ATTACHMENTS TO COUNCIL ITEMS

SPECIAL COUNCIL MEETING
08 APRIL 2014

From: Karina.Dennis@health.gov.au [mailto:Karina.Dennis@health.gov.au] **On Behalf Of** OGTR.Applications@health.gov.au
Sent: Thursday, 27 February 2014 12:39 PM
Subject: ICR1412827 - Request for advice on commercial release of GM canola – Application No: DIR 127 [SEC=UNCLASSIFIED]

Australian Government
Department of Health
Office of the Gene Technology Regulator

Dear CEO/Manager

Request for advice on licence application DIR 127 from Monsanto Australia Ltd: Commercial release of canola genetically modified for herbicide tolerance

I have received a licence application (DIR 127) from Monsanto Australia Ltd (Monsanto) for the commercial release of genetically modified (GM) canola into the environment. The *Gene Technology Act 2000* (the Act) sets out the process that I, as the Gene Technology Regulator, must follow in evaluating the application. Following an initial screening of the application, I am seeking advice on matters relevant to the preparation of a Risk Assessment and Risk Management Plan (RARMP) from a broad range of experts, agencies and authorities, including all local councils in Australia.

Please note that I realise Councils do not usually have specialist scientific advice available to them. The purpose in consulting your Council is to make you aware of the application and to seek comment from people who are familiar with the areas where the proposed release could take place.

The Application

Licence application DIR 127 is for unrestricted commercial release of the genetically modified (GM) canola variety MON 88302 (also referred to as TruFlex™ Roundup Ready® canola). MON 88302 contains one introduced gene that confers tolerance to the herbicide glyphosate.

Monsanto is seeking approval to release the MON 88302 canola in all canola growing areas of Australia. The GM canola and its products would enter general commerce, including use in human food and animal feed.

A summary of the application is attached along with a set of 'Questions and Answers' that provide an overview of the application and an outline of the assessment process. A copy of the application is available from my Office upon request.

Consultation process for this DIR application

As this application is for commercial purposes, the Act specifies two rounds of consultation. Before a RARMP is prepared in accordance with section 51 of the Act, I am required to seek advice from prescribed experts, agencies and authorities. This first round of consultation must

include the Gene Technology Technical Advisory Committee, State and Territory Governments, prescribed Australian Government agencies, any local council that I consider appropriate (which in this case I consider to be all local councils in Australia) and the Environment Minister. I am also consulting with a range of Australian Government agencies that, while not prescribed in the legislation, have maintained a strong interest in the implementation of the Act.

Public consultation is not required at this stage. However, I will be notifying receipt of the application by placing a Notification of Application, Summary of Application and Questions and Answers on the OGTR website and advising people and organisations that have registered on the OGTR mailing list.

The second round of consultation, required by section 52 of the Act, will occur after a consultation version of the RARMP has been prepared. I must seek advice on the RARMP from the same prescribed experts, agencies and authorities consulted initially. In addition, I must seek public comment on the RARMP.

Timeframe for comments

In order to comply with the legislative timeframe for this application, I require your advice on matters related to risks to human health and safety and the environment that I should consider in preparing the RARMP by **24 April 2014**.

Please note that if I do not receive advice by this date, subregulation 8(3) of the Gene Technology Regulations 2001 requires me to proceed with the evaluation. However, you will have a further opportunity to comment on the RARMP once it has been prepared.

Conclusion

My office would be happy to discuss any issues or concerns in relation to the application or the preparation of the RARMP. If you have any questions please contact the OGTR by email to ogtr@health.gov.au or by telephone on 1800 181 030 and quote application number DIR 127.

Yours sincerely

Dr Joe Smith
Gene Technology Regulator
27 February 2014

(Approved for electronic transmission)

Attachments:
Summary of Application
Questions and Answers

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are

notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Australian Government
Department of Health
Office of the Gene Technology Regulator

February 2014

Summary of Licence Application DIR 127

Introduction

An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Application number	DIR 127
Applicant:	Monsanto Australia Ltd (Monsanto)
Project Title:	Commercial release of canola genetically modified for herbicide tolerance (MON 88302)[1]
Parent organism:	Canola (*Brassica napus* L.)
Introduced gene and modified trait:	5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) gene derived from the bacterium *Agrobacterium* sp. strain CP4 (herbicide tolerance)
Proposed release dates:	Ongoing from date of approval
Proposed locations:	All canola growing areas of Australia

The proposed dealings

Monsanto proposes a commercial release of the genetically modified (GM) canola variety MON 88302 (also referred to as TruFlex™ Roundup Ready® canola). MON 88302 contains one introduced gene that confers tolerance to the herbicide glyphosate.

Monsanto is seeking approval for unrestricted commercial release of MON 88302 canola in all canola growing areas in Australia. Commercial canola production occurs mainly in New South Wales, Victoria, South Australia and Western Australia, and to a much lesser extent in Tasmania and southern Queensland. However, the commercial cultivation of GM canola is currently prohibited in South Australia and Tasmania under State legislation introduced for marketing reasons.

If a licence is issued, the GM canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from MON 88302. Authorities in the United States, Canada, Japan and Mexico have also approved food derived from MON 88302.

Parent organism

The parent organism, *Brassica napus* L., is commonly known as canola, and is exotic to Australia.

