Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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

Licence No.: DIR 197

Licence Holder: Novotech (Australia) Pty Ltd

Clinical trial of genetically modified *Lactobacillus brevis* for treatment of inflammatory bowel disease

Issued: 21 September 2023

Office of the Gene Technology Regulator

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 (the Regulator) in accordance with the *Gene Technology Act 2000* and, as applicable, corresponding State law.

In assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment, the 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, the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration, the Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Fisheries and Forestry. 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 197

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.

CONDITIONS OF THIS LICENCE

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 importing a gender include every other gender;

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

   (d) expressions used to denote persons generally (such as "person", "party", "someone", "anyone", "no one", "one", "another" and "whoever"), include a body politic or corporate as well as an individual;

   (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 a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;

   (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 law under which this licence is issued.

'CCI' means information that has been declared confidential commercial information under section 185 of the Act and is protected from public disclosure. The CCI is available to persons covered by the licence.

'Clinical trial site' means a medical facility in Australia such as a clinical trial facility and associated pharmacy, which are notified in writing to the Regulator for the purposes of conducting this clinical trial.

'Decontaminate' (or ***'Decontamination'***) means, as the case requires, kill the GMOs by one or more of the following methods:

   (a) chemical treatment;

   (b) autoclaving;

   (c) high-temperature incineration; or

   (d) 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.

'External service provider' means a person engaged by the licence holder solely in relation to transport, storage and/or disposal of the GMOs, and who is not undertaking any dealings with the GMOs that are not for those purposes.

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

'NLRD' is a notifiable low risk dealing. 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.

'Personal information' has the same meaning as in the *Privacy Act 1988*. 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.

'Sample' means any biological material collected from a treated trial participant for analysis as part of the trial.

'Serious adverse event' means any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

'Storage facility' is a facility used for storing GMO doses, but does not include a Clinical trial facility or the home of a trial participant.

Section 2 General conditions and obligations

Holder of licence

3. The licence holder is Novotech (Australia) Pty Ltd.

Remaining an Accredited Organisation

4. The licence holder must, at all times, remain an accredited organisation.

Validity of licence

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

Note: Although this licence has no expiry date, the duration of administration of the GMO is restricted in accordance with Condition 23.

Persons covered by this licence

6. The persons covered by this licence are:

   (a) the licence holder, and any employees, agents or External service providers engaged by the licence holder; and

   (b) the project supervisor(s); and

   (c) clinical trial participants; and

   (d) other persons who are, or have been, engaged or otherwise authorised by the licence holder or the project supervisor to conduct any of the dealings authorised by this licence.

7. The licence holder must keep a record of:

   (a) all persons covered by this licence; and

   (b) the contact details of the project supervisor(s) for the licence; and

(c) the contact details and home addresses of all clinical trial participants to whom GMO doses have been dispensed.

Note: Where External service providers are used, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.

8. The licence holder must provide information related to the persons covered by the licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Description of GMOs covered

9. The licence authorises specified dealings in respect of the GMOs identified and described in **Attachment A**.

Dealings authorised by this licence

10. The licence holder and persons covered by this licence may conduct the following dealings with the GMOs:

(a) import the GMOs;

(b) conduct the following experiments with the GMOs:

i) oral administration of the GMO to trial participants;

ii) collect Samples from trial participants;

iii) analyse the Samples described in 10(b)ii);

(c) transport the GMOs;

(d) dispose of the GMOs;

and may possess, supply, use or store the GMO for the purposes of, or in the course of, any of these dealings.

11. Supply of the GMOs for the purposes of dealings by a person or organisation not covered by this licence is only authorised by this licence if the Regulator provides prior written approval to the licence holder.

Note 1: For approval to be granted, the receiving person or organisation must have an appropriate authorisation to conduct dealings with the GMOs. This is likely to be an NLRD or a licence issued by the Regulator.

Note 2: For example, trial participants must not share their medication with other people.

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

Conditions imposed by the Act

Note: The Act mandates the following 3 conditions.

