

18th August 2020

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

DIR139 ANNUAL REPORT 2020

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 2019/2020. The areas grown in each state have been identified.

NSW – 0.87 ha

VIC – 0.85 ha

WA – 1.00 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 2019/2020.

Regards,


Regulatory Manager ANZ

Corteva Agriscience™

Office:

Mobile:

Email:

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

SUBMISSION: 2016 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 31 July 2015 – 31 July 2016
DATE: 31 July 2016

PREPARED BY:



Information and data submitted herein contains trade secrets, or privileged or confidential information the property of Monsanto Australia Limited and no government agency or representative thereof is authorized to disclose such data and information without written permission from Monsanto Australia Limited.

Contents

SECTION 1. LICENCE HOLDER DETAILS.....	3
SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS	4
Condition 3. Authorised Dealings	4
Condition 4. Duration of Licence	4
Condition 5. Holder of Licence.....	4
Condition 6. Project Supervisor	4
Condition 7. Persons covered by this GMO Licence	4
Condition 8. Dealings with GMOs as authorized by this Licence.....	4
Condition 9. Location	4
Condition 10. GMOs covered by this licence	4
Condition 11. Licence Conditions.....	4
Condition 12. Remaining an Accredited organization	4
Condition 13. Applicant to notify of circumstances that might affect suitability.....	4
Condition 14. Informing people of their obligations	5
Conditions 15 - 17. Applicant to notify of circumstances that might affect the risk assessment	5
Conditions 18 and 19. Persons covered by the licence	5
SECTION 3. GROWING THE GMOS	6
3.1 GMOs covered by this licence.....	6
3.2 Permitted dealings	6
3.3 Commercial Crop Locations	6
3.4 Trial/Research Crop Locations and Volumes by State	6

**SECTION 1. LICENCE HOLDER DETAILS**

Name: Monsanto Australia Limited

Address: 600 St Kilda Rd, Melbourne 3004
PO Box 6051
St Kilda Rd Central
Victoria, 8008

Telephone: (03)9522 7122

Facsimilie: (03)9522 6122

Contact email: [REDACTED]

**Accreditation
Number:** ACCR 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 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 Limited on 21 November 2014.

This report covers the period of time from 31 July 2015 to 31 July 2016.

SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS

Condition 3. 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.

Condition 4. Duration of Licence

DIR127 has not been suspended, cancelled or surrendered.

Condition 5. Holder of Licence

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

Condition 6. Project Supervisor

The project supervisor is [REDACTED].

Condition 7. 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.

Condition 8. Dealings with GMOs as authorized by this Licence

All dealings with the GMOs are permitted under this licence.

Condition 9. Location

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

Condition 10. GMOs covered by this licence

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

Condition 11. 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.

Condition 12. Remaining an Accredited organization

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

Condition 13. 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.

Condition 14. Informing people of their obligations

Monsanto Australia 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.

Conditions 15 - 17. 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.

Conditions 18 and 19. 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 with the GMOs 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 Locations

There were no crops of TruFlex Roundup Ready canola planted for commercial purposes during the reporting period.

3.4 Trial/Research Crop Locations and Volumes by State

State	Trial/Research ha
VIC	4.07
WA	5.20
NSW	0.90
QLD	0.00
Total TruFlex Roundup Ready canola ha planted	10.17

SHORT, Andrew

From: [REDACTED]
Sent: Tuesday, 30 July 2019 9:49 AM
To: OGTR Monitoring_&_Compliance
Subject: DIR155 Annual Report Condition 20 [SEC=No Protective Marking]

Hi OGTR

Nufarm has posted its announcement of the Half Year results for 2018/19 on the ASX on 20Mar2019. Detail can be found at

<https://www.asx.com.au/asx/markets/priceLookup.do?by=asxCodes&asxCodes=NUF>

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 this is that Europe require animal feed dietary exposure modelling, hence we are using the protein expression values already presented to the OGTR to model canola meal in feedlots in Europe. Europe also require a different statistical package for the composition and agronomy data, hence new reports are being generated. The Europe statistical package has not shown anything different or adverse for either composition or agronomy. 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 winter in 2019 in Victoria for non-commercial (research) purposes. The combined planted area of the two trial sites is 3.74 hectares.

