Australian Government
Department of Health
Office of the Gene Technology Regulator

21 December 2021

Summary of Licence Application DIR 188

Nuseed Pty Ltd 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 canola and Indian mustard genetically modified for altered oil content and herbicide tolerance[1]
Parent organisms	Canola (*Brassica napus* L.) Indian mustard (*Brassica juncea* (L.) Czern. & Coss.)
Genetic modifications	
Introduced genes	Seven genes involved in biosynthesis pathway for long-chain polyunsaturated fatty acids: • *Lackl-Δ12D* from yeast *Lachancea kluyveri* • *Picpa-ω3D* from yeast *Pichia pastoris* • *Micpu-Δ6D* from microalga *Micromonas pusilla* • *Pyrco-Δ6E* from microalga *Pyramimonas cordata* • *Pavsa-Δ5D* from microalga *Pavlova salina* • *Pyrco-Δ5E* from microalga *Pyramimonas cordata* • *Pavsa-Δ4D* from microalga *Pavlova salina* One herbicide tolerance and selectable marker gene: • *pat* gene from soil bacterium *Streptomyces viridochromogenes* for glufosinate tolerance
Genetic modification method	*Agrobacterium*-mediated transformation
Number of lines	Up to 80 lines
Principal purpose	To evaluate the altered oil content trait under field conditions
Previous releases	GM canola lines with similar genetic modifications were approved for field trials under licences DIR 123 and DIR 163 and for commercial release under licence DIR 155. GM Indian mustard lines with similar genetic modifications were approved for field trials under licence DIR 149.
Proposed limits	
Proposed use of GM plants	No use in commercial food or animal feed proposed
Proposed location/s	Trial sites to be selected from 96 possible local government areas in New South Wales, Victoria and Queensland
Proposed release size	Up to 150 ha per year
Proposed period of release	From November 2022 to December 2027

[1] The title of the licence application submitted by Nuseed Pty Ltd is "Limited and controlled release of GM Brassica plants [napus/juncea] genetically modified for altered oil content and herbicide tolerance".

Proposed Controls include measures to:

- restrict access to the trial sites by people and animals
- limit outcrossing to non-GM plants through the use of insect-proof tents or pollen traps and isolation zones
- ensure GM seeds 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 sites 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 a consultation version of the Risk Assessment and Risk Management Plan (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 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 **March 2022**.

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 188.
- have any questions about the application or the legislated evaluation process
- wish to register on the mailing list.

The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601
Telephone: 1800 181 030
Email: ogtr@health.gov.au