



7 January 2009

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK
MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 089
FROM
VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES**

Introduction

The Acting Gene Technology Regulator (the Acting Regulator) has made a decision to issue a licence for dealings involving the limited and controlled release of white clover genetically modified for resistance to Alfalfa mosaic virus (AMV) into the environment in respect of application DIR 089 from the Victorian Department of Primary Industries (DPI Victoria).

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 Regulator before making a decision whether to issue a licence to deal with a GMO. The decision is based upon a Risk Assessment and Risk Management Plan (RARMP) prepared by the Acting Regulator in accordance with the *Risk Analysis Framework* and finalised following consultation with a wide range of experts, agencies and authorities and the public¹.

The application

DPI Victoria applied for a licence for dealings involving the intentional release of one line² of GM white clover on a limited scale and under controlled conditions. The GM white clover line has been genetically modified to resist infection by AMV. The release will involve one site in the local government area of Corowa, NSW, on a maximum area of 633 m² per year, between March 2009 and August 2011.

The GM white clover contains a gene from a virus which provides resistance to AMV, as well as an antibiotic resistance gene which was used to identify transformed plants during initial development of the GM plant in the laboratory.

The purpose of the trial is to conduct experiments to evaluate the agronomic performance, including seed yield, of the GM white clover line under field conditions. Some seed would be collected and retained for analysis and possible future trials, subject to further approval(s). The GM white clover will not be used for human food or animal feed.

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 (Free call 1800 181 030 or at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1>>), and in the Regulator's *Risk Analysis Framework* (OGTR 2007) at <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>>.

² The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification made by one transformation event.

DPI Victoria proposed a number of controls to restrict the dissemination or persistence of the GM white clover line and the introduced genetic materials in the environment that have been considered during the evaluation of the application.

Confidential Commercial Information

Some details, including screening protocols, data from previous field trials and unpublished data produced to support weediness and gene flow assessments, 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, current scientific knowledge and advice relating to risks to human health and safety and the environment provided in submissions received during consultation on the RARMP.

A **hazard** identification process was used in the first instance to determine potential pathways that might lead to harm to people or the environment as a result of gene technology.

Nine events were considered whereby the proposed dealings might give rise to harm to people or the environment. This included 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 plants; or produce unintended changes in their biochemistry or physiology. The opportunity for gene flow to other organisms and its effects if this occurred was also assessed.

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

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 GMO in both time and space. This detailed consideration identified one event requiring further assessment. The potential adverse outcome to the environment associated with this event was enhanced spread and persistence (weediness). The remaining eight 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). The principle reasons comprise:

- limits on the size, location and duration of the release proposed by DPI Victoria
- suitability of controls proposed by DPI Victoria to restrict the dissemination or persistence of the GM white clover plants and their genetic material
- none of the GM plant materials or products 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 evidence of harm from them.

Risk of weediness

The event that might result in the introduced gene causing greater weediness than the parent non-GM white clover was:

- Expression of the introduced *AMV CP* gene in other white clover plants as a result of gene transfer leading to increased spread and persistence in native plant habitats. (Identified Risk 1).

The consequence and likelihood of harm that might result from the above event was assessed in the context of the current trial. The estimate of risk for the identified risk 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 health and safety of people or the environment for the identified risk was estimated as **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, a range of measures have been imposed to restrict the dissemination and persistence of the GMO and its genetic material in the environment and to limit the proposed release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

The licence conditions require DPI Victoria to **limit** the release to a total area of 633 m² per year at one site between March 2009 and August 2011. The **control** measures include containment provisions at the trial site, preventing the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with OGTR transportation guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed³.

Conclusions of the RARMP

The risk assessment concluded that this limited and controlled release of one GM white clover line on a maximum total area of 633 m² per year over two and a half years in the NSW local government area of Corowa, 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 have been imposed to restrict the dissemination and persistence of the GMO and its genetic material in the environment and to limit the release to the size, location and duration requested by the applicant as these were important considerations in establishing the context for assessing the risks.

³ The licence for DIR 089 is available on the OGTR website via the link to DIR 089 (<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir089-2008>)