Cheers

[REDACTED] Australian Regulatory and Compliance Manager

Nuseed Pty Ltd | [REDACTED]
[REDACTED]

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We create chemistry

BASF Agricultural Solutions Australia Pty Ltd.

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT 2601

Monday, 29 October 2018

Page 1 of 1

Sent to brian.weir@health.gov.au via email

Attention: Application Entry Point

Dear Sir/Madam,

Annual Report for DIR138 for the year 1 July 2017 to 30 June 2018

I refer to the requirements of the above licence (viz. Condition No. 20), to provide the OGTR with an annual report by the end of September each year for the previous financial year. We were contacted by OGTR to indicate that this report had not yet been lodged. I submit to you this report which has been derived from data from our internal record keeping system for events approved under DIR138.

From the period of 1 July 2017 to 30 June 2018, there were no plantings of *Brassica napus* containing any of the approved events under DIR138 in Australia.

As a result, no adverse effects were observed or reported to us as a result of dealings with *B. napus* events under licence DIR138.

Yours sincerely,

Regulatory Affairs Manager - Seeds - Australia & New Zealand

Phone:

Postal Address: BASF Australia Ltd.,

BASF Agricultural Solutions Australia Pty Ltd.
ABN 77 621 403 745

www.basf.com.au

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

SUBMISSION: 2017 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 31 July 2016 – 31 July 2017
DATE: 31 July 2017

PREPARED BY:

[REDACTED]
[REDACTED]

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SECTION 1. LICENCE HOLDER DETAILS	3
SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS	4
Condition 3. Authorised Dealings	4
Condition 4. Duration of Licence	4
Condition 5. Holder of Licence	4
Condition 6. Project Supervisor	4
Condition 7. Persons covered by this GMO Licence	4
Condition 8. Dealings with GMOs as authorized by this Licence	4
Condition 9. Location	4
Condition 10. GMOs covered by this licence	4
Condition 11. Licence Conditions	4
Condition 12. Remaining an Accredited organization	4
Condition 13. Applicant to notify of circumstances that might affect suitability	4
Condition 14. Informing people of their obligations	5
Conditions 15 - 17. Applicant to notify of circumstances that might affect the risk assessment	5
Conditions 18 and 19. Persons covered by the licence	5
SECTION 3. GROWING THE GMOS	6
3.1 GMOs covered by this licence	6
3.2 Permitted dealings	6
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3.4 Trial/Research Crop Locations and Volumes by State	6

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Telephone: (03)9522 7122

Facsimilie: (03)9522 6122

Contact email: [REDACTED]

**Accreditation
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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 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 Limited on 21 November 2014.
This report covers the period of time from 31 July 2016 to 31 July 2017.

SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS

Condition 3. 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.

Condition 4. Duration of Licence

DIR127 has not been suspended, cancelled or surrendered.

Condition 5. Holder of Licence

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

Condition 6. Project Supervisor

The project supervisor is [REDACTED]

Condition 7. 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.

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All dealings with the GMOs are permitted under this licence.

Condition 9. Location

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

Condition 10. GMOs covered by this licence

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

Condition 11. 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.

Condition 12. Remaining an Accredited organization

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

Condition 13. 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.

Condition 14. Informing people of their obligations

Monsanto Australia 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.

Conditions 15 - 17. 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.

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SECTION 3. GROWING THE GMOS

3.1 GMOs covered by this licence

The only dealings with GMOs under this licence were those with the GMOs 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 Locations

There were no crops of TruFlex Roundup Ready canola planted for commercial purposes during the reporting period.

3.4 Trial/Research Crop Locations and Volumes by State

State	Trial/Research ha
VIC	6.50
WA	6.43
NSW	4.56
QLD	0.00
Total TruFlex Roundup Ready canola ha planted	17.49



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

SUBMISSION: 2018 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 31 July 2017 – 31 July 2018
DATE: 31 July 2018

PREPARED BY:



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SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS.....	4
Condition 3. Authorised Dealings.....	4
Condition 4. Duration of Licence.....	4
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Victoria, 8008

Telephone: (03)9522 7122

Facsimilie: (03)9522 6122

Contact email: [REDACTED]

**Accreditation
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DIR127 has not been suspended, cancelled or surrendered.

