

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 169

Licence holder: The University of Queensland

Limited and controlled release of microalgae genetically modified for increased production of fatty acids

Issued: 16 January 2020

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 part of a nationally consistent regulatory system controlling activities involving 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 and the 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.

Dealings permitted by this licence may also be subject to the operation of State legislation recognising areas 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.

Further information on licence DIR 169

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with this licence application. This document can be obtained from the <u>Office of the Gene Technology Regulator website</u> or by telephoning the Office on 1800 181 030.

Section 1 Interpretations and Definitions

- 1. In this licence:
 - a. unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;
 - 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* (Commonwealth) or the corresponding State legislation under which this licence is issued.

'Contingency Plan' means a written action plan, as specified in Conditions 40 and 41.

'Cultivation Period' means a period of time commencing on the day that cultivation of the GMOs in one or more Culture Vessels or culture bags at the Site starts, and ending on the day that the Culture Vessels and any Equipment in contact with the GMOs during harvest have been Decontaminated.

'Culture Vessel' means any of six small ponds used in the intentional cultivation of the GMOs pursuant to this licence, as shown in Figure 1.

'Decontaminate' (or 'Decontamination') means, as the case requires:

- a. in relation to Equipment or a facility, remove and/or Destroy the GMOs; or
- b. in relation to an area specified in this licence as requiring Decontamination, Destroy GMOs, if present, to the reasonable satisfaction of the Regulator.

'Destroy' (or 'Destruction') means, as the case requires, killed by one or more of the following methods:

- a. treatment with a chemical disinfectant, decontaminant or herbicide;
- b. autoclaving;
- c. destructive analysis;
- d. desiccation; or
- e. a method approved in writing by the Regulator.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

'Equipment' includes, but is not limited to, Culture Vessels, lids fitted to Culture Vessels, culture bags, pipes, pumps, centrifuges, storage equipment, transport equipment (e.g. bags, containers and vehicles), footwear and tools.

'Extreme Weather' includes, but is not limited to, flooding, cyclones or torrential rain, that could disperse GMOs or affect the licence holder's ability to comply with licence conditions.

'GM' means genetically modified.

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

'Logbook' means a written or electronic record containing information required to be collected and maintained by this licence and which can be presented to the Regulator on request.

'NLRD' means a Notifiable Low Risk Dealing.

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

'Regulator' means the Gene Technology Regulator.

'Shed' means a building on the Site that contains a centrifuge for harvesting the GMOs, as shown in Figure 1.

'Sign Off' means a notice in writing from the Regulator that post-Decontamination obligations for the Site no longer apply.

'Site' means the concrete pad of the pilot plant facility, on which the Culture Vessels and associated reticulated systems capable of containing the GMOs are located, along with the Shed and Waste Water Tank, as shown in Figure 1.

'Waste Water Tank' means an effluent treatment tank and associated reticulated systems within the Site that is used to collect waste algae solution, as shown in Figure 1.

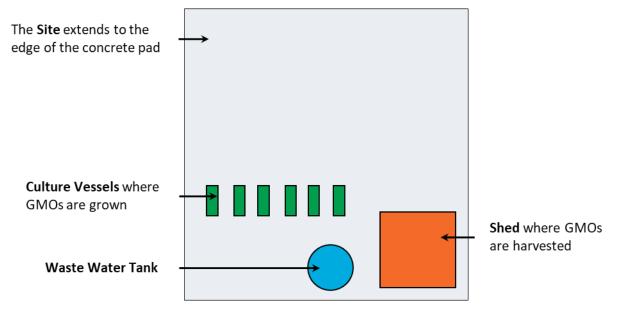


Figure 1 Diagram (not to scale) showing the relationship between the Culture Vessels, Shed and Waste Water Tank at the Site.

Section 2 General conditions and obligations

3. This licence does not authorise dealings with the GMOs 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 GMOs are authorised during any period of suspension.

Note: Although this licence has no expiry date, the period when GMOs may be cultivated is restricted in accordance with Condition 16.

5. The licence holder is The University of Queensland.

6. The persons covered by this licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by this licence.

- 7. The GMOs with which dealings are authorised by this licence are those listed at Attachment A.
- 8. The dealings authorised by this licence are to:
 - a. conduct experiments with the GMOs,
 - b. propagate the GMOs,
 - c. grow or culture the GMOs,
 - d. transport the GMOs,
 - e. dispose of the GMOs,

and possess, supply or use of the GMOs in the course of any of these dealings.

9. This licence does not apply to dealings with the GMOs conducted as an NLRD or pursuant to another authorisation under the Act.

Note: Dealings conducted as an NLRD must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.

