

**Office of the Gene Technology Regulator
Food Standards Australia New Zealand**

MDP 54
GPO Box 9848
CANBERRA ACT 2601

Annual Report for DIR 138 for the year 1 July 2020 to 30 June 2021

Dear Sir/Madam,

I refer to the requirements of the above licence, to provide the OGTR with an annual report by the end of September each year for the previous financial year.

This letter provides a consolidated report on activities under licence DIR 138 for annual reporting purposes over the period 1 July 2020 to 30 June 2021.

The following plantings were made of *Brassica napus* containing any of the approved events under DIR 138 in Australia during the stated period:

2 hectares in New South Wales
4 hectares in Victoria
2 hectares in Western Australia
2.1 hectares in South Australia

No adverse impacts, unintended effects, or new information relating to risks to human health and safety or the environment caused by the GMOs or material from the GMOs is available to report as a result of dealings with *B. napus* events under licence DIR 138.

If you require any further information, please do not hesitate to contact me [REDACTED] [@basf.com](mailto:[REDACTED]@basf.com); ph: [REDACTED]) or [REDACTED] [@basf.com](mailto:[REDACTED]@basf.com); ph: [REDACTED]).

Yours sincerely,

[REDACTED]

[REDACTED], Seeds and Traits - Australia New Zealand

Mobile: +[REDACTED], Email: [REDACTED] [@basf.com](mailto:[REDACTED]@basf.com)
Postal Address: BASF Australia Ltd., [REDACTED], Australia

LICENCE NO: DIR127
LICENCE HOLDER: Monsanto Australia Limited
ACCREDITATION NO: ACCR 034/2002

SUBMISSION: 2021 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 1 July 2020 – 30 June 2021
DATE: 31 July 2021

PREPARED BY: [REDACTED]

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SECTION 1. LICENCE HOLDER DETAILS

Name	Monsanto Australia Proprietary Limited
Address	Level 1, 8 Redfern Rd Hawthorn East VIC 3123
Telephone	██████████
Contact email	██
Accreditation Number	ACR 034/2002

SCOPE OF THE REPORT

This report addresses the annual reporting condition of the DIR127 commercial licence covering TruFlex™ Roundup Ready® canola trait issued to Monsanto Australia Proprietary Limited by the Office of the Gene Technology Regulator.

This report details compliance with general and specific conditions of Sections 2 to 3 of the DIR127 licence as issued to Monsanto Australia Proprietary Limited on 21 November 2014.

This report covers the period between the 1 July 2020 and 30 June 2021, including the 2021 canola growing season.

SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS**Authorised Dealings**

No dealings were conducted with GMOs under this licence that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Duration of Licence

DIR127 has not been suspended, cancelled or surrendered.

Holder of Licence

Monsanto Australia Proprietary Limited (Monsanto) remains the holder of the licence.

Project Supervisor

The project supervisor is ██████████

Persons covered by this GMO Licence

Monsanto acknowledges that any person, including the licence holder, may conduct any permitted dealings with the GMOs as covered by the licence.

Dealings with GMOs as authorized by this Licence

All dealings with the GMOs are permitted under this licence.

Location

The licence allows for dealings with GMOs to be conducted in all areas of Australia.

GMOs covered by this licence

The only dealings with GMOs under this licence were those with the GMOs described in DIR127 Licence.

Licence Conditions

Monsanto acknowledges that if the conditions of any prior licence authorising dealings with the GMO are inconsistent with the conditions of this licence, the conditions of this licence will prevail.

Remaining an Accredited organization

At all times, Monsanto remained an accredited organization and complied with the Act and with its instrument of accreditation.

Applicant to notify of circumstances that might affect suitability

During the reporting period, Monsanto Australia Ltd did not receive a relevant conviction occurring after the commencement of this licence; nor was there any revocation or suspension of a licence or permit held by Monsanto Australia Ltd under a law of the Australian Government, a State or foreign country, being a law relating to the health and safety of people or the environment; or any event or circumstance occurring after the commencement of this licence that would affect the capacity of Monsanto to meet the conditions of the DIR127 licence. Monsanto acknowledges that it must provide information related to its ongoing suitability to hold a licence, if requested, within a time period stipulated by the Regulator.

