



Australian Government

Department of Health

Office of the Gene Technology Regulator

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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT AND RISK MANAGEMENT PLAN

for

APPLICATION NO. DIR 071/2006

from

VICTORIAN DEPARTMENT OF PRIMARY INDUSTRIES

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) drought tolerant wheat lines into the environment, in respect of application DIR 071/2006 from the Victorian Department of Primary Industries (DPI Victoria).

The DIR 071/2006 licence permits the release of up to 30 GM wheat lines on a limited scale and under controlled conditions.

The *Gene Technology Act 2000* (the Act), 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

DPI Victoria applied for a licence to release up to 30 lines of wheat (*Triticum aestivum* L.) that have been genetically modified to enhance drought tolerance into the environment under limited and controlled conditions. The trial is authorised to take place at two sites in the local government areas of Horsham and Mildura, Victoria, on a maximum total area of 0.315 hectares¹ over one growing season (May 2007 – March 2008).

¹ In its initial application, DPI-Victoria proposed individual sites of 0.15 ha in the local government area of Horsham and 0.075 ha in the local government area of Mildura. The applicant subsequently clarified the

The GM wheat lines contain one of six different introduced genes derived from the plants thale cress (*Arabidopsis thaliana*) and maize (*Zea mays*), a moss (*Physcomitrella patens*) and a yeast (*Saccharomyces cerevisiae*). The introduced genes encode proteins that are intended to enable normal plant growth with reduced amounts of water (drought tolerance) either by regulating gene expression or modulating biochemical and signal transduction pathways in the wheat plants.

The GM wheat lines also contain a herbicide tolerance gene (*bar*, conferring tolerance to herbicides with glufosinate ammonium as the active ingredient) and an antibiotic resistance gene (*bla*, conferring resistance to ampicillin) that were used as markers to select for successful genetic modifications during initial research and development work in the laboratory. The applicant does not intend to apply glufosinate ammonium during the trial and the *bla* gene does not function in plants.

The purpose of the trial is to conduct early stage ('proof of concept') research to evaluate the agronomic performance, including yield, of the GM wheat lines under rain-fed, drought prone conditions. Seed will be collected and retained for analysis and possible future trials of lines that may be selected for further development (subject to additional approvals). No material from the release will be used in human food or animal feed.

DPI Victoria proposed a number of measures to limit the spread and persistence of the GM wheat lines and the introduced genetic materials that were considered during the evaluation of the application.

In accordance with the provisions of section 185 of the Act, DPI Victoria sought and received approval for some details of the application, including the names and classes of the introduced genes, the names and origins of the promoters (regulatory sequences), and data from previous international field releases of other plants expressing the same genes, to be declared Confidential Commercial Information (CCI). The CCI was made available to the various prescribed experts and agencies that are consulted on the preparation of all RARMPs for DIR applications.

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.

Fifteen events were identified and assessed whereby the release of the GM wheat lines might give rise to harm to people or the environment.

These 15 events 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. In addition, consideration was given to the opportunity for gene flow to other organisms, and its effects if this occurred.

experimental design and as a consequence the area of the proposed site at Horsham has increased slightly to 0.24 ha.

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 15 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 the GM wheat plants
- 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 allergenicity from these proteins
- limited capacity of the GM wheat lines to spread and persist outside the release sites
- limited ability and opportunity for the GM wheat lines to transfer the introduced genes to commercial wheat crops or other sexually related species.

Therefore, any risk of harm to the health and safety of people, or the environment, from the limited and controlled release of the GM wheat lines into the environment 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 15 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 0.315 hectares on two sites over one winter wheat growing season (2007/08) 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 destroyed².

Conclusions of the RARMP

The risk assessment concludes that this limited and controlled release of up to 30 GM wheat lines modified to enhance drought tolerance 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

² The licence for DIR 071/2006 is available on the OGTR website, via the link to [DIR 071/2006](#).

the size, duration and locations requested by the applicant, as these were important parameters in establishing the context for assessing the risks.