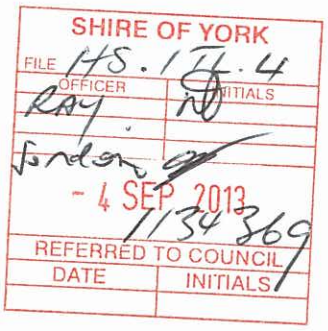
Records

ITEM 9.5.4
APPENDIX A

From: Andrew.Keal@health.gov.au on behalf of OGTR.Applications@health.gov.au
Sent: Wednesday, 4 September 2013 1:13 PM
Subject: Request for comment on proposed field trial of genetically modified (GM) canola - application no. DIR 123 [SEC=UNCLASSIFIED]
Attachments: DIR 123_Attachment A2 Consultation RARMP Summary .DOCX; DIR 123_Attachment F Q&A .DOCX

Australian Government
Department of Health and Ageing
Office of the GeneTechnology Regulator



Request for comment on a proposed field trial of GM canola by Nuseed Pty Ltd

On 24 June 2013, I issued a notification that your local government area has been proposed as a place where a trial site may be located for the above proposed 'limited and controlled release' of canola genetically modified (GM) for altered oil content. The primary purpose of the field trial is to evaluate the agronomic characteristics, oil content and genetic stability of the GM canola under field conditions. The trial is proposed to take place between March 2014 and March 2019, with trial sites selected from 153 possible local government areas (LGAs) in New South Wales, Victoria and Western Australia. The trial would be conducted at a maximum of four sites of up to 2 hectares (ha) in 2014, six sites of up to 10 ha in 2015 and ten sites of up to 20 ha in the subsequent years. The GM canola would not enter the human food or animal feed supply but some GM material may be used for small-scale experimental animal feeding studies.

Your comments are now being sought on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) that has been prepared by the Office of the Gene Technology Regulator (OGTR).

The consultation RARMP provides a comprehensive, science-based evaluation which concludes that the proposed field trial poses negligible risk to people or the environment. However, a range of draft licence conditions would limit the size, locations and duration of the release, as well as restrict the spread and persistence of the GMOs and the introduced genetic material.

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

A summary of the consultation RARMP and a set of Questions and Answers on this application are enclosed for your information. The full consultation RARMP and the *Risk Analysis Framework*, which guides the assessment of licence applications, are available from my Office's website (www.ogtr.gov.au; under "What's New"), or copies can be provided on request by contacting our toll free number (1800 181 030).

Consultation on the Risk Assessment and Risk Management Plan

Section 52 of the *Gene Technology Act 2000* (the Act) and equivalent provisions in corresponding State and Territory legislation set out the requirements for the consultation process in relation to finalising the RARMP, which then forms the basis of the Regulator's decision on whether or not to issue a licence.

Public consultation

As required by section 52(1) of the Act, public notification and an invitation for written submissions on the RARMP for this application are being undertaken. The consultation is more extensive than prescribed in the Act, and includes advertising in *The Land*, *The Weekly Times* and *Farm Weekly*, in addition to the required general circulation newspaper (*The Australian*), the *Australian Government Gazette* and the OGTR website. I will also issue an invitation to comment to interested parties who have registered on the OGTR mailing list.

Other consultation required under the Act

Under section 52(3) of the Act, the Regulator is required to seek advice on the RARMP from a range of experts, agencies and authorities. These comprise all State and Territory Governments, the Gene Technology Technical Advisory Committee, prescribed Australian Government agencies and the Australian Government Minister for the Environment, as well as relevant local councils.

The Act permits the Regulator to take any other actions considered appropriate for the purpose of considering this application. As is usual practice I will consult with a number of Australian Government agencies that, while not prescribed in the legislation, have maintained a strong interest in the implementation of the Act.

Please note that issues such as **food safety and labelling, agricultural chemical use** and **marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the Act as these are the responsibility of other agencies and authorities.

Timeframe

As the consultation RARMP has not identified a significant risk to human health and safety or the environment from the proposed release, the Act specifies a minimum public consultation period of 30 days. However, I am allowing six weeks for written comments to be lodged with my Office. Hence, the closing date for submissions will be **16 October 2013**. Please note that if your jurisdiction's advice is not received within the time period, Regulation 8(3) of the Gene Technology Regulations 2001 requires the Regulator to proceed without regard to that advice.

If you have any questions in relation to this consultation process or the RARMP, please contact the OGTR by e-mail to **ogtr@health.gov.au** or by phone on **1800 181 030**.

Yours sincerely

Dr Joe Smith
Gene Technology Regulator
4 September 2013

Attachments:

- Summary of Risk Assessment and Risk Management Plan (consultation version)
- Questions and Answers

Application and Licence Management Section
The Office of the Gene Technology Regulator
Ph: 1800 181 030
Fax: 6271 4202
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Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

4 September 2013

Summary of the Risk Assessment and Risk Management Plan
(Consultation Version) for
Licence Application No. DIR 123

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform his decision on whether or not to issue a licence.

The application

Application number	DIR 123
Applicant	Nuseed Pty Ltd
Project title	Limited and controlled release of canola genetically modified for altered oil content
Parent organism	Canola (*Brassica napus* L.)
Introduced genes and modified traits	• Seven genes involved in the biosynthesis of omega-3 fatty acids (altered oil content for human nutrition, animal nutrition and food processing) [1] • one gene from bacterium (selectable marker)[1]
Proposed locations	Sites are to be selected from 153 possible local government areas in NSW, Victoria and Western Australia
Proposed release size	Up to four sites in 2014 (maximum of 2 hectares per site), six sites in 2015 (maximum of 10 ha per site) and up to ten sites in each subsequent year (maximum of 20 ha per site)
Proposed release dates	March 2014 – March 2019
Primary purpose	To evaluate the agronomic characteristics, oil content and genetic stability of the GM canola under field conditions.

