



7 January 2009

**TECHNICAL 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 public<sup>1</sup>.

***The application***

DPI Victoria applied for a licence for dealings involving the intentional release of one line<sup>2</sup> of white clover (*Trifolium repens* L.) which has been genetically modified to resist infection by AMV on a limited scale and under controlled conditions. The trial is authorised to take place at one site in the local government area of Corowa, NSW, on a maximum area of 633 m<sup>2</sup> per year between March 2009 and August 2011.

The GM white clover line proposed for release was produced by transforming plants of the white clover cultivar 'Irrigation'. The GM plants were then conventionally bred with the white clover cultivar 'Mink' and then the white clover cultivar 'Grasslands Sustain' to produce the GM white clover proposed for release.

The GM white clover line contains the Alfalfa mosaic virus coat protein (*AMV CP*) gene intended to provide resistance to AMV, and an antibiotic resistance gene (*nptII*) encoding the protein neomycin phosphotransferase type II from *Escherichia coli* which provides resistance to the antibiotic kanamycin, which was used as a marker to select for modified plants in the laboratory.

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<sup>1</sup> 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>>.

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

The purpose of the trial is to conduct further experiments to evaluate the agronomic performance, including seed yield, of the GM white clover line previously released under Licence DIR 047/2003, 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.

DPI Victoria proposed a number of controls to restrict the dissemination or persistence of the GM white clover line and its genetic material into the environment. These controls 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 considered information contained in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge and issues relating to risks to human health and safety and the environment raised in submissions received from consultation with a wide range of prescribed experts, agencies and authorities on the application (summarised in Appendix B of the RARMP). Submissions received from the public on the consultation RARMP (four submissions), and how they were considered, is summarised in Appendix C of the RARMP. After considering advice on the consultation RARMP, the risk of weediness as a result of gene flow (Event 4; Identified Risk 1) has been considered as an identified risk.

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

The risk assessment begins with a hazard identification process to consider what harm to the health and safety of people or the environment could arise during this release of GMOs due to gene technology, and how it could happen, in comparison to the non-GM parent organism and in the context of the proposed receiving environment.

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.

The events that are considered to have the potential to lead to adverse outcomes are assessed further to determine the seriousness of harm (consequence) that could result and how likely it is that the harm would occur. The level of risk is then estimated using the Risk Estimate Matrix (see below and Chapter 2).

		RISK ESTIMATE			
		Low	Moderate	High	High
LIKELIHOOD	Highly Likely	Negligible	Low	High	High
	Likely	Negligible	Low	Moderate	High
	Unlikely	Negligible	Negligible	Low	Moderate
	Highly Unlikely	Marginal	Minor	Intermediate	Major
		CONSEQUENCES			

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 represent an identified risk and do not advance any further in the risk assessment process.

Nine events were identified 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.

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 associated with this event is increased 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.

The identified risk was assessed in comparison to the parent non-GM white clover, also taking into account, intended agronomic management practices, and the environmental conditions in the regions approved for the release.

The consequence and likelihood assessments that determined the risk estimates for the identified risk is summarised in Table 1 (the detailed risk assessment is in Chapter 3).

If a risk is estimated to be higher than **negligible**, risk treatment measures may be required to protect the health and safety of people or the environment. However, all risks were estimated to be **negligible** for this release.