Obligations of the Licence Holder

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

11. The licence holder must be able to access and control the Site to the extent necessary to comply with this licence, for the duration of the licence.

12. 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.
- 13. The licence holder must not permit a person covered by this licence to conduct any dealing unless:
 - a. the person has been informed of any applicable licence conditions, including any variation of them; and
 - b. the licence holder has obtained from the person a signed and dated statement that the person:
 - i. has been informed by the licence holder of the licence conditions including any variation of them; and
 - ii. has understood and agreed to be bound by the licence conditions, or variation.

14. The licence holder must inform the persons covered by this licence that any Personal Information relevant to the administration and/or enforcement of the licence may be released to the Regulator.

Obligations of persons covered by the licence

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

Section 3 Limits and Control Measures

3.1 Limits on the release

16. Cultivation of the GMOs may only occur within the following limits:

Duration

Period	Maximum number of Cultivation Periods	Maximum length of combined Cultivation Periods
From licence issue until December 2023	No limit	12 months

Note: The definition of Cultivation Period includes cultivation in culture bags and Culture Vessels.

Site location

Location	Local government area	State
The University of Queensland Centre for Solar Biotechnology pilot plant	Brisbane City	Qld
facility, Pinjarra Hills campus, Brisbane City, Qld		

3.2 Control measures

GMOs must not enter food or feed

17. The GMOs and any GM product derived from the GMOs must not be used, sold or otherwise disposed of for any purpose, which would involve or result in their use as food for humans or feed for animals.

Control measures related to dispersal of the GMOs

- 18. Cultivation of GMOs may only be undertaken in:
 - a. Culture Vessels; or
 - b. plastic culture bags with a volume of less than 25 litres; or
 - c. vessels approved in writing by the Regulator as Culture Vessels.

19. Plastic culture bags containing the GMOs for inoculation of nutrient medium in the Culture Vessels hung within the Site:

- a. must be protected from damage that may result in the dispersal of GMOs; and
- b. must not be hung in the Site for more than 48 hours; and
- c. are not required to comply with conditions that relate solely to cultivation in Culture Vessels.

Notes: The purpose of hanging culture bags containing the GMOs in the Site is to allow the GMOs to adapt to conditions at the Site. Conditions that relate solely to the cultivation of the GMOs in Culture Vessels are 20.c, 24.a and 24.b.

20. Inoculation of Culture Vessels and cultivation must be conducted in a manner that avoids dispersal of GMOs. This includes:

- a. ensuring that persons undertaking dealings with GMOs are suitably trained; and
- b. monitoring weather forecasts for Extreme Weather that could cause damage to Culture Vessels or dispersal of GMOs, and take preventative measures, as required and if reasonably practicable, before Extreme Weather affects the Site; and
- c. remote monitoring the liquid level in Culture Vessels for leaks.

21. The Culture Vessels must be located within the Site (as indicated in Figure 1). The outer edge of the Site must be bunded to contain spills and prevent runoff.

22. Equipment must be maintained in a manner to prevent the dispersal of the GMOs.

23. Any Equipment that has been in contact with the GMOs must remain within the Site until it has been Decontaminated.

24. During cultivation of the GMOs, and until all Culture Vessels and all Equipment in contact with GMOs have been Decontaminated:

- a. purpose-built plastic lids capable of limiting the dispersal of the GMOs, and approved in writing by the Regulator, must be securely fitted to Culture Vessels at all times, except for the purpose of Decontamination; and
- b. GMOs in the air outlet from the Culture Vessels must be killed using a method approved in writing by the Regulator; and
- c. any person that may come into contact with the GMOs must:
 - i. minimise the production of aerosols containing the GMOs,
 - ii. clearly label all containers of GMOs so as to indicate that they contain the GMOs, and
 - iii. Decontaminate clothing that may have come into contact with GMOs, and
 - iv. Decontaminate hands and footwear before leaving the Site.
- d. the Site must be maintained in a manner appropriate to allow the identification of spilled GMOs;
- e. all water within the Site (including rainfall or spills) must be collected in a Waste Water Tank and treated in a manner that will Destroy the GMOs; and
- f. non-GM microalgae grown at the Site must be grown in closed vessels.

25. From the commencement of cultivation of any GMOs until Sign Off, non-GM microalgae grown at the Site:

- a. must be grown in vessels that have been Decontaminated before commencing cultivation of the non-GM microalgae; and
- b. must not be used as an inoculum for further cultivation of non-GM microalgae at the Site or elsewhere.