Condition 5. Holder of Licence

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

Condition 6. Project Supervisor

The project supervisor is [REDACTED]

Condition 7. Persons covered by this GMO Licence

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Condition 9. Location

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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.

Condition 12. Remaining an Accredited organization

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

Condition 13. 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.

Condition 14. Informing people of their obligations

Monsanto Australia 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.

Conditions 15 - 17. 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.

Conditions 18 and 19. 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 with the GMOs 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 Locations

There were no crops of TruFlex Roundup Ready canola planted for commercial purposes during the reporting period.

3.4 Trial/Research Crop Locations and Volumes by State

State	Trial/Research ha
VIC	13.30
WA	26.7
NSW	10.7
QLD	0.0
Total TruFlex Roundup Ready canola ha planted	50.7



We create chemistry

BASF Australia Ltd
[Redacted]

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT 2601

Monday, 30 September 2019
[Redacted]

Page 1 of 1

Sent to brian.weir@health.gov.au via email

Attention: Application Entry Point

Dear Sir/Madam,

Annual Report for DIR138 for the year 1 July 2018 to 30 June 2019

I refer to the requirements of the above licence (viz. Condition No. 20), to provide the OGTR with an annual report by the end of September each year for the previous financial year.

Please note that from the period of 1 July 2018 to 30 June 2019, this licence was held by three (3) separated licence holders:

1. Bayer CropScience Pty. Ltd. from 1 July to 2 October 2018
2. BASF Agricultural Solutions Australia Pty Ltd from 2 October 2018 to 18 April 2019
3. BASF Australia Ltd from 18 April 2019 to the end of the reporting period

This letter provides a consolidated report on activities under licence DIR138 for annual reporting purposes over the period 1 July 2018 to 30 June 2019.

The following plantings were made of *Brassica napus* containing any of the approved events under DIR138 in Australia during the stated period:

Two (2) hectares in Victoria

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 DIR138.

BASF Australia Ltd.
ABN 62 008 437 967
[Redacted]

www.basf.com.au

SHORT, Andrew

From: WENZEL, Peter
Sent: Monday, 23 October 2017 10:01 AM
To: BERRY, Andrew
Subject: TRIM: FW: Annual reporting under OGTR Licences held by Bayer [SEC=UNCLASSIFIED]

Importance: High

From: [REDACTED]
Sent: Monday, 24 July 2017 8:34 AM
To: WENZEL, Peter
Subject: Annual reporting under OGTR Licences held by Bayer [SEC=No Protective Marking]
Importance: High

Hi Peter,

I received your phone message this morning (I was out of the office last week).

I can supply information readily on DIR113, DIR133, DIR138 and DIR143 at this time. I am currently seeking information on DIR021/2002 and DIR108 which I will forward presently.

For DIR113 nothing has been planted under this Licence since planting season 2014/2015 for which all planting data were provided to OGTR. All sites have been signed off by OGTR as they were subsumed by DIR143.

For DIR133 nothing has been planted under this Licence since planting season 2015/2016 for which all planting data were provided to OGTR. All sites have been signed off by OGTR as they were subsumed by DIR143.

No plantings have been made under DIR138.

And no plantings have been made under DIR143 either at the present time.

As a consequence of inactivity under these Licences, no opportunities have arisen to observe adverse impacts or unintended effects from the GMOs approved under these Licences during this reporting period.

Best regards,

[REDACTED]
Regulatory Affairs Manager, Seeds, Australia and New Zealand
Reg. Affairs / Compliance

Bayer: Science For A Better Life

Crop Science Division
Bayer CropScience Pty Limited
BCS AU-BIO-BGA-BCRA, Reg. Affairs / Compliance



Web: <http://www.bayer.com>

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SHORT, Andrew

From: [REDACTED]
Sent: Thursday, 27 September 2018 8:27 AM
To: OGTR Monitoring_& Compliance
Subject: DIR155 Condition 20 Annual Report [SEC=No Protective Marking]

Hi OGTR

Nufarm has posted its announcement of the Full Year results for 2017/18 on the ASX. Detail can be found at <https://www.asx.com.au/asx/markets/priceLookup.do?by=asxCodes&asxCodes=NUF>

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 this is that China requires the protein expression study to be conducted on three different generations. Nuseed submitted a study to OGTR on one generation and the expression of the proteins was only found (by design) in the immature seed and mature seed fractions of the crop. We have completed another generation (including segregants – EU requirement) which showed the same result, and a third generation is being analysed now. Other studies, including but not limited to toxicology, animal feeding, composition and agronomy, are being conducted. 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

Six sites were planted over winter in 2018 in Victoria for non-commercial (research) purposes. The combined planted area of the six trial sites is 5.073 hectares.

