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

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TECHNICAL SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR APPLICATION NO. DIR 113 FROM BAYER CROPSCIENCE PTY LTD

Introduction

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence in respect of a licence application (DIR 113) from Bayer CropScience Pty Ltd (Bayer). The licence authorises dealings involving the limited and controlled release of genetically modified (GM) cotton into the environment.

The *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state and territory law govern the comprehensive and highly consultative process undertaken by the Gene Technology Regulator (the Regulator) before making a decision whether or not to issue a licence to deal with a genetically modified organism (GMO).

The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Regulator in accordance with requirements of the legislation. RARMPs apply the *Risk Analysis Framework* and are finalised following consultation with a wide range of experts, agencies and authorities, and the public[1].

The application

Bayer has applied for a licence for dealings involving the intentional release of GM cotton into the environment on a limited scale and under controlled conditions. The GM cotton varieties have been genetically modified for insect resistance and herbicide tolerance. The field trial is authorised to take place at up to six sites per year in the LGAs of Narrabri, NSW, Wyndham-East Kimberly, WA, and Central Highlands, Qld, between May 2012 and May 2015. The maximum area of plantings will be 6 ha in the first year and 36 ha in the second and third years, giving a maximum cumulative area of 78 ha.

The purpose of the trial is to assess the agronomic performance of the GM cotton varieties, and to produce seed for use in further studies or releases (subject to additional approvals). The GM cotton varieties will not be permitted to enter the commercial human or animal food supply chains.

[1] More information on the process for 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/>), and in the Regulator's *Risk Analysis Framework* (OGTR 2009) at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

Up to 11 varieties of GM cotton are authorised for release. These cotton varieties contain different combinations of genes conferring insect resistance isolated from the common soil bacterium *Bacillus thuringensis* (Bt), and introduced genes conferring herbicide tolerance. Some varieties also contain an antibiotic resistance marker gene, which was used to select GM plants during initial development of the plants in the laboratory.

The GM cotton lines also contain short regulatory sequences that control expression of the introduced genes. Regulatory sequences were derived from plants (including thale cress), bacteria (*Agrobacterium tumefaciens, Escherichia coli*) or plant viruses.

The GM cotton varieties authorised for release include lines containing a single genetic modification (or 'transformation') event, as well as varieties containing two or more transformation events which have been combined (or 'stacked') by conventional cross-breeding between these lines. All but one of the GM cotton lines containing single transformation events have been previously approved by the Regulator for limited and controlled release in Australia. One GM cotton line, genetically modified for herbicide tolerance, had not been previously assessed by OGTR but has been approved for release by regulatory authorities in other countries.

Bayer proposed a number of controls to restrict the spread and persistence of the GM cotton varieties and their genetic material into the environment. These controls were considered during the evaluation of the application.

Confidential Commercial Information

Details of the genes and the specific genetic elements (coding and regulatory sequences) inserted into the GM cotton varieties have been declared Confidential Commercial Information (CCI) under section 185 of the Act. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

Risk assessment

The risk assessment took into account information in the application (including proposed containment measures), relevant previous approvals and current scientific/technical knowledge. Advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP was also considered. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

A reference document, *The Biology of* Gossypium hirsutum *L. and* Gossypium barbadense *L. (cotton),* was produced to inform the risk assessment process for licence applications involving GM cotton plants. The document is available from the OGTR or from the website <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1 >.

Initially, potential pathways that might lead to harm to people or the environment as a result of gene technology are postulated (risk scenarios), and those that warrant detailed characterisation are determined. This process is described as risk identification.

Six risk scenarios were postulated, including consideration of whether or not expression of the introduced genes could: result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the spread and persistence of the GM cotton varieties; or produce unintended changes in the biochemistry of the GMOs. The opportunity for gene flow to other organisms, and its effects if it were to occur, was also assessed.

A risk is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

The characterisation of the six risk scenarios in relation to both the seriousness and likelihood of harm, in the context of the control measures proposed by the applicant and considering both the short and the long term, did not identify any risks that could be greater than negligible. Therefore, they did not warrant further assessment.

The principal reasons for this include:

- widespread presence of the same or homologous genes and proteins in the environment
- toxicity of the proteins encoded by the introduced insect resistance genes is expected to be restricted to target insects and a limited range of related non-target insects
- plant characteristics and abiotic factors limiting the ability of GM or non-GM cotton plants to establish and persist in non-cultivated environments
- limited ability and opportunity for the GM cotton plants to transfer the introduced genes to commercial cotton crops or other cotton plants
- limits on the size, locations and duration of the release proposed by Bayer
- suitability of controls proposed by Bayer to restrict the spread and persistence of the GM cotton plants and their genetic material
- none of the GM plant materials or products will enter commercial human or animal food supply chains.