26. While the GMOs are being cultivated, the Site must be inspected by people trained to recognise spills containing GMOs, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Site	From the commencement of cultivation of any GMOs	At least once every 7 days	Spills containing GMOs	Implement Contingency Plan
	until the Culture Vessel and all Equipment in contact with GMOs has been Decontaminated.		Failures of reticulation system or Equipment	Repair

Note: Details of any inspection activity must be recorded in a Logbook (Condition 44) and reported to the Regulator (Condition 46.f).

27. While GMOs are being cultivated and until Culture Vessels and Equipment has been Decontaminated, measures must be implemented to:

- a. exclude large animals from the Site; and
- b. control rodents within the Site; and
- c. maintain the Site in a manner that does not attract or harbour rodents.

Note: Measures for rodent control may include traps or poison baits within or surrounding the Site.

- 28. The GMOs must be harvested separately from any non-GM microalgae.
- 29. Harvesting of GMOs must be conducted in a manner that avoids dispersal of GMOs. This includes:
 - a. placement of containers or absorbent material wetted with a chemical disinfectant under potential leak points when harvesting; and
 - b. the use of reticulated systems to transfer the GMOs to the centrifuge; and
 - c. covering the discharge tube of the centrifuge and the collection container to prevent dispersal from splashing or aerosolisation of biomass during harvest.
- 30. Centrifugation of the GMOs must only be conducted in the Shed.

Processing or experimentation with GMOs

31. If processing of GMOs or experimentation, analysis or storage of the GMOs is not conducted as an NLRD, then such activities may only be undertaken within:

- a. a facility which, at the time of the dealing, is certified by the Regulator as a PC2 laboratory; or
- b. a facility approved in writing by the Regulator.

32. GMOs that are not required for further experiments or for future cultivation must be Destroyed as soon as practicable.

Transport or storage of the GMOs

33. If transport or storage of the GMOs outside of the Site is not conducted as an NLRD, such activities must:

- a. only occur to the extent necessary to conduct the dealings permitted by this licence or other valid authorisation under the Act, or to the extent necessary to enable export of the GMOs; and
- b. be in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs for PC2 GM microorganisms as current at the time of transportation or storage; and
- c. comply with all other conditions of this licence.

Notes: Transport of the GMOs in volumes of 25 litres or less may be conducted in accordance with the record of assessment for an appropriate NLRD. Activities with the GMOs within the Site are not regarded as transport or storage. Condition 13 requires signed statements for persons transporting or disposing of the GMOs.

34. Methods and procedures used to transport GMOs must be recorded, and must be provided to the Regulator, if requested.

Note: The Contingency Plan must be implemented if the GMOs are unintentionally released (Condition 40).

Decontamination

35. If all GMOs in a Culture Vessel and at the Site have been Destroyed, then for the purposes of this licence:

- a. the GMOs are taken to have been harvested; and
- b. the Culture Vessel and the Site are taken to have been Decontaminated.

Note: Decontamination activities must be reported to the Regulator (Condition 46.e)

36. Areas and Equipment used in connection with the GMOs must be Decontaminated in a manner that avoids dispersal of GMOs as follows:

	Areas/Equipment to be Decontaminated	When	
a.	Culture Vessels and any Equipment in contact with the GMOs during harvest	As soon as practicable and without undue delay after harvest. Equipment must not be removed from the Site or used for any other purpose until Decontaminated.	
b.	any Equipment used in connection with the GMOs	As soon as practicable.	
c.	any area used to Decontaminate any Equipment used in connection with the GMOs	Equipment must not be removed from the Site unless Decontaminated or unless transported for the purpose	
d.	any area used to experiment with, analyse or store	of Decontamination as per Condition 33.	
	GMOs, including a facility approved under Condition 31.b	Areas or Equipment must not be used for any other purpose until Decontaminated.	
e.	Waste Water Tank	As required to minimise the likelihood of dispersal of GMOs.	

Notes: Decontamination activities must be reported to the Regulator (Condition 46.e). After all areas and Equipment have been Decontaminated, effluent in the Waste Water Tank is subject to sampling and testing (Condition 38).

37. Any Equipment which is not Decontaminated immediately after use with the GMOs must be stored within the Site in a manner that prevents dispersal of GMOs.

Post-Decontamination requirements

38. Post-Decontamination sampling and testing of effluent in the Waste Water Tank must be carried out by people trained to sample and identify the GMOs and non-GM microalgae, in a manner such that any GMOs present in the Waste Water Tank are reasonably likely to be detected, using a method approved in writing by the Regulator. Actions must be taken as follows:

Area	Period of testing	Testing frequency	Test for	Action
Waste Water Tank	From the commencement of cultivation of any GMOs at the Site until the Regulator has issued a Sign Off notice.	Prior to any release of effluent from the Waste Water Tank into the environment. Water (including algae solutions) must not be added to the Waste Water Tank during the period between sampling for testing and release of effluent into the environment.	GMOs	Destroy GMOs, if present. Effluent must not be released if GMOs are present.

