



29 July 2008

**TECHNICAL 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 (DIR 082/2007) to the Victorian Department of Primary Industries (DPI Victoria) for dealings involving the intentional release of genetically modified (GM) perennial ryegrass and tall fescue lines into the Australian 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 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 up to 2000 plants comprising 500 lines² of perennial ryegrass and tall fescue (*Lolium perenne* L. and *Lolium arundinaceum* (Schreb) Darbysh.) on a limited scale and under controlled conditions. The GM perennial ryegrass and tall fescue lines have been genetically modified to improve forage qualities. The trial is authorised to take place at one site in the shire of Southern Grampians, Victoria, on an area of 800 m² per year over two years between July 2008 and July 2010.

The GM perennial ryegrass and tall fescue lines were produced by transforming plants of experimental cultivars, which are not grown commercially in Australia. The identity of the introduced genes has been declared commercial confidential information (see below).

Up to 250 of the GM perennial ryegrass lines contain one or more of three introduced perennial ryegrass genes encoding proteins involved in fructan biosynthesis in 15 different combinations. The expression of these genes is expected to alter the level of

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>>

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

fructan carbohydrates in the GM plants to increase available energy and enhance animal productivity.

Up to 250 lines of GM perennial ryegrass and GM tall fescue contains one or more of nine introduced genes from perennial ryegrass or tall fescue encoding proteins involved in lignin metabolism in 15 different combinations. The expression of these genes is expected to alter lignin metabolism in the GM plants to increase cell wall digestibility and enhance animal productivity.

In addition, all of the GM perennial ryegrass and tall fescue lines contain an antibiotic resistance marker gene, *hph*, from the bacterium, *Escherichia coli*. The *hph* gene encodes *hygromycin phosphotransferase* and was used to select for modified plants in the laboratory. Hygromycin will not be applied to the plants during the proposed field trial.

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 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. These controls were considered during the evaluation of the application.

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 took into account information contained in the application, 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 on the RARMP with a wide range of prescribed experts, agencies and authorities (summarised in Appendix B of the RARMP). No new risks to people or the environment were identified from the advice received on the consultation RARMP. However, feedback on the consideration of previously raised issues enabled their clarification in the final RARMP.

Advice received from the public on the consultation RARMP (one submission) and how it was considered, is summarised in Appendix C.

A reference document on the parent organism, *The Biology of Lolium multiflorum Lam. (Italian ryegrass), Lolium perenne L. (perennial ryegrass) and Lolium arundinaceum (Schreb.) Darbysh. (tall fescue)*, was produced to inform the risk assessment process for licence applications involving GM perennial ryegrass and tall

fescue plants. The document is available from the OGTR or from the website <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir082-2007>.

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.

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 represent an identified risk and do not advance any further 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. The principle reasons for this include:

- 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 perennial ryegrass and tall fescue plants and their genetic material
- limited capacity of the GM perennial ryegrass and tall fescue lines to spread and persist outside the areas proposed for release
- limited ability and opportunity for the GM perennial ryegrass and tall fescue lines to transfer the introduced genes to other perennial ryegrass and tall fescue plants or other sexually related species
- 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, and end products produced as a result of the activity of, the introduced genes in the environment and lack of known toxicity or evidence of harm from them.

Therefore, any risks of harm to the health and safety of people or the environment from the proposed limited and controlled 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 proposed release **do not pose a significant risk** to either people or the environment³

³ As none of the proposed dealings were considered to pose a significant risk to people or the environment, section 52(2)(d)(ii) of the *Gene Technology Act 2000* mandates a minimum period of 30 days for consultation on the RARMP. However, the Regulator allowed up to 6 weeks for the receipt of submissions from prescribed experts, agencies and authorities and the public.

Risk management

The risk management process builds upon the risk assessment to determine whether measures are required in order to protect people 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 is 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 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.

Licence conditions to manage this limited and controlled release

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

- conduct the release on an area of up to 800 m² per year at one site in the shire of Southern Grampians, Victoria, between July 2008 and July 2010
- establish a 2 m monitoring zone around the trial site that is maintained in a manner that enables the identification of stoloniferous growth
- remove the GM plants from the field before flowering
- surround the 800 m² trial site with a 250 m border of *Triticale sp.*
- enclose the trial site with a 1 m high fence with a lockable gate
- locate the trial site at least 50 m away from natural waterways
- not permit any materials from the release to be used in human food or animal feed
- following harvest, clean the site, monitoring zone and equipment used on the site
- monitor the site for at least 12 months and destroy any perennial ryegrass and tall fescue plants that may grow until no volunteers are detected for a continuous 6 month period
- at the end of the trial, destroy all plant materials not required for further analysis.

The Regulator has issued guidelines and policies for the transport, supply and storage of GMOs (*Guidelines for the transport of GMOs; Policy on transport and supply of GMOs*). Licence conditions based on these guidelines and policies have also been proposed 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)⁴.

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 any of these GM perennial ryegrass and tall fescue lines that may be selected for further development or to justify a reduction in containment conditions. This would include:

- characterisation of the introduced genetic material in the plants, including genotypic stability
- additional data on the potential toxicity of plant materials from the GM perennial ryegrass and tall fescue lines
- additional data on the potential allergenicity of pollen from the GM perennial ryegrass and tall fescue
- characteristics indicative of weediness including measurement of altered sexual and asexual reproductive capacity including seed persistence and plant establishment; altered growth rates, tolerance to drought, cold and other environmental stresses; and disease and pest susceptibility.
- information on characteristics indicative of weediness which may be conferred by the GM traits if gene transfer occurred to sexually compatible species.

Suitability of the applicant

The 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 OGTR legislation 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 consultation 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.

⁴ 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>>.

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 GMO and its genetic material in the environment and 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.