The genetic modification and its effect

MON 88302 contains an introduced *cp4 epsps* gene from the common soil bacterium *Agrobacterium tumefaciens* strain CP4. The gene encodes 5-enolpyruvylshikimate-3-phosphate

[1] The title of the licence application submitted by Monsanto is "General release of *Brasica napus* genetically modified for herbicide tolerance (MON 88302) in Australia".

synthase (EPSPS), an enzyme of the shikimic acid pathway which is involved in the biosynthesis of aromatic compounds, including some amino acids. In non-GM plants, glyphosate binds to and blocks the activity of the natural plant version of this enzyme, which results in the plant being deprived of essential amino acids for growth and development. However, as glyphosate does not bind to the introduced CP4 EPSPS enzyme, expression of the introduced *cp4 epsps* gene enables the GM canola plants to produce aromatic amino acids in the presence of glyphosate. Herbicides containing glyphosate could then be used for weed control in the GM canola crop.

The introduced *cp4 epsps* gene is under the control of a chimeric constitutive promoter containing enhancer sequences from the Figwort mosaic virus 35S promoter combined with sequences of the *Tsf1* gene promoter from *Arabidopsis thaliana* (thale cress).

Other short regulatory sequences that contribute to control the expression of the *cp4 epsps* gene are also present in MON 88302. These are derived from *A. thaliana* and *Pisum sativum* (common garden pea).

MON 88302 canola differs from the already commercially grown Roundup Ready® canola by expression of the *cp4 epsps* gene in all tissue types, particularly in pollen. It can therefore tolerate higher rates of glyphosate herbicides and has a wider window for herbicide application. The applicant advises that this is intended to allow optimisation of herbicide applications to suit environmental and weed growth conditions, providing improved weed control. It is not intended to increase the number of herbicide applications.

Method of genetic modification

MON 88302 was generated using *Agrobacterium tumefaciens*-mediated transformation. This transformation method has been widely used in Australia and overseas for introducing genes into plants. More detailed information on methods of genetic modification can be found in the document *Methods of plant genetic modification* available from the Risk Assessment References page on the OGTR website.

Previous releases of the same or similar GMOs

Field trials of MON 88302 have been conducted in Australia under licence DIR 105. Environmental release of MON 88302 canola has also been approved in the United States and Canada.

Other GM canola modified for herbicide tolerance have been approved in Australia for field trials, and for commercial release (DIR 020/2002: Roundup Ready® canola; DIR 021/2002: InVigor® canola; and DIR 108: InVigor® × Roundup Ready® canola). Roundup Ready® canola also contains an introduced *cp4 epsps* gene.

There have been no credible reports of adverse effects on human health and safety or the environment resulting from any of these releases.

Assessment and consultation process for this DIR application

The Act and the Gene Technology Regulations 2001 set out requirements for considering licence applications, including matters that the Gene Technology Regulator (the Regulator) must take into account before deciding whether or not to issue a licence.

Since this application is for commercial purposes, the Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of a Risk Assessment and Risk Management Plan (RARMP), in accordance with section 50 of the Act. This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, Australian Government agencies, any local council that the Regulator considers appropriate and the Environment Minister.

While the Regulator is not required to seek public comment at this stage, copies of the application are available on request from the OGTR. Please quote application number DIR 127.

In a second round of consultation, the Regulator will seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and will inform the Regulator's decision whether or not to issue a licence.

At this stage, **the RARMP is expected to be released for comment in July 2014.** The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website, or in hard copy from the OGTR.

More information on Australia's national scheme for regulation of gene technology and the assessment process can be found at the Office of The Gene Technology Regulator's website (www.ogtr.gov.au).

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

The Office of the Gene Technology Regulator, MDP 54 GPO Box 9848 Canberra ACT 2601

Telephone: 1800 181 030 Facsimile: 02 6271 4202 Email: ogtr@health.gov.au

Website http://www.ogtr.gov.au

Questions & Answers on licence application DIR 127 – Commercial release of genetically modified canola

What is this application for?

Monsanto Australia Ltd (Monsanto) is seeking approval for the commercial release of one variety of genetically modified (GM) canola, referred to as MON 88302 or TruFlex™ Roundup Ready® canola, which has been modified for herbicide tolerance.

The GM canola is proposed to be grown in all canola growing areas in Australia, and its products would enter general commerce, including use in human food and animal feed.

How has the GM canola been modified?

The GM canola contains an introduced gene derived from a common soil bacterium, which confers tolerance to the herbicide glyphosate. This enables the GM canola plants to grow in the presence of the herbicide, which can be used to control weeds in the GM canola crop.

How is the GM canola different from existing commercial GM Roundup Ready® canola?

In the 2013 season, GM Roundup Ready® canola constituted about 10% of the Australian canola crop. Both MON 88302 canola and Roundup Ready® canola are tolerant to herbicides containing glyphosate, however MON 88302 canola can tolerate higher rates of glyphosate and has a wider window for herbicide application. The applicant advises that this is intended to allow optimisation of herbicide applications to suit environmental and weed growth conditions, providing improved weed control. It is not intended to increase the number of herbicide applications.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Gene Technology Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to human health and safety and to the environment that may be posed by the proposed commercial release. Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised taking into account submissions received, and inform the Regulator's decision whether or not to issue a licence.

Has the GM canola received any other approvals?

Food Standards Australia New Zealand, as well as authorities in the United States, Canada, Japan and Mexico, have approved food made from MON 88302 canola. Environmental release of MON 88302 canola has been approved in the United States and Canada.

How can I comment on this application?

The comprehensive Risk Assessment and Risk Management Plan for this application is expected to be released for public comment in July 2014. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the application by contacting the OGTR (contact details below). Please quote the application number DIR 127. As the application is quite lengthy, you may prefer to view a summary of the application, which is posted on the OGTR website along with this document (under 'What's New'), or a copy can be obtained by contacting the OGTR.

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