Australian Government
Department of Health
Office of the Gene Technology Regulator

September 2021

Summary of Licence Application DIR 186

The University of Adelaide has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Project Title	Limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance
Parent organisms	Wheat (*Triticum aestivum* L.) and barley (*Hordeum vulgare* L.)
Genetically modified organisms	
Genetic modifications	• Expression of three genes involved in yield enhancement (expressed both individually and in combination) • Modified expression of five genes involved in yield enhancement and water use efficiency (expressed individually) • Expression of three selectable marker genes (expressed both individually and in combination)
Number of lines	Up to 100 lines[1] in total
Principal purpose	To assess agronomic performance of the GM wheat and barley lines under field conditions
Proposed limits	
Proposed use of GM plants	No use in human food or animal feed is proposed
Proposed locations/s	The trial is proposed to take place at two sites – one site in South Australia (Light Council), and one site in Western Australia (Shire of Merredin)
Proposed release size	Up to a total of 2 ha per year across both sites
Proposed period of release	From April 2022 to January 2027
Previous releases	Wheat and barley lines containing all or some of the three introduced genes for yield enhancement have previously been released under DIR 102, DIR 128 and DIR 152.

[1] The term 'line' is used to denote plants derived from a single plant containing a specific genetic modification resulting from a single transformation event.

Proposed Controls include measures to:

- restrict access to the trial site by people and animals
- limit outcrossing to non-GM plants through the use of buffer, monitoring and isolation zones
- ensure GM seeds and plant material are contained during transport and storage in accordance with the Regulator's guidelines
- ensure that GM plants do not remain after harvest through regular inspection of the trial site and destruction of any GM plants found before flowering.

Consideration as a limited and controlled release (field trial)

This application is considered to be a limited and controlled release application under section 50A of the Act, as the Regulator was satisfied that:

- its principal purpose is to enable the applicant to conduct experiments; and
- the applicant has proposed limits and controls that are of a kind that the Regulator is not required to consult before preparing the consultation version of the RARMP.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **late November 2021**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- documents on genetic modification methods and selectable marker genes
- information on Australia's national scheme for regulation of gene technology
- information on the DIR application process.

Please use the contact details below, if you:

- would like a copy of the application. Please include the identifier DIR 186.
- have any questions about the application or the legislated evaluation process
- wish to register on the mailing list.

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