Informing people of licence conditions (section 63)

13. The licence holder must inform any person covered by the 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.

Monitoring and audits (section 64)

14. 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.

Additional information to be given to the Regulator (section 65)

15. The licence holder must immediately inform the Regulator if they become aware of:

(a) additional information about 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 1: For the purposes of this condition:

(a) The licence holder is taken to have become aware of additional information if they were reckless as to whether such information existed; and

(b) The licence holder is taken to have become aware of contraventions, or unintended effects, if they were reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note 2: Contraventions of the licence may occur through the action or inaction of a person.

Note 3: An example of informing immediately is contact made at the time of the incident via the OGTR free call phone number 1800 181 030.

Informing the Regulator of any material changes of circumstance

16. 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 after the commencement of this licence, of a licence or permit held by the licence holder under a law of the Commonwealth, 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 licence holder to meet the conditions in it.

17. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Further conditions with respect to informing persons covered by the licence

18. If a particular condition, including any variation of it, applies to an External service provider covered by this licence, the licence holder must not permit that person to conduct any dealings unless the person has been informed of the condition, including any variation of it.

Note: Information required under Condition 18 may be provided to External service providers who are engaged solely for storage and transport of the GMO through labelling of the outermost container of the GMOs in accordance with Condition 44(a).

19. If a particular condition, including any variation of it, applies to a person with respect to any dealing, other than to an External service provider, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

(a) 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 condition and, when applicable, its variation; and

ii) has understood and agreed to be bound by the condition, or its variation; and

iii) has been trained in accordance with sub-condition 19(b) below; and

(b) the licence holder has trained that person in a manner which enables them to conduct the dealings in accordance with the conditions of this licence.

20. The licence holder must notify all persons covered by the licence, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

21. The licence holder must ensure that a copy of the licence is readily available to all persons covered by the licence, other than External service providers and trial participants, who are conducting dealings with the GMO.

Note: The licence may be made available electronically.

Section 3 Limits and control measures

Limits on clinical trials conducted under this licence

22. The GMO may be administered to a maximum of 28 trial participants.

Note: This number excludes trial participants who are enrolled in the clinical trial and receive treatment that does not contain the GMO, such as placebo.

23. The GMO must not be administered to any trial participant for a period longer than 15 days.

24. The administration of the GMO must be completed within 7 years from the date of issuing of the licence.

Administration of the GMOs

25. Administration of the GMO to trial participants must not commence prior to approval by a Human Research Ethics Committee.

26. All Clinical trial sites must be located in the Melbourne Urban Centre, as defined by the Australian Bureau of Statistics.

Note: A map of the Melbourne Urban Centre boundaries can be found at https://maps.abs.gov.au using the Urban Centres and Localities filter.

27. GMO doses for administration must be either:

(a) administered at a Clinical trial site; or

(b) dispensed to trial participants at a Clinical trial site for self-administration at home.

Note: Before any of these activities take place, the details of each Clinical trial site must have been notified to the Regulator in accordance with Condition 50(a).

28. GMO doses for administration must be in the form of [CCI].

29. GMO [CCI] dispensed to trial participants must be packaged in [CCI] inside boxes. Both containers must be labelled to indicate:

(a) that they contain GMO; and

(b) to keep out of the reach of children.

Conditions relating to trial participants

30. The licence holder must notify each trial participant, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

31. The licence holder must ensure that the following persons are not enrolled in the trial:

(a) pregnant and breastfeeding persons; and

(b) persons under the age of 18; and

(c) persons who have been diagnosed with inflammatory bowel disease.

32. Before the GMO is dispensed to any trial participant for self-administration at home, the licence holder must obtain written agreement from the trial participant that:

(a) their home during the period of the clinical trial is located in the Melbourne Urban Centre, as defined by the Australian Bureau of Statistics; and

(b) the toilet/s at their home are connected to mains sewerage.

Note: A map of the Melbourne Urban Centre boundaries can be found at https://maps.abs.gov.au using the Urban Centres and Localities filter.

