseed has an altered ratio of fatty acids, with increased oleic acid levels (monounsaturated fatty acid) and decreased levels of linoleic (polyunsaturated fatty acid with low stability) and palmitic acids (saturated fatty acid associated with blood cholesterol-raising properties). Oil from GM HO cottonseed is expected to have a greater stability than non-GM cottonseed oils. This may enable direct use in frying or for margarine hard stock, without the need for hydrogenation that current cottonseed oil requires.

Seed from the non-GM pollen trap rows will be destroyed and none of the cotton plants, or their by-products, will be used for animal feed or human food. Use of oil from GM HO cottonseed for human consumption will not be permitted as this would require prior approval by Food Standards Australia New Zealand (FSANZ). However, the CSIRO proposes to sell lint from the release. Lint does not contain genetic material, protein or fatty acids. Transport of the GM material, post-harvest management of the trial site and monitoring will be in accordance with guidelines issued by the Regulator.

GM HO cotton has not previously been approved for release in Australia. However, the use of the antibiotic selectable marker gene, *nptII*, has been thoroughly assessed in previous applications for field trials and general releases of GM cotton in Australia (refer to DIR 005/2001, DIR 006/2001, DIR 009/2002 and DIR 012/2002). In these applications, the introduction of the *nptII* gene into cotton was considered not to pose a significant risk to human health and safety, or the environment.

GM soybean with high oleic acid levels has been approved for commercial release in other countries. FSANZ has recently approved oil from GM HO soybean for human consumption. The applicant has not as yet applied to FSANZ for approval of GM HO cottonseed oil due to the early stage of the research.

## **THE EVALUATION PROCESS**

Licence application DIR 039/2003 from CSIRO has been evaluated and a RARMP prepared in accordance with the Act and the Regulations, using a Risk Analysis Framework. This framework was developed by the Regulator in consultation with the public and key State, Territory and Australian Government stakeholders and the Gene Technology Technical Advisory Committee, and is available at [www.ogtr.gov.au/pdf/public/raffinal.pdf](http://www.ogtr.gov.au/pdf/public/raffinal.pdf).

Details of the process that the Regulator must follow, including the prescribed consultation process on the application, and the matters that must be considered in preparing a RARMP, are set out in Appendix 7 of the RARMP. The complete RARMP can be obtained from the OGTR or from the OGTR's web site at [www.ogtr.gov.au](http://www.ogtr.gov.au).

The risk assessment considered information relevant to the evaluation of potential impacts on human health and safety and the environment contained in the application (including information required by Act and the Regulations on the GMO, the parent organism, the proposed dealings and containment measures), submissions received during consultation with expert groups and authorities, and current scientific knowledge.

Through this process, potential hazards for human health and safety or the environment that may be posed by the proposed release of GM HO cotton were identified. These have been evaluated on the basis of the likelihood of each hazard occurring and the likely impact of the hazard, were it realised. Potential hazards that could arise from the genetic modifications, introduced gene products or altered traits, include:

- **toxicity and allergenicity for humans** : could GM HO cotton be more toxic or allergenic than non-GM cotton?
- **toxicity for other organisms**: could GM HO cotton be more harmful to other organisms than non-GM cotton?
- **weediness**: could GM HO cotton become a significant weed compared to non-GM cotton? and
- **transfer of introduced genes to other organisms** : could there be adverse consequences from potential transfer of the introduced genes to non-GM cotton crops, feral or native cottons, or to other organisms?

## **CONCLUSIONS OF THE RISK ASSESSMENT**

The Regulator considers that the limited and controlled release of GM HO cotton will not pose any significant risk to public health and safety, or to the Australian environment, that cannot be managed. The assessment of each potential hazard identified above is summarised under a separate heading below.

## **Toxicity or allergenicity to humans**

GM HO cotton is unlikely to prove more toxic or allergenic to humans than non-GM cotton. Expression of the modified fatty acid desaturase gene (derived from cotton) results in altered fatty acid ratios in cottonseed but no novel fatty acid is expected to be produced. The types of major fatty acid components in GM HO cottonseed, and their proportions, are similar to olive oil and other widely available oils. However, FSANZ is responsible for human food safety assessment, and FSANZ approval would be needed before products of these GM cottons could be used in human food.

Cottonseed from the proposed release will not be permitted to be used for human food or animal feed. However, lint from the release will be sold commercially for use in fabric and other non-food products. Lint contains no DNA, protein or fatty acid.

The antibiotic protein, NPTII, is the same as that expressed in previously released GM cottons (DIR 005/2001, DIR 006/2001, DIR 009/2002 and DIR 012/2002). It is naturally widespread in the environment and has no known toxicity or allergenicity to humans.

## **Toxicity to other organisms**

GM HO cotton is unlikely to prove more toxic to other organisms than non-GM cotton and the limited scale of the trials would restrict the potential for exposure. Expression of the modified fatty acid desaturase gene (derived from cotton) results in altered fatty acid ratios in cottonseed but no novel fatty acids are expected to arise. The profile of the major fatty acid components in GM HO cottonseed is similar to olive oil and other widely available oils.

