



Australian Government

Department of Health

Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of GMOs into the environment

Licence No.: DIR 021/2002

Licence holder: BASF Australia Ltd

Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system for use in the Australian cropping system

Issued: 25 July 2003
Varied: 28 September 2010
Varied: 6 December 2016
Transferred: 2 October 2018
Transferred: 18 April 2019
Varied: 4 August 2021

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling the development and use of genetically modified organisms (GMOs).

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State Law.

The Gene Technology Regulator is required to consult with, and take into account advice from a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GMOs into the Australian environment.

Other agencies that also regulate GMOs or GM (genetically modified) products include Food Standards Australia New Zealand, Australian Pesticide and Veterinary Medicine Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme and Department of Agriculture, Water and the Environment. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the GMOs listed in Attachment A of this licence.

Dealings permitted by this licence may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

Further Information on Licence DIR 021

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator (OGTR) website or by telephoning the Office on 1800 181 030.

Note in relation to Herbicide Resistance Management

Note: The GMOs referred to in this licence are modified to confer tolerance to the herbicide glufosinate ammonium. The AVPMA has responsibility for setting registration conditions for the use of herbicides in Australia which may include the implementation of herbicide resistance management programs.

Section 1 Interpretations and Definitions

In this licence:

- (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meanings as they do in the Act and the Gene Technology Regulations 2001;
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning.
- (g) specific conditions prevail over general conditions to the extent of any inconsistency.

In this licence:

‘Act’ means the *Gene Technology Act 2000* (Cth) and equivalent provisions in corresponding State law.

‘Annual Report’ means a written report provided to the Regulator by the end of September each year covering the previous financial year containing all the information required by this licence.

‘Canola’ means plants of the species *Brassica napus* L.

‘Deal with’ in relation to a GMO means one or more of the following:

- (a) conduct experiments with the GMOs;
- (b) make, develop, produce or manufacture the GMOs;
- (c) breed the GMOs;
- (d) propagate the GMOs;
- (e) use the GMOs in the course of manufacture of a thing that is not the GMOs;
- (f) grow, raise or culture the GMOs;
- (g) import the GMOs;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g).

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms listed in Attachment A and authorised for release by this licence.

‘OGTR’ means the Office of the Gene Technology Regulator.

‘Location’ means an area of land where the GMOs are planted and grown for the purposes of a licence.

‘Regulator’ means the Gene Technology Regulator.

Section 2 Licence Conditions

Duration of licence

1. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMOs are authorised during any period of suspension.

Holder of licence

2. The holder of this licence ('the licence holder') is BASF Australia Ltd.

Contact Details

4. The licence holder must immediately notify the Regulator in writing if any of its contact details change.

Note: please address correspondence to OGTR.M&C@health.gov.au.

GMOs covered by this licence

5. The GMOs covered by this licence ('the GMOs') are identified and described at Attachment A.

Location

6. This licence permits dealings with the GMOs to be conducted in all areas of Australia.

Persons covered by this GMO licence

7. Subject to condition 8, any person, including the licence holder, may conduct any Dealing with the GMOs.
8. Where the GMOs authorised by this licence are planted or in any other way Dealt with as part of a subsequent licence, or subsequent licence variation, authorising a dealing under the Act, then, for purposes of the subsequent licence, or subsequent licence variation:
 - (a) only the persons covered by the subsequent licence or licence variation are permitted to grow or otherwise deal with the GMOs, and
 - (b) the conditions of the subsequent licence or the licence containing the licence variation, and not the conditions of this licence, will apply to the dealing with the GMOs.

Example: If a subsequent licence contemplates the planting of these GMOs in a Location containing another GMO authorised by that later licence, the conditions of the subsequent licence and not the conditions of this licence will apply to the GMOs for purposes of the dealings conducted under that licence.

Informing people of their obligations

9. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:
 - (a) the particular condition (including any variations of it);
 - (b) the cancellation or suspension of the licence;
 - (c) the surrender of the licence.

Licence holder to notify of circumstances that might affect suitability

10. The licence holder must immediately, by notice in writing, inform the Regulator of:
 - (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
 - (b) any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
 - (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

Licence holder must provide information on matters related to suitability

11. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

People dealing with GMOs must allow auditing and monitoring of the dealing

12. If a person authorised 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 authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Remaining an accredited organisation

13. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and comply with its instrument of accreditation.