Note: Suitable methods for identifying GMOs include PCR. Sampling and testing activities, and release of effluent from the Waste Water Tank, must be recorded in a Logbook (Condition 44) and reported to the Regulator (Condition 46.f).

39. While post-Decontamination testing requirements apply to the Waste Water Tank the area must be maintained in a manner appropriate to allow identification of spilled waste water.

Contingency plan

Note: A Contingency Plan must be provided to the Regulator before commencing any dealings with the GMOs (Condition 45.f).

40. A Contingency Plan must be written detailing measures to be undertaken in the event of an unintentional release of the GMOs.

Note: An unintentional release includes a spill of GMOs within or outside the Site or a facility, or accidental release of untreated effluent from the Waste Water Tank.

- 41. The Contingency Plan must include procedures to:
 - a. ensure the Regulator is notified immediately if the licence holder becomes aware of a spill of the GMOs outside of the Site; and
 - b. ensure the Regulator is notified in accordance with Condition 41 if the licence holder becomes aware of a spill of the GMOs within the Site; and
 - c. contain the GMOs to prevent further dispersal; and
 - d. Decontaminate the exposed area using a method demonstrated to Destroy the GMOs.

42. The licence holder must immediately implement the Contingency Plan in the event of the unintended release of the GMOs.

Section 4 Sign off

43. The licence holder may make written application to the Regulator that cultivation restrictions and testing requirements no longer apply to the Culture Vessels, Waste Water Tank and other areas requiring Decontamination, if these areas have been demonstrated to be free from GMOs.

Note: The Regulator will take into account the management and testing history for the Waste Water Tank and associated areas, application of chemical treatments and occurrence of spilled GMOs, in deciding whether or not further testing is required to manage persistence of the GMOs. Once the Regulator has issued a Sign Off, the licence holder may apply to the Regulator for surrender of the licence.

Section 5 Reporting and Documentation

The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR.

Logbook

44. Details of any inspection, sampling and testing activity, and release of effluent, must be recorded in a Logbook and must include (where relevant):

- a. date of inspections or sampling;
- b. name of the person(s) conducting inspections, sampling or testing;
- c. details of areas inspected;
- d. details of any significant non-conformities of the Culture Vessels, Waste Water Tank or associated reticulated system, and spilled volumes of GMOs greater than one litre observed during inspections, including quantity, location and reason for the spill(s);
- e. date(s) and method(s) of Destruction of any spilled GMOs;
- f. date(s) of release of effluent from the Waste Water Tank into the environment; and
- g. details of rodent control methods used and any evidence of rodent activity.

Note: Information in the Logbook must be provided to the Regulator (Condition 46.f).

Notifications to the Regulator

45. General notifications must be sent to the Regulator as follows:

Note: Please send all correspondence related to the licence to OGTR.M&C@health.gov.au

	Notice	Content of notice	Timeframe
a.	Changes to contact details	Changes to any of the contact details of the project supervisor that were notified in the licence application or subsequently.	As soon as practicable
b.	Ongoing suitability to hold a licence	 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 	Immediately after any of these events occur.
		 iv. any information related to the licence holder's ongoing suitability to hold a licence, that is requested by the Regulator. 	Within the timeframe stipulated by the Regulator.
С.	People covered by the licence	 Names of all organisations and persons, or functions or positions of the persons, who will be covered by the licence, with a description of their responsibilities; and <i>Note: Examples of functions or positions are 'project supervisor', site manager', etc.</i> details of how the persons covered by the licence will be informed of licence conditions. 	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change).
d.	Culture Vessels	Details of purpose-built plastic lids (Condition 24.a) and method of killing GMOs in air outlets (Condition 24.b) for approval by the Regulator.	