An additional site 1733_PAT (Site 33 DIR123) was transitioned from DIR123 to DIR155. At the time DIR155 was issued, Nuseed had a research nursery site growing in the field with NS-B50027-4. A request was made to the OGTR to sign-off on DIR123 Site 33, given only NS-B50027-4 had been planted at this site and the issuing of DIR155 which covered NS-B50027-4. Sign-off for DIR123 Site 33 was granted by the OGTR on 05Mar2018. The planted area of this additional site under DIR155 was 0.235 hectares.

Cheers

[REDACTED] Australian Regulatory and Compliance Manager

Nuseed Pty Ltd | [REDACTED]
[REDACTED]

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

SUBMISSION: 2015 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 31 July 2014 – 31 July 2015
DATE: 31 July 2015

PREPARED BY:



Information and data submitted herein contains trade secrets, or privileged or confidential information the property of Monsanto Australia Limited and no government agency or representative thereof is authorized to disclose such data and information without written permission from Monsanto Australia Limited.

Contents

SECTION 1. LICENCE HOLDER DETAILS.....	3
SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS	4
Condition 3. Authorised Dealings	4
Condition 4. Duration of Licence	4
Condition 5. Holder of Licence.....	4
Condition 6. Project Supervisor	4
Condition 7. Persons covered by this GMO Licence	4
Condition 8. Dealings with GMOs as authorized by this Licence.....	4
Condition 9. Location	4
Condition 10. GMOs covered by this licence	4
Condition 11. Licence Conditions.....	4
Condition 12. Remaining an Accredited organization	4
Condition 13. Applicant to notify of circumstances that might affect suitability.....	4
Condition 14. Informing people of their obligations	5
Conditions 15 - 17. Applicant to notify of circumstances that might affect the risk assessment	5
Conditions 18 and 19. Persons covered by the licence	5
SECTION 3. GROWING THE GMOS	6
3.1 GMOs covered by this licence.....	6
3.2 Permitted dealings	6
3.3 Commercial Crop Locations	6
3.4 Trial/Research Crop Locations and Volumes by State	6

**SECTION 1. LICENCE HOLDER DETAILS**

Name: Monsanto Australia Limited

Address: 600 St Kilda Rd, Melbourne 3004
PO Box 6051
St Kilda Rd Central
Victoria, 8008

Telephone: (03)9522 7122

Facsimilie: (03)9522 6122

Contact email: [REDACTED]

**Accreditation
Number:** ACCR 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 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 Limited on 21 November 2014.

This report covers the period of time from 31 July 2014 to 31 July 2015.

SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS

Condition 3. 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.

Condition 4. Duration of Licence

DIR127 has not been suspended, cancelled or surrendered.

Condition 5. Holder of Licence

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

Condition 6. Project Supervisor

The project supervisor is [REDACTED]

Condition 7. 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.

Condition 8. Dealings with GMOs as authorized by this Licence

All dealings with the GMOs are permitted under this licence.

Condition 9. Location

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

Condition 10. GMOs covered by this licence

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

Condition 11. 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.

Condition 12. Remaining an Accredited organization

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

Condition 13. 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.

Condition 14. Informing people of their obligations

DIR127 was issued in November 2014. Monsanto Australia 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 the Monsanto accreditation program and contractual obligations, which includes information on regulatory obligations as well as management of the crop. Accreditation requires all 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.

Conditions 15 - 17. 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.

Conditions 18 and 19. 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 with the GMOs 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.

In order to be eligible to sign such an agreement, a grower is required to also complete an accreditation.

3.3 Commercial Crop Locations

There were no crops of TruFlex Roundup Ready canola planted for commercial purposes during the reporting period.