Additional information to be given to the Regulator

14. The licence holder must inform the Regulator if the licence holder:
 - (a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
 - (b) becomes aware of any contraventions of the licence by a person covered by the licence; or
 - (c) becomes aware of any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition that:

- (a) *the licence holder will be taken to have become aware of additional information if he or she was reckless as to whether such information existed; and*
- (b) *the licence holder will be taken to have become aware of contraventions, or unintended effects, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

Note: Contraventions of the licence may occur through the action or inaction of a person.

15. The licence holder must provide the information required by paragraphs (a), (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible, and must also include the information in the Annual Report.

Note: An example of informing without delay is contact made within a day of becoming aware of new information via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours.

16. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:
 - (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 15(a); and
 - (b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 15(b); and
 - (c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 15(c); and
 - (d) research, including by way of survey, to verify findings of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment; and
 - (e) scientific literature and reports in respect of the GMO(s) authorised by this licence, for a nominated period; and
 - (f) details of any refusals of applications for licences or permits (however described) to deal with the GMO(s) made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

17. If the Regulator invites the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant the progress of the release of the GMO, the licence holder may make such a submission to the Regulator within 30 days of receipt of the invitation.

Annual Report

18. The licence holder must provide an Annual Report to the Regulator.
19. An annual report must include the following:
 - (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;
 - (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;

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

Note: nil plantings should also be reported under conditions 19(b) and 19(c).

Testing Methodology

- 20. At least 14 days prior to conducting any dealings with the GMO, the licence holder must provide a written methodology to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMOs and the presence of the genetic modifications described in this licence (at Attachment A) in a recipient organism. The detection method(s) must be capable of identifying, to the satisfaction of the Regulator, each genetic modification event described in this licence.

Note: please address correspondence to OGTR.M&C@health.gov.au.

Attachment A

Licence number: DIR021/2002

***Full Title:** Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system for use in the Australian cropping system

Organisation Details

Postal address: BASF Australia Ltd
Level 12, 28 Freshwater Place
Southbank, VIC 3006

Phone No: (03) 8855 6600

Fax No: (03) 8855 6511

Accreditation No: **Accr-239**

Purpose of the Dealing with the GMOs:

The aim of the proposed release is to allow commercial production of the GMOs in all areas of Australia, and for products of the GMOs to enter general commerce.

GMOs Description

Parent Organism(s) Common Name: Canola

Parent Organism(s) Scientific Name: *Brassica napus* L.

Modified Trait(s):

Category: Herbicide tolerance
Hybrid Breeding System

Description:

Canola has been genetically modified to:

- express a gene conferring tolerance to the herbicide glufosinate ammonium;
- introduce a novel hybrid breeding system for canola, based on genetically modified male sterile (MS) and fertility restorer (RF) lines;
- express an antibiotic resistance gene.

SPECIFIC INFORMATION ABOUT THE GMOs COVERED BY THIS LICENCE

The GMOs covered by this licence are:

- (a) hybrids of canola containing transformation event MS8 and canola containing transformation event RF3
- (b) the GMOs described in the table below

Table of GMOs covered by this licence

Column	GMO	Traits	Gene for glufosinate ammonium tolerance	Gene for hybrid breeding system	Gene for antibiotic resistance
1	Canola containing transformation event T45	glufosinate ammonium tolerant	<i>pat</i>		
2	Canola containing transformation event Topas 19/2	glufosinate ammonium tolerant, antibiotic resistant	<i>pat</i>		<i>nptII</i>
3	Canola containing transformation event RF1	glufosinate ammonium tolerant, antibiotic resistant, fertility restorer	<i>bar</i>	<i>barstar</i>	<i>nptII</i>
4	Canola containing transformation event RF2	glufosinate ammonium tolerant, antibiotic resistant, fertility restorer	<i>bar</i>	<i>barstar</i>	<i>nptII</i>
5	Canola containing transformation event RF3	glufosinate ammonium tolerant, fertility restorer	<i>bar</i>	<i>barstar</i>	
6	Canola containing transformation event MS1	glufosinate ammonium tolerant, male sterile, antibiotic resistant	<i>bar</i>	<i>barnase</i>	<i>nptII</i>
7	Canola containing transformation event MS8	glufosinate ammonium tolerant, male sterile	<i>bar</i>	<i>barnase</i>	

Note: the transformation events are described in the Risk Assessment and Risk Management Plan prepared in connection with this licence.