Notice	Content of notice	Timeframe
e. Inspection strategiesf. Sampling and	Details of proposed management of inspection activities, including strategies for the detection and Destruction of GMOs in spills, e.g. type of chemical treatment, detection of spills, e.g. liquid level sensors, and rodent control. A written methodology to detect reliably the GMOs	At least 14 days prior to conducting any dealings with the GMOs (to be updated within 14 days if the notified details change).
testing methodology	(Condition 38). The detection method must be capable of identifying, to the satisfaction of the Regulator, each GM <i>Nannochloropsis oceanica</i> cell line cultivated under this licence.	
g. Contingency Plan	A Contingency Plan to respond to inadvertent presence of the GMOs.	
h. Training records	Copies of the signed and dated statements referred to in condition 13 if requested by the Regulator.	Within the timeframe stipulated by the Regulator.
i. Additional information required by the Act	 i. 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 ii. any contraventions of the licence by a person covered by the licence; or iii. any unintended effects of the dealings authorised by the licence. Note: The Act requires, for the purposes of the Condition 45.i, that: the licence holder will be taken to have become aware of additional information of a kind mentioned in Condition 45.i if he or she was reckless as to whether such information existed; and the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in Condition 45.i, 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. Note: Additional information includes any changes at the Pinjarra Hills campus, which might increase the likelihood of dispersal of the GMOS. 	Without delay after becoming aware of any new information. Note: An example of notification without delay is contact made within a day of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location, if required.
 Further details regarding additional information 	Any further details requested by the Regulator in relation to information provided under Condition 45.i.	Within the timeframe stipulated by the Regulator.

46. Notifications pertaining to a Cultivation Period and post-Decontamination obligations must be sent to the Regulator as follows:

	Notice	Content of notice	Timeframe
a.	Intention to cultivate	 i. Identity of the GMOs to be grown in the Culture Vessels, e.g. lines or construct details. ii. Intended cultivation volume. iii. Date on which GMO cultivation will commence iv. Date(s) when harvesting is expected. 	At least 7 days prior to each cultivation (to be updated within 7 days if the notified details change).
b.	Cultivation	 i. Actual date(s) of commencement of cultivation of the GMOs. ii. Any changes to the details provided under part (a) of this condition. 	Within 7 days of any cultivation commencing.
c.	Extreme weather	Any Extreme Weather event that is expected to affect or has already affected an area where the GMOs are or may be present. Note: The Contingency Plan must be implemented if the GMOs are unintentionally released (Condition 42).	As soon as reasonably practicable.
d.	Harvest	Actual date(s) of harvesting the GMOs.	Within 35 days of commencement of any harvesting.
e.	Decontamination	 Actual date(s) on which any areas needing Decontamination were Decontaminated Method of Decontamination 	Within 35 days of completion of any Decontamination.
f.	Inspection, sampling and testing activities, and release of effluent from the Waste Water Tank	Information recorded in a Logbook (Conditions 26, 38 and 44).	Within 35 days of inspection, sampling, testing or effluent release.

Note: Please send all correspondence related to the licence to <u>OGTR.M&C@health.gov.au</u>

ATTACHMENT A

DIR No: 169

Full Title:	Limited and controlled release of microalgae genetically modified for increased production of fatty acids		
Organisation Details			
Postal address:	The University of Queensland Brisbane QLD 4072		
Phone No:	(07) 3365 1111		
IBC Details			
IBC Name:	The University of Queensland Institutional Biosafety Committee		
GMO Description			
GMOs covered by this licence	::		
<i>Nannochloropsis oceanica</i> genetically modified by introduction and deletion of only the genetic elements listed below.			
Parent Organisms:			
Common Name:	Microalgae		
Scientific Name:	Nannochloropsis oceanica Suda & Miyashita		
Modified traits:			
Categories:	Altered fatty acid composition		

Description: Nannochloropsis oceanica modified by the insertion of one gene for increased production of medium chain fatty acids and deletion of two genes for ability to use nitrate as listed in Table 1. Associated regulatory sequences for the inserted gene are also listed in Table 1.

Introduced genetic elements and deleted genes in the GM microalgae lines

Genetic element	Gene source	Description	Function
Introduced	elements		
P-LDSP	N. oceanica NIES-2145	Lipid droplet surface protein gene promoter	Promoter sequence
VCP1SP	N. oceanica NIES-2145	Chloroplast transit sequence of violaxanthin/chlorophyll a binding protein gene	Transit peptide for import into the chloroplast
NTE	N. oceanica NIES-2145	Gene encoding acyl-acyl carrier protein thioesterase	Encoded enzyme terminates acyl elongation
T-VCP1	N. oceanica NIES-2145	Terminator of violaxanthin/chlorophyll a binding protein gene	Terminator sequence
Deleted ge	nes		
NRT	N. oceanica NIES-2145	Nitrate transporter gene	Inability to use nitrate
NR	N. oceanica NIES-2145	Nitrate reductase gene	Inability to use nitrate

Purpose of the dealings with the GMOs:

The purpose of the trial is to assess and optimise growth characteristics and production conditions of the GM *Nannochloropsis oceanica* under outdoor conditions. The GM microalgae are not permitted to be used for human food or animal feed.