**Table 1. Summary table for the risk assessment**

Event that may give rise to weediness	Consequence assessment	Likelihood	Risk estimate	Does risk require treatment?
<p><b>Identified Risk 1</b></p> <p>Expression of the introduced <i>AMV CP</i> gene in other white clover plants as a result of gene transfer leading to increased spread and persistence in native plant habitats.</p>	<p><b>Minor</b></p> <ul style="list-style-type: none"> <li>• Non-GM white clover mainly impacts on herbaceous plants in native plant habitats and AMV-resistant white clover is expected to do the same.</li> <li>• Many native plant habitats have no AMV infection and therefore white clover with resistance to AMV will have no selective advantage.</li> <li>• The genetic modification will not extend the range of white clover with resistance to AMV compared to non-GM white clover.</li> <li>• In native plant habitats where AMV is present, the degree to which AMV-resistance white clover may adversely impact native vegetation is uncertain.</li> </ul>	<p><b>Highly unlikely</b></p> <ul style="list-style-type: none"> <li>• Outcrossing to other white clover plants would be rare due to containment measures proposed by the applicant, and the small size and short duration of the trial.</li> <li>• The chance of volunteer GM plants arising from seed dispersal finding suitable conditions to establish as weeds would be no greater than for non-GM white clover.</li> <li>• Aphids and AMV must both be present in a native plant habitat and a white clover population must be limited by AMV before a selective advantage could potentially be conferred.</li> <li>• Although resistance to AMV infection may offer a small competitive advantage, abiotic and biotic factors, such as temperature, soil type, water and nutrient availability, are likely to be more important in limiting the spread and persistence of white clover.</li> </ul>	Negligible	No

### ***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 from the risk identified in the assessment process 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, conditions 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.

### ***Licence conditions to manage this limited and controlled release***

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

- locate the trial site more than 50 metres away from natural waterways
- surround the release site by both a livestock-proof and a rabbit-proof fence to reduce seed dispersal by grazing animals

- surround the GM white clover plot by a pollen trap, consisting of an inner one metre wide band of non-GM white clover, surrounded by a band of lucerne at least 35 metres wide, and an outer one metre wide band of non-GM white clover
- monitor the GM white clover fortnightly during flowering, and remove flowers from the GM white clover plants in the event of less than 25% of the lucerne plants in the pollen trap flowering at the same time as the GM white clover plants
- monitor the lucerne band monthly and destroy any white clover plants prior to flowering
- monitor monthly for, and destroy any, white clover plants that may occur within 500 metres of the release site
- specific containment, transport and storage conditions in accordance with OGTR guidelines
- destroy bees, honey and pollen from beehives used on the trial site
- destroy all GM plant material not required for testing or future trials
- monitor for, and destroy any, volunteer GM white clover that may occur in the release area for at least five years after completion of the trial.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs*<sup>3</sup>, *Policy on transport and supply of GMOs*<sup>4</sup>). Licence conditions based on these guidelines and policies have also been imposed to control possession, use or disposal of the GMOs for the purposes of, or in the course of, the authorised dealings.

### ***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. Dealings conducted under a licence issued by the Regulator may also be subject to regulation by other agencies that also regulate GMOs or GM products including Food Standard Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Australian Quarantine Inspection Service (AQIS)<sup>5</sup>.

As the trial involves early stage research, the applicant does not intend any material from the GM white clover line proposed for release to be used in human food. All genetically modified foods intended for sale in Australia must undergo a safety evaluation by FSANZ.

Accordingly, the applicant has not applied to FSANZ to evaluate the GM white clover line. However, in the event of a commercial release, FSANZ approval may need to be obtained before materials or products derived from the GM white clover line could be sold for human consumption.

The APVMA, which has regulatory responsibility for the use of agricultural chemicals, including herbicides and insecticidal products, in Australia, has previously issued a research permit for the small scale use of the AMV CP in GM white clover plants released under

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<sup>3</sup> Guidelines for the transport of GMOs

<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/transport-guide-1>>

<sup>4</sup> Policy on transport and supply of GMOs

<<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/policies-1>>

<sup>5</sup> 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>>.

DIR 047/2003. DPI Victoria would require a research permit for this proposed release of GM white clover containing the *AMV CP* gene.

### ***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 this GM white clover line, or to justify a reduction in containment conditions. This would include:

- additional data on the potential toxicity of plant materials from the GM white clover line
- weediness of the GM white clover under Australian field conditions, including invasiveness and enhanced reproductive capacities
- the degree to which AMV limits white clover spread and persistence outside of pastoral situations, in particular in native plant habitats
- additional data on gene transfer to non-GM white clover.

### ***Suitability of the applicant***

The Acting Regulator determined, at the commencement of the assessment process for this application, that DPI Victoria is suitable to hold a DIR licence under the requirements of section 58 of the Act. The Acting Regulator is satisfied that DPI Victoria remains suitable as 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 confirmed its ability to comply with the licence conditions.

### ***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 m<sup>2</sup> 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.