



Australian Government

Department of Health

Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 108

Licence holder: BASF Australia Ltd

Title: Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system

Issued: 2 December 2011

Varied: 6 December 2016

Transferred: 2 October 2018

Transferred: 18 April 2019

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 website](#), or by telephoning the Office on 1800 181 030.

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 products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemicals Notification and Assessment Scheme, National Health and Medical Research Council and Department of Agriculture and Water Resources. 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 genetically modified organism(s) 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.

Section 1 Interpretations and Definitions

1. In this licence:

- (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
- (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 has a corresponding meaning;
- (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

2. In this licence:

‘Act’ means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

‘Annual Report’ means a written report provided to the Regulator within 90 days of each anniversary of the date of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

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

‘GM’ means genetically modified.

‘GMOs’ means the genetically modified organisms that are the subject of the dealings authorised by this licence.

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

‘Personal Information’ means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information is true or not; and
- (b) whether the information is recorded in a material form or not.

Section 2 Licence conditions

Duration of licence

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

Holder of licence

4. The holder of this licence (‘the licence holder’) is BASF Australia Ltd.

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

Project Supervisor

7. The licence holder must immediately notify the Regulator in writing if any of the contact details of the project supervisor change.

Persons covered by this GMO licence

8. Any person, including the licence holder, may conduct any permitted dealing(s) with the GMO.

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.

10. The licence holder must notify the project supervisor and all persons to whom a particular licence condition applies that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Additional information to be given to the Regulator

11. 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; and
- (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; and
- (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.

12. 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.

13. The licence holder must inform the Regulator, as soon as practically and reasonably possible, 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.*

14. 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 13 (a)
- (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 13 (b)
- (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 13 (c)
- (d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment
- (e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period
- (f) details of any refusals of applications for licences or permits (however described) to deal with the GMO 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.

Note: The Regulator may invite 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 GMO.

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

15. If a person is 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.

GMO covered by this licence

16. The GMOs covered by this licence are described in Attachment A of the licence.

Permitted dealings

17. All dealings with the GMOs are permitted.

18. To the extent that 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.

Location

19. This licence permits dealings with the GMO to be conducted in all areas of Australia.

Section 3 Reporting and Documentation Requirements

Annual Report

20. The licence holder must provide an Annual Report to the Regulator. 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.

Testing methodology

21. The licence holder must provide a written instrument 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 in a recipient organism. The detection method must be capable of reliably distinguishing between the categories of GMOs described in this licence. The instrument must be provided within 30 days of the issuing of this licence.

DIR No: 108

Full Title: Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system

Organisation Details

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

Phone No: (03) 8855 6600

IBC Details

IBC Name: BASF Australia IBC

GMOs covered by this licence:

Brassica napus L. genetically modified by introduction of only the genes and genetic elements listed below.

Parent Organisms:

Common Names: Canola
Scientific Names: *Brassica napus* L.

Modified traits:

Categories: Herbicide tolerance
Hybrid breeding

Description: The GM canola is the product of conventional breeding between GM canola lines approved for commercial release under licences DIR 021/2002 (including lines MS1, MS8, RF1, RF2, RF3, T45, and Topas 19/2, and hybrids of these) and DIR 020/2002 (canola line GT73).

Genetic elements responsible for conferring the modified traits:

Gene (source)	Protein produced	Protein function	Promoter (source)	Terminator (source)	Additional elements (source)
<i>cp4 epsps</i> (<i>Agrobacterium</i> sp. strain CP4)	CP4 EPSPS	tolerance to the herbicide glyphosate	P-CMoVb (figwort mosaic virus)	E9 3' (<i>Pisum sativum</i>)	AEPSPS/CTP2 (<i>Arabidopsis thaliana</i>)
<i>goxv247</i> (<i>Ochrobactrum anthropi</i> strain LBAA)	glyphosate oxidoreductase	tolerance to the herbicide glyphosate	PCMoVb (figwort mosaic virus)	E9 3' (<i>Pisum sativum</i>)	SSU1A/CTP1 (<i>Arabidopsis thaliana</i>)
<i>bar</i> (<i>Streptomyces hygroscopicus</i>)	phosphinothricin acetyl transferase	tolerance to the herbicide glufosinate ammonium	PSsuAra (<i>Arabidopsis thaliana</i>)	3' g7 (<i>Agrobacterium tumefaciens</i>)	-
<i>pat</i> (<i>Streptomyces viridichromogenes</i>)	phosphinothricin acetyl transferase	tolerance to the herbicide glufosinate ammonium	P-35S (Cauliflower mosaic virus)	T-35S (Cauliflower mosaic virus)	-

Gene (source)	Protein produced	Protein function	Promoter (source)	Terminator (source)	Additional elements (source)
<i>barnase</i> (<i>Bacillus amyloliquefaciens</i>)	Barnase (RNase)	Male sterility	PTA29 (<i>Nicotiana Tabacum</i>)	3'-nos (<i>Agrobacterium tumefaciens</i>)	-
<i>barstar</i> (<i>Bacillus amyloliquefaciens</i>)	Barstar (RNase inhibitor)	Restoration of fertility	PTA29 (<i>Nicotiana tabacum</i>)	3'-nos (<i>Agrobacterium tumefaciens</i>)	-
<i>nptII</i> (<i>Escherichia coli</i>)	neomycin phosphotransferase	resistance to antibiotics such as kanamycin and neomycin (selectable marker)	P-nos (<i>Agrobacterium tumefaciens</i>)	3'-ocs (<i>Agrobacterium tumefaciens</i>)	-

Purpose of the dealings with the GMOs:

The licence allows commercial production of the GM canola in all areas of Australia, and for products of the GMOs to enter general commerce.