



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

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

Licence No.: DIR 020/2002

Licence holder: Monsanto Australia Limited

Title: “General Release of Roundup Ready® canola (*Brassica napus*) in Australia”

Issued: 19 December 2003

Varied: 15 April 2009

Varied: 28 September 2010

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 at <<http://www.ogtr.gov.au>>, or by telephoning the Office on 1800 181 030.

Gene Technology Regulation in Australia

The Gene Technology Act (2000) and corresponding State and Territory legislation form an integral part of a range of regulatory measures which control the development and use of genetically modified organisms (GMOs) in Australia.

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

Note continuing operation of other State laws relating to GMOs

This licence does not authorise dealings with GMOs that are otherwise prohibited by State laws that declare GM, GM-free zones or both for marketing purposes. These laws are administered and enforced by the States and Territories.

Note in relation to herbicide resistance management

The GMO referred to in this licence has been modified to be tolerant to a herbicide. The APVMA has responsibility for setting registration conditions for the use of herbicides in Australia, including implementation of herbicide resistance management programs. Conditions of this licence do not relate to use of herbicide, and do not displace any conditions set by the APVMA.

The licence holder must comply with any conditions imposed by the APVMA in relation to the use of herbicides in connection with the GMO.

SECTION 1 GENERAL CONDITIONS

Duration of Licence

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

Holder of Licence

The holder of this licence ('the licence holder') is Monsanto Australia Ltd.
ACN 006 725 560.

Project Supervisor

The Project Supervisor in respect of this licence is identified at Attachment A.

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

No dealings with GMO except as authorised by this licence

Persons covered by this licence must not deal with the GMO except as expressly permitted by this licence.

GMO covered by this licence

The GMO covered by this licence is described at Attachment B.

Permitted dealings

The permitted dealings with the GMO are all dealings with the GMO.

Persons covered by this GMO licence

The persons covered by this licence are all persons in Australia.

Informing people of their obligations

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

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 his licence to meet the conditions in it.

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

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

Remaining an accredited organisation

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

SECTION 2 INTERPRETATION AND DEFINITIONS

In this licence:

Words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

Words importing a gender include any other gender;

Words in the singular include the plural and words in the plural include the singular;

Words importing persons include a partnership and a body whether corporate or otherwise;

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;

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;

Specific conditions prevail over standard conditions to the extent of any inconsistency.

‘Act’ means the *Gene Technology Act 2000* (Cth).

‘GM’ means genetically modified.

‘GMO’ means the genetically modified organism covered by this licence described at Attachment B.

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

‘Project Supervisor’ means the person identified as the Project Supervisor at Attachment A.

‘Regulator’ means the Gene Technology Regulator.

SECTION 3 SPECIFIC CONDITIONS

Additional information to be given to the Regulator

1. 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.*
2. 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.
3. 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 1(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 1(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 1(c); and
 - (d) information about the actual or anticipated regional location and volumes of the GMO(s) grown, for a nominated period; and
 - (e) 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
 - (f) scientific literature and reports in respect of the GMO(s) authorised by this licence, for a nominated period; and
 - (g) 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.

4. 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.

Testing Methodology

5. 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 GMO and any transferred genetically modified material that might be present in a recipient organism. The instrument must be provided within 30 days of this licence being issued.

Annual Report

6. Each year, the licence holder must prepare a written annual report on the administration of the licence for the previous year.

The period for an annual report is the year ending on anniversary of the day this licence is issued.

An annual report must be provided to the Regulator within 90 days of the end of each period. An annual report must be prepared and provided in accordance with any Guidelines issued by the Regulator in relation to annual reporting.

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 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;
- (c) Information about the volumes of the GMO grown for non-commercial (eg research) purposes in each State and Territory for each growing season in the period;
- (d) Other information on the progress of the release of the GMO, including annual surveys, conducted in consultation with the OGTR, unless such information was previously provided to the Regulator pursuant Specific Condition 3 above.

ATTACHMENT A

DIR No.: 020/2002

***Full Title:** General release of Roundup Ready[®] canola (*Brassica napus*) in Australia

Organisation Details

Postal address: Monsanto Australia Ltd
PO Box 6051, St Kilda Rd Central
MELBOURNE VIC 8008

Phone No: (03) 9522 7122

Fax No: (03) 9522 6122

Project Supervisor Details

Surname: Leader

First Name: Michael

Title: Mr

Phone No: (03) 9522 7149

Fax: (03) 9522 6109

Email Address: michael.leader@monsanto.com

Position: Regulatory Affairs Lead, Australia/New Zealand

Organisation: Monsanto Australia Ltd

Postal Address: Monsanto Australia Ltd
PO Box 6051, St Kilda Rd Central
MELBOURNE VIC 8008

IBC Details

IBC Name Monsanto IBC

* Information that must be included in the Record of GM Products and GMOs Dealings

ATTACHMENT B

GENERAL INFORMATION ABOUT THE GMO COVERED BY THIS LICENCE:

GMOs Description

Parent Organism(s) Common Name: Canola

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

Modified Trait(s):

Category: Herbicide tolerance

Description:

Roundup Ready[®] Canola has been genetically modified by transformation event GT73 to express genes (*CP4 EPSPS* and *goxv247*) conferring tolerance to the herbicide glyphosate.

SPECIFIC INFORMATION ABOUT THE GMOs COVERED BY THIS LICENCE

The GMO covered by this licence is Roundup Ready[®] canola containing transformation event GT73.

Note: more information in connection with the GMO is detailed in the Risk Assessment and Risk Management Plan prepared in connection with this licence.