



Office of the Gene Technology Regulator

EXECUTIVE SUMMARY

of

The Risk Assessment and Risk Management Plan

(Finalised version)

for Application No. DIR 022/2002

from

Monsanto Australia Ltd

(Continued commercial release of GM insecticidal cotton (INGARD[®] 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 or the environment that cannot 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.

THE APPLICATION

A risk assessment and risk management plan has been prepared in response to a licence application (application number DIR 022) from Monsanto Australia Limited (Monsanto) for the continued commercial release of genetically modified (GM) insecticidal (INGARD[®]) cotton, event 531, in the cotton growing regions of New South Wales and Queensland south of latitude 22° South. Monsanto also proposes phasing-out INGARD[®] cotton over the next two growing seasons while GM insecticidal Bollgard II[®] cotton (which was approved for commercial release in September 2002, DIR 012/2002) is phased-in over the same period.

In 1996, the insecticidal gene present in INGARD[®] cotton was registered as an agricultural chemical product by the Australian Pesticides and Veterinary Medicines Authority (APVMA) (then the National Registration Authority for Agricultural and Veterinary Chemicals (NRA)) based on advice from the Genetic Manipulation Advisory Committee (GMAC) and other Commonwealth and State Government agencies. In the same year INGARD[®] cotton received an advice to proceed for a general (commercial) release (GR-3) under the previous voluntary system that was overseen by GMAC. A 'deemed' licence for the commercial release of INGARD[®] cotton was issued to Monsanto before the commencement of the Act on 21 June 2001. The deemed licence is effective during the transition period, i.e. 2 years from the commencement of the Act and expires in June 2003. Approval of application DIR 022 would enable the continued commercial release of genetically modified INGARD[®] cotton.

INGARD[®] cotton is resistant to lepidopteran caterpillar pests that attack cotton. The GM cotton contains an insecticidal gene derived from a common soil bacterium that produces a protein that is toxic to specific insects. It also contains bacterial genes conferring resistance to antibiotics that were used solely as selectable markers in the initial laboratory stages of developing the GM cotton.

Monsanto seeks approval for continued commercial release of INGARD[®] cotton in all Australian cotton growing regions south of latitude 22° South without limitations on transportation or storage. Monsanto intends that GM cotton plants and their by-products, including cotton seed, be used in general commerce in the same manner as conventional cotton, including for human food and stock feed. Cotton seed is processed for oil that is used in a variety of food products and for cotton linters (a type of short fibre that does not contain any genetic material) that are used as a cellulose base in some foods. Food Standards Australia New Zealand, FSANZ, (formerly the Australia New Zealand Food Authority, ANZFA) approved the use of oil and linters from INGARD[®] cotton in human food in 1999.

The APVMA is responsible for determining the total planting area each season of INGARD[®] cotton. It currently allows up to 30% of the cotton crop to be planted to this GM cotton, to preserve the effectiveness of the product by guarding against the evolution and emergence of resistant insects.

Prior to commercial release of INGARD[®] cotton, 56 limited and controlled releases involving INGARD[®] cotton were conducted under the voluntary system overseen by GMAC. There have been no reports of adverse effects on human health or the environment resulting from any of these field trials. Nor, has an ongoing research and monitoring program revealed any such reports since the commercial release of INGARD[®] cotton.

THE EVALUATION PROCESS

Licence application DIR 022/2002 from Monsanto has been evaluated and a risk assessment and risk management plan (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 Commonwealth government stakeholders and the Gene Technology Technical Advisory Committee, and is available at www.ogtr.gov.au.

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 8 of the RARMP. The complete RARMP can be obtained from the OGTR or from the OGTR's website at www.ogtr.gov.au.

The risk assessment considered information contained in the application (including information required by the Act and the Regulations on the GMO, the parent organism, the proposed dealings and on potential impacts on human health and safety and the environment), submissions received during consultation and current scientific knowledge.

Through this process, potential hazards to human health and safety or the environment that may be posed by the release of INGARD[®] cotton identified. These have been evaluated on the basis of the likelihood of the hazard occurring and the likely impact of the hazard were it to be realised. The identified potential hazards relate to:

- **toxicity and allergenicity for humans** : could INGARD[®] cotton be harmful to human health if it were more toxic or allergenic than non-GM cotton, as a result of the novel gene products or because of unforeseen or unintended effects;

- **toxicity for non-target organisms** : could INGARD[®] cotton be harmful to non-target organisms as a result of the novel gene products or because of unforeseen or unintended effects;
- **weediness**: could INGARD[®] cotton be harmful to the environment because of inherent weediness or increased potential for weediness;
- **transfer of introduced genes to other organisms** : could the new genes introduced into the cotton transfer to non-GM cotton crops, feral or native cottons, or to other organisms, with adverse consequences for the environment; and
- **insecticide resistance**: could target insects might develop resistance to the insecticidal protein produced by the introduced insecticidal gene in INGARD[®] cotton.

CONCLUSIONS OF THE RISK ASSESSMENT

Consistent with GMAC's original evaluation, and in the light of extensive experience with this GMO in the Australian environment, the Regulator considers that no risks to human health and safety, or to the Australian environment, will result from the continued commercial release of INGARD[®] cotton, above the very low risks posed by commercial production of non-GM cotton. The assessment of each potential hazard identified above is summarised under a separate heading below.