Informing people of their obligations

Monsanto Australia Proprietary Limited informed all persons covered by the DIR127 licence of the obligations imposed on them as a result of the conditions of the licence. This was primarily achieved through implementation of the Monsanto Stewardship policy which includes training and information on regulatory obligations and management of the crop. This requires persons having management responsibility for TruFlex Roundup Ready canola crops to undergo training.

Monsanto recognizes that any persons covered by the DIR127 licence, to whom a particular condition of the licence applies, must be informed of particular conditions and any variations, the cancellation, suspension or surrender of the licence. This is achieved through training and contractual obligations.

Applicant to notify of circumstances that might affect the risk assessment

During the reporting period, Monsanto Australia Ltd did not become aware of any risks to the health and safety of people, or to the environment, associated with the dealings authorised under DIR127; or of any contraventions of the licence by a person covered by the licence; or any unintended effects of the dealings authorised by the licence.

Monsanto acknowledges that should it be required to inform the regulator of additional information under these licence conditions it must do so without delay.

Persons covered by the licence

Monsanto acknowledges that the persons covered by the licence must not deal with the GMOs except as expressly permitted by this licence.

Monsanto acknowledges that if a person authorized by this licence to deal with GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorized by the Regulator, to enter the premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

SECTION 3. GROWING THE GMOS

3.1 GMOs covered by this licence

The only dealings with GMOs under this licence were those described in the DIR127 Licence.

3.2 Permitted dealings

Planting of TruFlex Roundup ready canola was undertaken using Site and Grower Agreements which set out the conditions for planting and growing a TruFlex Roundup Ready crop.

3.3 Commercial Crop Volumes by State in the 2021 growing season.

State	Seed (kg)
NSW	40,800
VIC	32,680
WA	336,360
SA	43,740
Total (kg)	453,580

3.4 Trial/Research Crop Volumes by State in the 2021 growing season.

State	Seed (kg)
NSW	300
VIC	260
WA	1000
SA	300
Total (kg)	1860

From: [REDACTED]
To: [OGTR Monitoring & Compliance](#)
Cc: [REDACTED]
Subject: DIR155 Condition 20 Annual Report 2020/2021
Date: Friday, 6 August 2021 1:56:46 PM
Attachments: [image001.png](#)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hello OGTR,

Condition 20a

Nuseed continues to develop the regulatory package for NS-B50027-4 with studies required for deregulation in other world areas. There has been no new information pertaining to any adverse impacts, unintended effects or risks.

An example of additional information that has been developed is the White paper on Nutriterra, which is the oil from DHA canola for use in human nutrition. The results have been positive and can be found at <https://nutriterraomega3.com/whitepaper/>

To date nothing adverse or unintended has been found to change the risk profile of NS-B50027-4.

Condition 20b

There have been zero hectares of NS-B50027-4 grown for commercial purposes.

Condition 20c

Two sites were planted over the course of 2020/2021 in Victoria for non-commercial (research) purposes. The combined planted area of the Victorian trial sites is 3.55 hectares.

Two sites were planted over the course of 2020/2021 in Queensland for non-commercial (research) purposes. The combined planted area of the Queensland trial sites is 0.29 hectares.

Regards,

[REDACTED] | Compliance Manager

Nuseed | [REDACTED]
[REDACTED]



www.nuseed.com.au

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26th August 2021

Office of Gene Technology Regulator
11th Floor, Scarborough House
Atlantic Street
Woden Town Centre
ACT 2606

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As per licence condition 20, the following statements are made:

- (a) Information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs;

No adverse impacts, unintended effects or new information relating to risks, to human health and safety or the environment have been caused by or found in relation to Optimum GLY® Canola

- (b) Information about the volumes of the GMOs grown for commercial purposes, including seed increase operations, in each State and Territory for each growing season in the period;

Optimum GLY® Canola has not been produced commercially in any state or territory in Australia since the issuing of Licence No.: DIR 139 by the OGTR

- (c) Information about the volumes of the GMOs grown for non-commercial (e.g. research) purposes in each State and Territory for each growing season in the period.

Optimum GLY® Canola has been produced for non-commercial (e.g. research) purposes in the following states and territories in the financial year 2020/2021. The areas grown in each state have been identified:

NSW - 1.02 ha

VIC - 0.11 ha

WA - 0.50 ha

Optimum GLY® Canola has not been produced for non-commercial (e.g. research) purposes in any other Australian states or territories in the financial year 2020/2021.

Best regards,



Regulatory Manager ANZ

Corteva Agriscience™

Office:  Mobile: 

Email: 