Risks to the health and safety of people, or the environment, from the proposed release of the GM cotton into the environment are assessed to be negligible.

Risk management plan

Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through licence conditions.

As none of the six risk scenarios characterised in the risk assessment give rise to an identified risk that requires further assessment, the level of risk from the proposed dealings is assessed to be negligible. The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation in the risk management plan. However, conditions have been imposed to restrict the spread and persistence of the GMOs and their genetic material in the environment and to limit the release to the size, locations and duration proposed in the application, as these were important considerations in establishing the context for assessing the risks.

Licence conditions

The Regulator has imposed a number of licence conditions, including requirements to:

- limit the release to a total cumulative area of 78 ha in three LGAs between May 2012 and May 2015
- restrict gene flow via pollen from field trial sites using one of the following measures:
  - surround the trial site with a 100 m monitoring zone and maintain a 3 km isolation distance between the site and intentionally planted cotton crops, or

  - surround the trial site by a 20 m pollen trap of non-GM cotton or commercially approved GM cotton, and treating the pollen trap plants in the same way as the GMOs
- harvest and gin all cotton plant material separately from other cotton crops
- clean all equipment used in connection with the cotton plant material
- after harvest, destroy all cotton plant material not required for further analysis or future planting
- after cleaning of sites, apply measures to promote germination of any cotton seeds that may be present in the soil
- after cleaning of sites, monitor for and destroy any GM cotton that may grow for at least 12 months, and until no volunteers are observed for a continuous 6 month period
- transport and store the GM plant material in accordance with the Regulator's guidelines or other specific conditions
- not allow GM plant material or products to be used for human food or animal feed.

Other regulatory considerations

Australia's gene technology regulatory system operates as part of an integrated legislative framework that avoids duplication and enhances coordinated decision making. The Regulator is responsible for assessing risks to the health and safety of people and the environment associated with the use of gene technology. However, dealings conducted under a licence issued by the Regulator may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and Australian Quarantine Inspection Service (AQIS)[2].

FSANZ is responsible for human food safety assessment and food labelling, including GM food. FSANZ has previously assessed all of the GM cotton lines produced by single transformation events that are proposed for limited and controlled release and has given approval for their use in food. These approvals would also cover the stacked GM cotton varieties produced by conventional cross-breeding between approved lines. However, the applicant will not use materials generated from the GM cotton varieties in the release in human food or in animal feed.

APVMA has regulatory responsibility for agricultural chemicals, including herbicides and insecticidal products, in Australia. Some of the GM cotton varieties proposed for release meet the definition of an agricultural chemical product under the *Agricultural and Veterinary Chemicals Code Act 1994*, due to their production of insecticidal substances, and therefore these plants are subject to regulation by the APVMA. The applicant intends to apply herbicide to the GM cotton lines during the trial, which is also subject to regulation by the APVMA.

A permit from AQIS will be required to enable import of GM cotton seed from the USA.

In addition, dealings authorised by the Regulator may be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

[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/internet/ogtr/publishing.nsf/Content/riskassessments-1>.

Identification of issues to be addressed for future releases

Additional information has been identified that may be required to assess an application for a large scale or commercial release of these GM cotton varieties, or to justify a reduction in containment conditions. This would include:

- additional data on potential increases in toxicity to non-target invertebrates as a result of stacked insect resistance genes
- additional phenotypic characterisation of the GM cotton varieties, in particular of traits which may contribute to weediness
- additional molecular and biochemical characterisation of the GM cotton varieties.

Suitability of the applicant

The Regulator has assessed the suitability of Bayer to hold a DIR licence as required by the Act. Bayer is considered suitable as the Regulator is satisfied that no relevant convictions have been recorded, no licences or permits have been cancelled or suspended under laws relating to the health and safety of people or the environment, and the organisation has the capacity to meet the conditions of the licence.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of up to 11 varieties of GM cotton on a maximum cumulative area of 78 ha over three years in the LGAs of Narrabri, NSW, Wyndham-East Kimberley, WA, and Central Highlands, Qld, poses negligible risks to the health and safety of people or the environment as a result of gene technology.

The risk management plan concluded that these negligible risks do not require specific risk treatment measures. However, licence conditions are imposed to limit the release to the size, locations and duration proposed in the application, and to require controls in line with those proposed by the applicant as these were important considerations in establishing the context for assessing the risks.