The antibiotic protein, NPTII, is the same as that expressed in previously released GM cottons (DIR 005/2001, DIR 006/2001, DIR 009/2002 and DIR 012/2002). It is naturally widespread in the environment and has no known toxicity to mammals, birds, fish, non-target invertebrates and soil microorganisms. Exposure of other organisms to the NPTII protein and GM cottonseed with its altered fatty acid composition will be low, and cottonseed from the release will not be used for stockfeed.

## **Weediness**

Cotton is not known to be a weed in Australia and has a low potential for dispersal by natural means. The modified traits in GM HO cotton (altered fatty acid ratios and antibiotic resistance) are unlikely to affect these characteristics. The major constraints on weediness of non-GM cotton, including soil moisture, nutrient availability, plant competition, herbivory, frost and fire are likely to apply equally to GM HO cotton. The antibiotic protein, NPTII, is the same as that expressed in previously released GM cottons (DIR 005/2001, DIR 006/2001, DIR 009/2002 and DIR 012/2002). It is not known to increase the potential for weediness of GM cotton.

## **Transfer of introduced genes to other organisms**

Although the overall frequency of out-crossing in cotton is very low, some gene transfer from GM HO cotton to other cultivated cottons would be likely under uncontrolled conditions. It is highly unlikely, however, that the inserted genes would increase the frequency of such gene transfers. Transfer of introduced genes to other cultivated cotton would pose the same risks as for GM HO cotton, which are assessed as low. Licence conditions have been

imposed to minimise the transfer of introduced genes to other cotton crops (refer to key licence conditions below).

Transfer of introduced genes to feral/naturalised cotton is unlikely due to geographic isolation and the risk of transferring the introduced genes to native cottons is negligible because of hybrid infertility. The likelihood of transfer of the introduced genes to other organisms is negligible because of sexual incompatibility.

### **Additional data**

The proposed release is a proof of concept trial of these GMOs to test their abilities to produce cottonseed with high oleic acid when grown under field conditions. There is limited data on expression and molecular characterisation of the introduced genes. Information on altered plant properties is limited to glasshouse trials.

As genes inserted by genetic modification, can have an influence on multiple, sometimes unrelated, plant traits, unintended effects of the inserted genes may result in changes to characteristics that affect toxicity or allergenicity to humans, toxicity to other organisms, or weediness. The applicant proposes to assess the agronomic characteristics of GM HO cotton to identify any such unintended effects.

The applicant does not intend to conduct further trials with these lines. However, the evaluation process identified further data that, while not necessary for managing the risks posed by the proposed release, would be required before any future application for significantly larger scale trials with similarly modified lines or requests for reduced containment conditions could be evaluated.

### **THE RISK MANAGEMENT PLAN (KEY LICENCE CONDITIONS)**

As part of the evaluation process for this licence application, a risk management plan has been developed to address the risks identified (refer to Conclusion of the risk assessment, above). This plan is given effect by licence conditions. The key licence conditions are outlined below.

#### **Toxicity or allergenicity to humans**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release (single site of two hectares and one growing season);
- prevent entry of the GMOs and products derived from the GMOs into the human food supply;
- destroy all seed not required for assessment of the HO trait; and
- securely transport and store the GMOs.

#### **Toxicity to non-target organisms**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release (single site of two hectares and one growing season);

- prevent cottonseed from the trial being used as stockfeed;
- destroy all seed not required for assessment of the HO trait; and
- securely transport and store the GMOs.

### **Weediness**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release (single site of two hectares and one growing season);
- surround the GM cotton lines by a 20 m pollen trap of non-GM cotton;
- securely transport and store the GMOs;
- prevent cottonseed from the trial being used as stockfeed;
- clean equipment used at the release site; and
- monitor release site after harvest and destroy volunteers.

### **Transfer of introduced genes to other organisms**

Licence conditions have been imposed which require the applicant to:

- limit the scale of the release (single site of two hectares and one growing season);
- surround the GM cotton lines by a 20 m pollen trap of non-GM cotton;
- securely transport and store the GMOs;
- clean equipment used at the release site; and
- monitor release site after harvest and destroy volunteers.

In addition, the licence conditions require the applicant to undertake a research program to obtain data to validate previous research on the efficacy of the pollen trap.

### **General conditions**

The licence issued by the Regulator also contains a number of general conditions, which are also relevant to risk management. These include, for example,

- identification of the persons or classes of person covered by the licence;
- a requirement that the applicant allow access to the release site by the Regulator, or persons authorised by the Regulator, for the purposes of monitoring or auditing; and
- a requirement to inform the regulator if the applicant becomes aware of any additional information about risks to human health or safety or to the environment.

## **Monitoring and enforcement of compliance by the OGTR**

As well as the legislative capacity to enforce compliance with licence conditions, the Regulator has additional options for risk management. The Regulator can direct a licence holder to take any steps the Regulator deems necessary to protect the health and safety of people or the environment. The OGTR also independently monitors releases that the Regulator has authorised. At least 20% of all field trial sites will be inspected each year, in accordance with a monitoring and compliance strategy based on risk profiling, to determine whether licence holders are complying with the licence conditions, or whether there are any unintended effects.

## **FURTHER INFORMATION**

Detailed information on the evaluation of the application, including the licence conditions, is available in the risk assessment and risk management plan document for this application, which can be obtained from the website of the Office of the Gene Technology Regulator ([www.ogtr.gov.au](http://www.ogtr.gov.au)), or by calling 1800 181 030 (please quote application number DIR 039/2003).