Conditions related to the conduct of the dealings

33. Conditions that apply to dealings with GMOs do not apply to:

(a) blood and urine Samples; and

(b) other Samples, materials and waste, that are reasonably expected not to contain the GMO. Upon request from the Regulator, the licence holder must provide a written justification for this expectation.

34. The licence holder must ensure that dealings are only conducted in a manner which:

(a) does not compromise the health and safety of people; and

(b) minimises the exposure of persons conducting the dealings to the GMO, other than intended exposure of trial participants.

35. The licence holder must ensure that procedures are in place to account for all GMO doses from import to destruction/export. The licence holder must track all GMO doses dispensed to trial participants and whether the doses have been used as intended. Records must be kept and made available to the Regulator on request.

36. Any trial participant who has been dispensed GMO doses for self-administration at home must return all unused GMO doses to a clinical trial site either within one week after their final self-administration of the GMO or within one week after being directed to do so by the licence holder, whichever is the earliest. Unused GMO doses include GMO [CCI] that are unused due to:

(a) withdrawal of the trial participant from the clinical trial; or

(b) [CCI] being damaged, spilled or soiled; or

(c) any other reason.

37. The licence holder must issue spill kits to all trial participants who have been dispensed GMO doses for self-administration at home, at the time when GMO doses are dispensed. The spill kits must include means to:

(a) collect any GMO [CCI] that is unsuitable for ingestion because it is spilled, broken, damaged or soiled; and

(b) clean any area that may be contaminated with the GMO; and

(c) return the GMO to the clinical trial site in a sealed bag that is labelled to indicate that it contains GMO.

38. The licence holder must instruct the trial participants in correct use of the spill kits described in Condition 37.

39. Any trial participant who has been dispensed GMO doses for self-administration at home must inform the licence holder as soon as practicable if any of the following events occur:

(a) spill of GMO [CCI]; or

(b) loss of GMO [CCI]; or

(c) ingestion of GMO [CCI] by persons other than trial participants.

40. The licence holder must instruct clinical trial participants in hygiene measures to follow during the clinical trial. The hygiene measures must include:

(a) thorough hand washing with soap or hand sanitiser after toilet use or any contact with stool or vomit; and

(b) cleaning any non-disposable items contaminated with stool or vomit using detergent or cleaning chemicals; and

(c) discarding any disposable items contaminated with stool or vomit into either a toilet or a bin destined for landfill; and

(d) avoiding passing stools in an outdoor location where no toilets are available.

Transport, storage and disposal of the GMOs

41. The licence holder must ensure that transport of the GMOs is conducted only for the purposes of, or in the course of, another dealing permitted by this licence, for supply in accordance with Condition 11, or for export.

42. For the purposes of import or export, and transport between the border and either a Storage facility or a Clinical trial site, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with International Air Transport Association (IATA) shipping classification UN 3245.

43. For the purposes of transport between the border and a Clinical trial site via a Storage facility, if the GMO is not repackaged at the Storage facility, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with International Air Transport Association (IATA) shipping classification UN 3245.

44. The licence holder must ensure that transport and storage of the GMOs within or between Clinical trial sites and Storage facilities, unless conducted according to Condition 43, follows these sub-conditions:

(a) GMOs must be contained within a sealed, unbreakable container, with the outer packaging labelled to indicate at least:

i) that it contains GMOs; and

ii) the contact details for the licence holder; and

iii) instructions to notify the licence holder in case of loss or spill of the GMOs; and

(b) procedures must be in place to ensure that GMOs can be accounted for and that a loss of GMOs during transport or storage or failure of delivery can be detected; and

(c) access to the GMOs is restricted to authorised persons for whom Condition 18 or Condition 19 has been met (i.e. the GMOs are within a locked unit or an area which has restricted access). This includes situations where containers are left for collection in a holding area, or left unattended prior to Decontamination; and

Note: All stored GMOs remain the responsibility of the licence holder.

(d) if the GMO is being transported or stored with a coolant (e.g. dry ice, liquid nitrogen or any other coolant) which will release a gas, a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected; and

Note: When transporting and storing with coolants, it is preferable for coolants to be used outside of the primary container.