3.4 Trial/Research Crop Locations and Volumes by State

State	Trial/Research ha
VIC	0.10
WA	10.06
NSW	2.00
QLD	3.56
Total TruFlex Roundup Ready ha planted	15.72

DIR127 OGTR ANNUAL REPORT 2019 SEASON

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

SUBMISSION: 2019 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines
REPORTING PERIOD: 31 July 2018 – 31 July 2019
DATE: 31 July 2019

PREPARED BY:

[REDACTED]
[REDACTED]

Information and data submitted herein contains trade secrets, or privileged or confidential information the property of Monsanto Australia Proprietary Limited and no government agency or representative thereof is authorized to disclose such data and information without written permission from Monsanto Australia Proprietary Limited.

Contents

SECTION 1. LICENCE HOLDER DETAILS.....	2
SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS.....	2
SECTION 3. GROWING THE GMOS	4

SECTION 1. LICENCE HOLDER DETAILS

Name	Monsanto Australia Proprietary Limited
Address	Level 1, 8 Redfern Rd Hawthorn East VIC 3123
Telephone	(03)9248 6888
Facsimile	(03)9248 6800
Contact email	[REDACTED]
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 of time from 31 July 2018 to 31 July 2019.

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 [REDACTED]

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 Locations

State	Commercial ha
VIC	1,873
WA	18,136
NSW	800
QLD	0
Total TruFlex Roundup Ready canola ha planted	20,809

3.4 Trial/Research Crop Locations and Volumes by State

State	Trial/Research ha
VIC	135
WA	686
NSW	391
QLD	6
Total TruFlex Roundup Ready canola ha planted	1,218



PIONEER HI-BRED AUSTRALIA PTY LTD

ABN 52 009 947 684

PMB 9200 - 204 TOOWOOMBA - KARARA ROAD
WESTBROOK 4350. QUEENSLAND AUSTRALIA
PHONE (07) 4699 0100.

16th July 2018

Office of the Gene Technology Regulator
(MDP54)
GPO Box 9848
Canberra ACT 2601

DIR139 ANNUAL REPORT 2016

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 2016. The areas produced in each state have been identified.

NSW – 1.3ha

VIC – 0.4ha

Optimum GLY® Canola has not been produced for non-commercial (e.g. research) purposes in any other Australian states or territories in 2016.

Regards,

[Redacted Signature]

[Redacted Name]

Regulatory and Stewardship Manager

Corteva Agriscience™

Agriculture Division of DowDuPont

Office: [Redacted] Mobile: [Redacted]

Email: [Redacted]

13th September 2019Office of Gene Technology Regulator
11th Floor, Scarborough House
Atlantic Street
Woden Town Centre
ACT 2606**DIR139 ANNUAL REPORT 2019**

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 2018. The areas produced in each state have been identified.

NSW – 1.90ha

VIC – 1.51ha

WA – 1.74ha

Optimum GLY® Canola has not been produced for non-commercial (e.g. research) purposes in any other Australian states or territories in 2019.

Regards,


Regulatory and Stewardship Manager ANZ
Corteva Agriscience™Office:  Mobile: 
Email: 

SHORT, Andrew

From: [REDACTED]
Sent: Tuesday, 1 September 2020 4:52 PM
To: OGTR Monitoring_& Compliance
Subject: DIR155 Annual Report Condition 20 [SEC=No Protective Marking]

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.

Hi OGTR,

Nufarm has posted its announcement of the Half Year results for 2019/20 on the ASX on 25Mar2020, with the full year reporting due at the end of September. Detail of the half year results can be found at

<https://www.asx.com.au/asxpdf/20200325/pdf/44gcfstttd2sl0.pdf>

Note that Nufarm are changing their financial year from 01Aug-31Jul, to 01Oct-30Sep of each year in 2020. The announcement can be found at <https://www.asx.com.au/asxpdf/20200723/pdf/44kscpz98b4vni.pdf>

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 Aquaterra, which is the oil from DHA canola for use in aquaculture diets. The results have been positive and can be found at

<https://aquaterraomega3.com/whitepaper/>

Further a broad summary of DHA canola has now been published, and can be found at

<https://www.frontiersin.org/articles/10.3389/fpls.2020.00727/full>

Additionally, food, feed and environmental release approvals have been granted in Canada for DHA canola. An announcement can be found at <https://www.asx.com.au/asxpdf/20200730/pdf/44l02hkssv5ky9.pdf>

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

Three sites were planted over the course of 2019/2020 in Victoria for non-commercial (research) purposes. The combined planted area of the trial sites is 3.56 hectares.