Toxicity or allergenicity to humans

INGARD[®] cotton shows no indication of being more toxic or allergenic to humans than conventional cotton. There have been no reports of adverse health effects associated with INGARD[®] cotton since trials first began in 1993. As noted above, FSANZ has previously approved the use of oil and linters from INGARD[®] cotton in food, concluding that these products are as safe as those from non-GM cotton. Therefore it is not considered necessary to impose any management conditions in relation to potential toxicity or allergenicity.

Toxicity to non-target organisms

INGARD[®] cotton shows no indication of being more toxic to non-target organisms than conventional cotton. The introduced proteins have been found to be non-toxic to non-target organisms and INGARD[®] cotton seed and seed meal have been used as stock feeds with no reports of adverse effects. Therefore it is not considered necessary to impose any management conditions in relation to potential non-target toxicity.

Weediness

The risk of INGARD[®] cotton establishing as a weed in cotton-growing areas of Australia south of latitude 22° South is very low, and not likely to be greater than that of conventional cotton. The germination and/or persistence of non-GM and GM cotton in southern Australia are effectively limited by the prevailing conditions in relation to soil moisture, soil nutrients and frosts. Therefore it is not considered necessary to impose any conditions to manage the risk of weediness in southern Australia.

There is a low risk of INGARD[®] cotton becoming weedy in specific habitats in northern Australia, however this can be managed. INGARD[®] cotton seed has been used as stockfeed in northern Australia since its commercial release in 1996. Currently there is no indication that INGARD[®] cotton volunteers have become a problematic weed species, or are more prevalent than conventional cotton. Although the risk is low, licence conditions have been imposed to monitor INGARD[®] cotton volunteers at sites in northern Australia where the GMO is fed to stock.

Transfer of introduced genes to other organisms

Some gene transfer from INGARD[®] cotton to other cultivated cotton is likely, but the overall frequency of out-crossing will be very low. If this occurs, it would not pose any risks additional to those posed by the GM cotton itself. The conventional farming practice of using certified (pure) seed every season minimises the presence of the new genes in non-GM crops.

The potential for transfer of the introduced genes to native cotton species is negligible, because of genetic incompatibility with all native species and, for many, geographic isolation.

The potential for gene transfer to feral (naturalised) cotton is low because of the geographical isolation of known feral populations in Western Australia and the Northern Territory from areas of NSW and Queensland in which INGARD[®] cotton will be grown. Although herbarium records suggest that feral cotton populations may also occur in Queensland, there is a relative lack of detailed information on the location of such populations. For this reason, a licence condition has been imposed requiring the applicant to document the location of these populations, if they exist, in Queensland and determine their distance from cotton production locations, to assess whether additional controls are required.

The likelihood of transfer of the introduced genes to other organisms is negligible, but even if such transfer occurred, it will not pose any hazard to human health and safety or the environment.

Insecticide resistance

The likelihood of the targeted insects developing resistance to the insecticidal protein in the long term is high, however this risk is being managed by the APVMA.

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 that were identified (refer to Conclusion of the Risk Assessment, above). The plan is given effect by the licence conditions, which are outlined below.

Management of toxicity or allergenicity

Based on the risk assessment, it is not considered necessary to impose any management conditions in relation to potential toxicity or allergenicity of the GM cotton.

Management of weediness

Based on the risk assessment, it is not considered necessary to impose any conditions to manage the risk of weediness in southern Australia.

Conditions have been imposed to limit the spread and persistence of GM cotton that may be used for stockfeed in northern Australia. The licence includes conditions that require:

- the use of covered vehicles for transport of GM cottonseed north of latitude 22° South;
- the licence holder to develop, in consultation with the OGTR, a strategy to communicate the importance of control of volunteer cotton plants to recipients of GM cottonseed north of latitude 22° South; and
- the licence holder to conduct an annual survey of the incidence of volunteer cotton in areas where GM cottonseed is used as stockfeed and of the effectiveness of the communication strategy required above.

Management of gene transfer

A licence condition has been imposed requiring the applicant to determine the remnants of feral cotton populations in this region, as indicated by the herbarium records, and their distance from cotton production locations.

Management of insecticide resistance

The licence does not impose any management conditions in relation to insecticide resistance because this risk is being managed effectively by the APVMA, as the relevant statutory authority. The licence indicates the applicant's obligation to comply with the APVMA's Insecticide Resistance Management Strategy and conditions of this licence do not replace or over-ride any conditions set by the APVMA.

General conditions

Any 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 or persons covered by the licence and informing the Regulator if the applicant becomes aware of any adverse effects or additional information about risks to human health and safety or to the environment.

Monitoring and enforcement of compliance by the OGTR

As well as 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.

FURTHER INFORMATION

Detailed information on the evaluation of this application, including the licence conditions imposed, is available in the RARMP document, which can be obtained from the web site of the OGTR (www.ogtr.gov.au), or by calling 1800 181 030 (please quote application number DIR 022/2002).