(e) a consolidated record of all GMOs being stored under this condition is maintained and made available to the Regulator upon request; and

(f) for the purposes of transport entirely within a building, where the GMOs are accompanied by an authorised person for whom Condition 19 has been met, Conditions 44(a)ii), 44(a)iii) and 44(b) do not apply.

45. The licence holder must ensure that all GMO doses and all waste reasonably expected to contain GMO doses are Decontaminated:

(a) prior to disposal, unless the method of disposal is also a method of Decontamination; and

(b) before or upon suspension, cancellation or surrender of the licence, unless covered by another authorisation under the Act, or exported; and

(c) by autoclaving, chemical treatment, high-temperature incineration or any other method approved in writing by the Regulator.

46. Where transport is conducted by External service providers for the purpose of destruction, the licence holder must ensure that the GMO doses, or waste reasonably expected to contain GMO doses, enters the clinical waste stream for Decontamination.

Note: In the event of a spill during transport by an External service provider, compliance with relevant State or Territory legislation and regulations to manage clinical or biohazardous spills is sufficient.

Contingency plans

47. The licence holder must ensure that any person (other than a trial participant) who consumes GMO [CCI] is offered prompt medical advice. The clinician must be provided with any relevant information about the GMO.

48. If there is a spill or an unintentional release of GMO at a Storage facility or Clinical trial site, the following measures must be implemented:

(a) the GMOs must be contained to prevent further dispersal; and

(b) persons cleaning up the GMO must wear appropriate personal protective equipment (PPE); and

(c) the exposed area must be Decontaminated with an appropriate chemical disinfectant effective against the GMOs; and

(d) any material used to clean up the spill or PPE worn during clean-up of the spill must be Decontaminated; and

(e) the licence holder must be notified as soon as reasonably possible.

Section 4 Reporting and Documentation

Note: The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR. Notices and reports may be emailed to OGTR.M&C@health.gov.au. A summary of notification and reporting requirements is provided at ***Attachment B****.*

49. The licence holder must notify the Regulator, in writing, of the name and address of each Storage facility before commencement of dealings at that location.

50. At least 14 days prior to first administering the GMO at each Clinical trial site, or a timeframe agreed in writing by the Regulator, the licence holder must provide the Regulator with a Compliance Management Plan for that Clinical trial site, specifying:

(a) the name, address and description of the Clinical trial site, including any associated storage areas/analytical facilities;

(b) the key persons responsible for the management of the trial at the site;

(c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and has been consulted regarding site specific procedures;

(d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of any self-reported incidents for the purposes of Condition 52;

(e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;

(f) how return of unused doses in accordance with condition 36 will be facilitated;

(g) how trial participants can report any spill of GMO, loss of GMO or ingestion of GMO by a person other than a trial participant in accordance with Condition 39;

(h) where, within the site, the GMO is expected to be administered; and

(i) the expected date of first administration.

Note: For the purpose of finding out whether the Act has been complied with, an OGTR inspector may, if entry is at a reasonable time, enter any premises occupied by the licence holder or a person covered by the licence and exercise monitoring powers.

51. For each Clinical trial site, the licence holder must notify the Regulator, in writing, of the end of the clinical trial, no later than 30 days after:

(a) the final dose being administered; or

(b) the decision that no further participants will be treated at that site.

52. The licence holder must inform the Regulator as soon as reasonably possible:

(a) in the event of a trial participant experiencing a Serious adverse event which may be related to the GMO;

(b) in the event of a loss or spill of the GMO;

(c) in the event of the exposure of a person other than a trial participant to the GMO; and

(d) if a trial participant has not followed the procedures described in the instructions provided by the licence holder.

53. Upon request from the Regulator, the licence holder must provide any records, signed statements, written agreements or documentation collected under a condition of this licence, within a time period stipulated by the Regulator.

