



29 July 2008

**EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND
RISK MANAGEMENT PLAN
FOR
APPLICATION NO. DIR 082/2007
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 up to 500 perennial ryegrass and tall fescue lines genetically modified (GM) to improve forage qualities, into the environment in respect of application DIR 082/2007 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 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 up to 2000 plants comprising 500 lines of genetically modified (GM) perennial ryegrass and tall fescue on a limited scale and under controlled conditions. The GM perennial ryegrass and tall fescue lines have been modified to improve forage qualities. The trial would take place at one site in the shire of Southern Grampians, Victoria, on an area of 800 m² per year between 2008 and 2010.

The GM perennial ryegrass and tall fescue lines contain one or more of 12 genes derived from perennial ryegrass and tall fescue. Expression of the introduced genes is expected to improve forage qualities by changing carbohydrate levels and improving digestibility of these pasture grasses.

The GM perennial ryegrass and tall fescue lines also contain an antibiotic resistance selectable marker gene that was used to identify transformed plants during initial development of GM plants in the laboratory.

The purpose of the trial is to conduct proof of concept research to assess the agronomic performance and forage qualities of the GM lines grown under field

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/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>>.

conditions. GM plants will be transferred from the trial site to a PC2 glasshouse prior to flowering for controlled breeding experiments. Seed and tissue samples will be collected and retained for analysis and possible future trials of lines that may be selected for further development, subject to further approval(s). The GM perennial ryegrass and tall fescue plants 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 perennial ryegrass and tall fescue lines and the introduced genetic materials in the environment.

Confidential Commercial Information

Some details, including the names of the introduced genes, the names and origins of the promoters and terminators (regulatory sequences), and details of the cultivars used for transformation 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 takes into account information in the application (including proposed containment measures), relevant previous approvals, current scientific knowledge, advice received from a wide range of experts, agencies and authorities consulted on the RARMP, and a submission from the public.

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

Seven 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.

The characterisation of the seven events in relation to both the magnitude and probability of harm, in the context of the control measures proposed by the applicant, did not give rise to any identified risks that required further assessment.

Therefore, any risks of harm to the health and safety of people, or the environment, from the proposed release of the GM perennial ryegrass and tall fescue lines into the environment are considered to be **negligible**. Hence, the Acting Regulator considers that the dealings involved in this limited and controlled release **do not pose a significant risk** to either people or the environment.

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 seven events characterised in the risk assessment are considered to give rise to an

identified risk that requires further assessment, the level of risk from the proposed dealings 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 in the risk management plan. However, a range of measures have been imposed to restrict the dissemination and persistence of the GMOs and their 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 an area of 800 m² per year at one site between July 2008 and July 2010. The **control** measures to restrict the spread and persistence of the GMOs include 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 to ensure all GMOs are destroyed.

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 500 GM perennial ryegrass and tall fescue lines on an area of 800 m² per year over two years in the Victorian shire of Southern Grampians poses **negligible** risks to the health and safety of people or 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 restrict the dissemination and persistence of the GMOs and their genetic material in the environment and 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.