Cheers

[REDACTED] Australian Regulatory & Compliance Manager

Nuseed | [REDACTED]



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www.nuseed.com

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WESTBROOK 4350. QUEENSLAND AUSTRALIA
PHONE (07) 4699 0100.

16th July 2018

Office of the Gene Technology Regulator
(MDP54)
GPO Box 9848
Canberra ACT 2601

DIR139 ANNUAL REPORT 2018

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 2018. The areas produced in each state have been identified.

NSW – 4.10ha

VIC – 2.66ha

WA – 1.32ha

Optimum GLY® Canola has not been produced for non-commercial (e.g. research) purposes in any other Australian states or territories in 2018.

Regards,

Regulatory and Stewardship Manager

Corteva Agriscience™

Agriculture Division of DowDuPont

Office: Mobile:

Email:



We create chemistry

BASF Australia Ltd

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT 2601

Monday, 8 October 2020

Page 1 of 1

Sent to OGTR.M&C@health.gov.au via email

Attention: Application Entry Point

Dear Sir/Madam,

Annual Report for DIR138 for the year 1 July 2019 to 30 June 2020

I refer to the requirements of the above licence (viz. Condition No. 20), 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 DIR138 for annual reporting purposes over the period 1 July 2019 to 30 June 2020.

The following plantings were made of *Brassica napus* containing any of the approved events under DIR138 in Australia during the stated period:

One (1) hectare in New South Wales
One (1) hectare in Victoria
One (1) hectare in Western Australia
Ten (10) 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 DIR138.

Yours sincerely,



Regulatory Affairs Manager - Seeds - Australia & New Zealand

Phone:

Postal Address: BASF Australia Ltd.,

BASF Australia Ltd.
ABN 62 008 437 867


www.basf.com.au



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WESTBROOK 4350. QUEENSLAND AUSTRALIA
PHONE (07) 4699 0100.

16th July 2018

Office of the Gene Technology Regulator
(MDP54)
GPO Box 9848
Canberra ACT 2601

DIR139 ANNUAL REPORT 2017

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 2017. The areas produced in each state have been identified.

NSW – 6.0ha

VIC – 1.8ha

Optimum GLY® Canola has not been produced for non-commercial (e.g. research) purposes in any other Australian states or territories in 2017.

Regards,

[Redacted Signature]

[Redacted Name]

Regulatory and Stewardship Manager

Corteva Agriscience™

Agriculture Division of DowDuPont

Office: [Redacted] Mobile: [Redacted]

Email: [Redacted]

DIR127 OGTR ANNUAL REPORT 2020 SEASON

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

SUBMISSION: 2020 Annual Report for Commercial release of GM herbicide tolerant (MON 88302) canola lines

REPORTING PERIOD: 1 July 2019 – 30 June 2020

DATE: 31 July 2020

PREPARED BY:

[REDACTED]
[REDACTED]

Information and data submitted herein contains trade secrets, or privileged or confidential information the property of Monsanto Australia Proprietary Limited and no government agency or representative thereof is authorized to disclose such data and information without written permission from Monsanto Australia Proprietary Limited.

Contents

SECTION 1. LICENCE HOLDER DETAILS	2
SECTION 2. LICENCE CONDITIONS AND OBLIGATIONS	2
SECTION 3. GROWING THE GMOS	4

SECTION 1. LICENCE HOLDER DETAILS

Name	Monsanto Australia Proprietary Limited
Address	Level 1, 8 Redfern Rd Hawthorn East VIC 3123
Telephone	(03)9248 6888
Contact email	[REDACTED]
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 2019 and 30 June 2020, including the 2020 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 [REDACTED]

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 2020 growing season.

State	Seed (kg)
VIC	18,160
NSW	13,020
WA	173,700
Total (kg)	204,880

3.4 Trial/Research Crop Volumes by State in the 2020 growing season.

State	Seed (kg)
VIC	620
NSW	980
WA	2,150
QLD	400
Total (kg)	4,150