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 178

Licence holder: BASF Australia Ltd

Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11 × RF3 and MS11 × RF3 × MON 88302)

Issued: 16 September 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.

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 genetically modified organisms into the Australian environment.

Other agencies that also regulate genetically modified organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the 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 genetically modified organism(s) listed in Attachment A of this licence.

Further information on licence DIR 178

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.

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 Gene Technology Regulations 2001;

   (b) words denoting a gender include any other gender;

   (c) words in the singular include the plural and words in the plural include the singular;

   (d) words denoting 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 general 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.

'**GM**' means genetically modified.

'**GMO**' means the genetically modified organism that is the subject of the dealings authorised by this licence.

'**OGTR**' means the Office of the Gene Technology Regulator.

'**Regulator**' means the Gene Technology Regulator.

Section 2 Licence conditions and obligations

3. This licence does not authorise dealings with the GMO that are otherwise prohibited as a result of the operation of State legislation recognising an area as designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes.

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

5. The licence holder is BASF Australia Ltd.

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

7. All dealings with the GMO are permitted.

8. Dealings with the GMO may be conducted in all areas of Australia.

9. This licence authorises dealings with the GMO described in **Attachment A**.

2.1 General obligations of the licence holder

10. The licence holder must notify the Regulator as soon as practicable if any of its contact details change.

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

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following two conditions address ongoing suitability of the licence holder.

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

12. The licence holder must:

(a) inform the Regulator as soon as practicable after any of these events occur:

i. any relevant conviction of the licence holder; or

ii. 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; or

iii. any event or circumstances that would affect the capacity of the licence holder to meet the conditions of the licence; and

(b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested by the Regulator, within the timeframe stipulated by the Regulator.

13. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

(a) the particular condition (including any variations of it); and

(b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

2.2 Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.

14. The licence holder must inform the Regulator if the licence holder becomes aware of:

(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; or

(b) any contraventions of the licence by a person covered by the licence; or

(c) 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 of a kind mentioned in condition 14 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, of a kind mentioned in condition 14, 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. If the licence holder is required to inform the Regulator under condition 14, the Regulator must be informed without delay.

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 14(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 14(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 14(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 to the progress of the dealings with the GMO.

2.3 Obligations of persons covered by the licence

17. If a person is authorised by this licence to deal with the GMO 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.

Section 3 Reporting and documentation

3.1 Annual Report

18. The licence holder must provide an annual report to the Regulator by the end of September each year covering the previous financial year. An annual report must include:

(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 GMO or material from the GMO;

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

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

Note: nil plantings should also be reported under conditions 18(b) and 18(c).

3.2 Testing methodology

19. At least 14 days prior to conducting any dealings with the GMO, the licence holder must provide to the Regulator a written methodology to reliably detect the GMO, or the presence of the genetic modifications described in this licence 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

DIR No: 178

Full Title: Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11 × RF3 and MS11 × RF3 × MON 88302)

Organisation Details

Postal address: BASF Australia Ltd
GPO Box 4705
Melbourne VIC 3001

Phone No: 03 8855 6600

GMO Description

GMOs covered by this licence

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

Parent Organism

Common Name: Canola

Scientific Name: *Brassica napus* L.

Modified traits

Category: Herbicide tolerance
Hybrid breeding system

Description: The GMOs are the result of conventional breeding between GM canola lines MS11, RF3 and MON 88302, which are individually authorised for commercial release under licences DIR 175, DIR 021/2002 and DIR 127, respectively. The altered genes and associated regulatory elements are listed in Table 1 of this attachment.

Purpose of the dealings with the GMO

The purpose of the dealings is commercial production of the GM canola lines in all areas of Australia, and for products of the GMOs to enter general commerce.

Table 1 Genetic elements responsible for conferring the modified traits

Gene (source)	Promoter (source)	Terminator (source)	Additional elements (source)	Protein produced	Protein function
bar (*S. hygroscopicus*)	*PSsuAra* (*A. thaliana*)	*3' g7* (*A. tumefaciens*)	-	PAT (phosphinothricin acetyl transferase)	Glufosinate tolerance
barnase (*B. amyloliquefaciens*)	*PTa29* (*N. tabacum*)	*3'-nos* (*A. tumefaciens*)	-	Barnase (RNase)	Male sterility
barstar (*B. amyloliquefaciens*)	*PTa29* (*N. tabacum*)	*3'-nos* (*A. tumefaciens*)	-	Barstar (RNase inhibitor)	Restoration of fertility
	Pnos (*A. tumefaciens*)	*3' g7* (*A. tumefaciens*)	-	Barstar (RNase inhibitor)	Enhancing trans-formation efficiency
cp4 epsps (*Agrobacterium* sp. strain CP4)	*P-FMV/Tsf-1* (FMV and *A. thaliana*)	*E9 3'* (*P. sativum*)	L-Tsf1 (leader sequence) & I-Tsf1 (intron) Ctp2 (chloroplast transit peptide) (*A. thaliana*)	CP4 EPSPS (5-enolpyruvylshikimate -3-phosphate synthase)	glyphosate tolerance