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

28 March 2007

Executive Summary of the Risk Assessment And Risk Management Plan
for
Application No. DIR 069/2006
from **Bayer CropScience Pty Ltd**

INTRODUCTION

The Gene Technology Regulator (the Regulator) has made a decision to issue a licence for dealings involving the intentional release of genetically modified (GM) canola and Indian mustard lines containing genes for herbicide tolerance and a novel hybrid breeding system into the environment, in respect of application DIR 069/2006 from Bayer CropScience Pty Ltd (Bayer).

The DIR 069/2006 licence permits the release of the GM canola and Indian mustard lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations) and corresponding State and Territory law 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 accordance with the *Risk Analysis Framework* and in consultation with a wide range of experts, agencies and authorities, and the public.

More information on the comprehensive assessment undertaken 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/>.

THE APPLICATION

Bayer applied for a licence to release GM canola and Indian mustard lines containing introduced genes for herbicide tolerance and a hybrid breeding system into the environment, on a limited scale and under controlled conditions. The trial will take place on a maximum of 252 hectares, comprising up to 42 sites of no more than 6 ha per site, over 6 seasons between 2007 and 2010. Up to 8 sites per winter and 6 sites per summer season will be used. Potential sites have been identified in 24 shires in New South Wales, South Australia and Victoria.

Bayer's novel breeding system emulates the natural phenomenon of hybrid vigour when progeny of genetically distinct parents provide improved agronomic performance over the parental lines. The GM canola and Indian mustard lines contain either the *barnase* gene or *barstar* gene which confer male sterility (MS) or restore fertility (Rf), respectively. Conventional breeding between genetically modified MS and Rf lines results in GM hybrid lines with restored fertility. Bayer may release genetically modified MS, Rf and hybrid lines of canola and Indian mustard. All GM canola and Indian mustard lines are also herbicide tolerant.

In accordance with the provisions of section 185 of the *Gene Technology Act 2000*, Bayer sought and received approval for certain information, including details of the trait for herbicide tolerance, to be declared Confidential Commercial Information (CCI). The CCI was made available to the various prescribed experts and agencies that are required to be consulted on the preparation of all RARMPs for DIR applications.

The purpose of the trial is to evaluate agronomic traits such as herbicide tolerance, germination efficiency, and flowering times in the GM canola and Indian mustard lines compared to conventional non-GM canola and Indian mustard, as well as previously approved GM InVigor® canola lines.

Seed of the GM canola and Indian mustard lines will be imported from Canada. Seeds collected during the trial may be shipped back to Canada for further trait evaluation. Bayer envisages that seeds from promising lines may be further assessed in future seasons in Australia (subject to further approvals).

Bayer proposed a number of measures to limit the spread and persistence of the GMO and the introduced genetic materials that were considered during the evaluation of the application. None of the GM plants materials, or their by-products, will be used for stock feed or human food.

RISK ASSESSMENT

The hazard identification process considered the circumstances by which people or the environment may be exposed to the GMOs, GM plant materials, GM plant by-products, the introduced genes, or products of the introduced genes.

A hazard (source of potential harm) may be an event, substance or organism. A risk is identified when a hazard is considered to have some chance of causing harm. Those events that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process.

Nineteen events were identified and assessed whereby the proposed release of the GM canola and Indian mustard lines might give rise to harm to people or the environment.

These 19 events included consideration of whether 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 plants, or produce unintended changes in their biochemistry or physiology. In addition, consideration was given to the opportunity for gene flow to other organisms, and its effects if this occurred.

All events were characterised in relation to both the magnitude and probability of harm in the context of the controls proposed by the applicant to limit the spread and persistence of the GMOs in both time and space. This detailed consideration concluded that none of the nineteen events gave rise to an identified risk that required further assessment. The principal reasons comprise:

- the scale of the trial is limited in both area and duration
- containment, monitoring and disposal measures proposed by the applicant to limit the spread and persistence of GM canola and Indian mustard plants
- none of the GM plant materials or products from the GM plants will be used in human food or animal feed
- widespread presence of the same or similar proteins encoded by the introduced genes in the environment and lack of known toxicity or allergenicity from these proteins
- limited capacity of the GM canola and Indian mustard lines to spread and persist in natural ecosystems or undisturbed areas
- limited ability and opportunity for the GM canola and Indian mustard lines to transfer the introduced genes to related species or other organisms.

Therefore, any risk of harm to the health and safety of people, or the environment, from the limited and controlled release of the GM canola and Indian mustard lines is considered to be **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. As none of the 19 events characterised in the risk assessment are considered to give rise to an identified risk that requires further assessment, the level of risk is considered to be **negligible**.

The Regulator's *Risk Analysis Framework* defines negligible risks as insubstantial, with no present need to invoke actions for their mitigation. However, conditions have been imposed on the licence to restrict the release to the size, duration and locations 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 size and duration of the release to a maximum total area of 252 hectares over 3 years (2007-10) and prevent the use of the GMOs, or materials from the GMOs for any other purposes. Containment measures include maintaining physical isolation of the release sites; transport requirements; and the conduct of post-harvest monitoring to ensure GMOs are destroyed.

CONCLUSIONS OF THE RARMP

The risk assessment concludes that this limited and controlled release of GM canola and Indian mustard lines containing genes for herbicide tolerance and a hybrid breeding system 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 these **negligible** risks do not require specific risk treatment measures. However, licence conditions have been imposed to contain the release to the size, duration and locations requested by the applicant, as these were important parameters in establishing the context for assessing the risks.