Attachment A

DIR No: 197

Full Title: Clinical trial of genetically modified *Lactobacillus brevis* for treatment of inflammatory bowel disease

Organisation Details

Postal address: Novotech (Australia) Pty Ltd
Level 2, 15-31 Pelham St
Carlton VIC 3053

Phone No: (03) 9341 1900

GMO Description

GMOs covered by this licence:

Lactobacillus brevis genetically modified only by the genetic modifications listed in Table 1 below.

Common Name: *Lactobacillus brevis* bacteria

Scientific Name: *Lactobacillus brevis*

Modified traits:

Categories: Human therapeutic

Description: The GMO, known as LIV001, secretes a homologue of human vasoactive intestinal peptide (VIP). The GMO is intended to reduce inflammation in the gastrointestinal tract.

Table 1. Genetic modifications responsible for conferring the modified traits

Source, identity, nature of modification	Modified trait description
• Introduction of gene encoding synthetic homologue of human vasoactive intestinal peptide (VIP)	Reduce inflammation
• Additional genetic modifications that are CCI	Traits that are CCI

Purpose of the dealings with the GMOs:

The purpose of the clinical trial is to assess the safety of single and multiple ascending doses of the GMO in healthy clinical trial participants.

Confidential commercial information (CCI)

The name of the parental strain of the GMO and information about genetic modifications other than the introduction of the VIP gene have been declared CCI under Section 185 of the *Gene Technology Act 2000*.

Attachment B – Summary of reporting requirements*

Prior to the commencement of the trial	Condition	Timeframe for reporting
The name and address of each Storage facility	49	Before commencement of dealings at that location
A written Compliance Management Plan for each Clinical trial site: (a) the name, address and description of the Clinical trial site, including any associated storage areas/analytical facilities; (b) the key persons responsible for the management of the trial at the site; (c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and has been consulted regarding site specific procedures; (d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of any self-reported incidents for the purposes of Condition 52; (e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings; (f) how return of unused doses in accordance with condition 36 will be facilitated; (g) how trial participants can report any spill of GMO, loss of GMO or ingestion of GMO by a person other than a trial participant in accordance with Condition 39; (h) where, within the site, the GMO is expected to be administered; and (i) the expected date of first administration.	50	At least 14 days prior to the first administration of the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator
Information to be provided at any time during the clinical trial	**Condition**	**Timeframe for reporting**
Any additional information related to the health and safety of people and the environment associated with the dealing covered by the licence, or any unintended effect of the dealing authorised by the licence	15(a), (c)	Immediately
Information related to any contravention of the licence by a person covered by the licence	15(b)	Immediately
Any relevant conviction of the licence holder	16(a)	Immediately

Any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment	16(b)	Immediately
Any event or circumstances that would impact the licence holder capacity to meet the licence conditions	16(c)	Immediately
Provide notification to the Regulator, in writing, of the end of the clinical trial at each Clinical trial site	51	Within 30 days of the final administration of the GMO or the decision to cease GMO administration at that particular Clinical trial site.
Any Serious adverse event which may be related to the GMO	52(a)	As soon as reasonably possible
Any loss or spill of the GMO, or exposure of a person other than the trial participant to the GMO	52(b), (c)	As soon as reasonably possible after becoming aware of the event
Any event where a trial participant has not followed the procedures described in the instruction provided by the licence holder	52(d)	As soon as reasonably possible after becoming aware of the event
Information to be provided on request by the Regulator	**Condition**	**Timeframe for reporting**
Information related to the persons covered by the licence	8	Within a timeframe stipulated by the Regulator
Information related to the licence holder's ongoing suitability to hold a licence	17	Within a timeframe stipulated by the Regulator
Copies of signed and dated statements and training records	19	Within a timeframe stipulated by the Regulator
Copies of agreements in writing	32	Within a timeframe stipulated by the Regulator
Records of GMO dose tracking and all GMOs being stored	35, 44(e)	Within a timeframe stipulated by the Regulator
Any records or documentation collected under a condition of this licence	53	Within a timeframe stipulated by the Regulator

***** Notifications and documents to be sent to OGTR.M&C@health.gov.au