Omega-3 fatty acids are oil constituents that are considered to have health benefits for humans, especially the long chain omega-3 fatty acids. The main sources of long chain omega-3 fatty acids in the human diet are oily fish, other fish and seafood. The genetic modification is expected to allow the GM canola to produce these oils. Nuseed proposes to undertake some small-scale

[1] The identities of the genes are the subject of a request for declaration of Confidential Commercial Information (CCI) under section 185 of the Act.

animal feeding experiments with GM material produced during this trial. If this project is successful, in the long term Nuseed may investigate the use of material from GM canola lines as supplements for use in animal feed and human food.

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible.

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application (including proposed limits and controls), relevant previous approvals and current scientific/technical knowledge. Both the short and long term are considered.

Credible pathways to potential harm that were considered included: unintended exposure to the GM plant material; unintended effects of the genetic modification; increased spread and persistence of the GM canola relative to unmodified plants; and transfer of the introduced genetic material to non-GM canola or other sexually compatible plants. Potential harms associated with these pathways included toxicity to people and other animals, allergic reactions in people and environmental harms associated with weediness.

The principal reasons for the conclusion of negligible risks are that the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; the introduced genetic modifications are unlikely to cause harm to people or the environment; and genes similar to the introduced genes are common in the environment.

Risk management plan

The risk management plan concludes that risks posed by the proposed dealings can be managed so as to protect people and the environment by imposing conditions on the release. Draft licence conditions are detailed in Chapter 4 of the RARMP.

Risk management is used to control or mitigate risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, as this is a limited and controlled release, the draft licence includes limits on the size, locations and duration of the release, as well as controls including containment provisions at the trial sites; prohibiting the use of GM plant materials in human food; allowing use for animal feed only under experimental conditions; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's guidelines; and conducting post-harvest monitoring at the trial sites to ensure all GMOs are destroyed.

Call for comment

The Regulator invites submissions on the RARMP, including the draft licence conditions, for application DIR 123 from Nuseed Pty Ltd.

The closing date for written submissions is **16 October 2013**.

The Regulator would particularly value comments on risks to the health and safety of people or the environment that may be posed by the proposed field trial.

Please note that issues such as food safety and labelling, the use of agricultural chemicals and marketing and trade implications do **not** fall within the scope of the evaluations that the Regulator is required to conduct. These are the responsibilities of other agencies and authorities.

The consultation RARMP and other supporting documentation can be accessed on the OGTR website via 'What's New'. You can also request a copy of the RARMP or the application from the OGTR - please quote application number **DIR 123**.

If you have any questions about the RARMP or the evaluation process, please contact:

The Office of the Gene Technology Regulator
MDP 54 GPO Box 9848 Canberra ACT 2601
Tel: 1800 181 030
Fax: 02 6271 4202
Email: ogtr@health.gov.au
Website: http://www.ogtr.gov.au

Questions & Answers on licence application DIR 123 – field trial of genetically modified (GM) canola

What is this application for?

Nuseed Pty Ltd is seeking approval to trial, under limited and controlled conditions, canola plants that have been genetically modified for altered oil content. The proposed field trial would take place between March 2014 and March 2019, with trial sites selected from 153 possible local government areas (LGAs) in New South Wales, Victoria and Western Australia. Up to four sites of up to 2 hectares (ha) are proposed in 2014, six sites of up to 10 ha in 2015 and ten sites of up to 20 ha in each subsequent year.

How has the GM canola been modified?

The GM canola has been modified to alter the oil content in the seed, specifically to produce long chain omega-3 oils. Short-chain omega-3 oils are naturally produced in canola seeds. The production of long chain omega-3 oils is achieved in the GM canola by introduction of a number of genes from other organisms which naturally make long chain omega-3 oils. Additionally, the GM canola contains a selectable marker gene, which was used to select genetically modified plant cells and plants during initial development of the GM plants in the laboratory.

What is the purpose of the trial?

The purpose of the field trial is to assess the agronomic characteristics, oil content and genetic stability of the GM canola under Australian field conditions, following testing conducted under glasshouse conditions. Omega-3 oils, especially the long chain ones, are considered to have health benefits for humans. The main sources of long chain omega-3 oils in the human diet are oily fish, other fish and seafood. No GM plant material would enter the human food or animals feed supply as part of this proposed trial, however small-scale animal feeding experiments may be conducted. If this project is successful, in the long term material from a GM canola producing omega-3 oils may have potential for use as supplements in animal feed and human food. However such uses are not part of the proposed trial and would require further relevant regulatory assessments and authorisations.

What controls are proposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the proposed release poses negligible risks to people or the environment. However, a range of draft licence conditions would limit the size, locations and duration of the release, as well as restrict the spread and persistence of the GM canola and the introduced genetic material. Control measures include conditions to isolate trial sites from other canola crops, secure transport and storage of the GM plant materials, and post-harvest monitoring at trial sites to ensure all GM canola plants are destroyed. Full details of the draft licence conditions are set out in the RARMP.

How can I comment on this application?

You are invited to submit your comments on the consultation version of the RARMP that has been prepared for application DIR 123. The full consultation RARMP and a Summary are available on the OGTR website (http://www.ogtr.gov.au under "What's New") or via the Freecall number below. Your advice would be appreciated on any risks to **the health and safety of people** or to **the environment** that may be posed by the proposed release. Please note that the consultation period closes on **16 October 2013** and written submissions are required by that date.

What are the next steps in the evaluation process?

Matters raised in submissions relating to the protection of people or the environment during the proposed release are taken into account in finalising the RARMP, which then forms the basis of the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

Tel: 1800 181 030 E-mail: ogtr@health.gov.au

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