



**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 159**

**Licence holder: The University of Queensland**

**Title: Limited and controlled release of genetically modified insect-specific viruses as vaccines against Kunjin virus infection in farmed crocodiles**

Issued: 9 May 2018

Varied: 27 November 2018

Varied: 30 July 2020

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the [Office of the Gene Technology Regulator website](#) or by telephoning the Office on 1800 181 030.

### **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 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, Water and the Environment. 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 declaring areas to be GM, GM free, or both, for marketing purposes.

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.

## Section 1 Interpretations and Definitions

1. In this licence:

- (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001 (the Regulations);
- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing 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 standard conditions to the extent of any inconsistency.

2. In this licence:

**'Act'** means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

**'Annual Report'** means a written report provided to the Regulator by 30 September of each year containing all the information required by this licence to be provided in the Annual Report for the preceding financial year.

**'APVMA'** means the Australian Pesticides and Veterinary Medicines Authority.

**'Berrimah Farm'** means the Northern Territory Government Department of Primary Industry and Resources' farm at Berrimah, Northern Territory.

**'BVL'** means the Northern Territory Government Department of Primary Industry and Resources' Berrimah Veterinary Laboratory building at Berrimah Farm.

**'Crocodile'** means Salt water crocodile (*Crocodylus porosus*).

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

- a) chemical treatment;
- b) autoclaving;
- c) high-temperature incineration;
- d) deep burial; and
- 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 vials, needles, swabs, clothing, gloves, cleaning equipment and tools.

**'General crocodile population'** means a place where there are crocodiles that have not been inoculated with a GMO.

**'GM'** means genetically modified.

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

**'GMO stock'** means the undiluted GMOs as supplied to crocodile farms from the University of Queensland.

**'LAH'** means the Large Animal House building at Berrimah Farm.

**'OGTR'** means the Office of the Gene Technology Regulator.

**'Participating farm'** means a crocodile farm, or Berrimah Farm, on which a Trial area exists.

**'Pen'** means a building, or enclosure within a building, with concrete floor, walls and enclosed roof that are sufficient to physically separate and contain the crocodiles.

**'Personal information'** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

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

**'Regulator'** means the Gene Technology Regulator.

**'Sample'** means any biological material collected for analysis from a crocodile, mosquito or other source at a Participating farm, and which may reasonably be expected to contain GMOs.

**'Trial area'** means an area within a Participating farm where the GMO is stored, prepared or used as part of the trial. This includes, but is not limited to, the following:

- (a) Pens where crocodiles are inoculated with the GMO and subsequently housed;
- (b) areas where Samples are taken from, or autopsies conducted on, GMO-inoculated crocodiles;
- (c) areas used to prepare the GMOs for inoculation; and
- (d) storage areas for the GMO stock, carcasses and waste that may potentially be contaminated with the GMO.

## **Section 2      General conditions and obligations**

3. The holder of this licence ('the licence holder') is the University of Queensland.

4. The GMOs covered by this licence are GM insect-specific flaviviruses, as described in **Attachment A** of the licence.

5. The dealings authorised by this licence are to:

- a) conduct experiments with the GMOs;
- b) transport of the GMOs;
- c) disposal of the GMOs;

and the possession (including storage) and supply of the GMO for the purposes of, or in the course, of any of these dealings.

6. This licence does not authorise dealings with the GMOs that are otherwise prohibited as a result of the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

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

8. 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 as part of the field trial, and (to the extent that the GMO may be present at the time) persons who subsequently transport or handle waste containing GMOs.

9. The licence holder must keep a record of all persons covered by this licence who are engaged in the field trial on a Participating farm (including for transport to or from a Participating farm), and must keep a record of the contact details of the project supervisor(s) for the licence.

*Note: Where contractors are used to conduct transport or decontamination/disposal, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.*

### **Obligations of the Licence Holder**

10. The licence holder must notify the Regulator in writing as soon as practically possible if any of the contact details of the contact person(s) for the licence or project supervisor(s) change from that notified in the licence application or subsequently.

*Note: Please address correspondence to [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au)*

11. The licence holder must notify the Regulator in writing, and supply a copy, of any permit issued by the APVMA related to the dealings covered under this licence, within 14 days of the permit being issued or any change to permit conditions being made.

*Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.*

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

13. The licence holder must:

- (a) inform the Regulator immediately in writing, of:
  - i) any relevant conviction of the licence holder occurring after the issue of this licence; and
  - 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; and
  - iii) any event or circumstances occurring after the issue of this licence that would affect the capacity of the holder of this licence to meet the conditions in it; and
- (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

14. The licence holder must be able to access and control all Trial areas to the extent necessary to ensure compliance with conditions of this licence for the duration of the life of the licence.

*The following conditions seek to ensure that persons conducting the dealings covered by licence conditions are aware of the licence conditions and appropriate processes are in place to inform people of their obligations.*

15. Prior to conducting any dealings with the GMOs, the licence holder must provide to the Regulator (for each Participating farm) the following information:

- (a) names of all organisations and persons, or functions or positions of the persons, who will be engaged in the dealings covered by the licence, with a description of their responsibilities;

*Note: Examples of functions or positions are 'project supervisor', 'farm manager', 'farm labourer' etc.*

- (b) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them;

*Note: This may include a description of any contracts, training, labelling, contractual agreements with other organisations or persons such as a Participating farm owner(s), commercial waste providers or courier companies.*

- (c) how the licence holder will access and control Trial areas to the extent necessary to ensure compliance with conditions of this licence for the duration of the licence; and

*Note: This may include a description of any contracts, agreements, or other enforceable arrangements.*

- (d) written methodology to reliably detect the GMOs, or the presence of the genetic modifications in a recipient organism.

16. Any changes to the information provided under Condition 15 must be communicated in writing to the Regulator within 14 days of the changes occurring.

17. 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.

18. 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 particular licence conditions that apply to them, 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 of the particular licence condition(s) including any variation of them; and
  - ii) has understood and agreed to be bound by the licence conditions, or variation.

19. The licence holder must ensure that all persons undertaking dealings at the Trial areas (e.g. handling the GMO, GMO-inoculated crocodiles, or any Equipment or waste potentially contaminated with GMO) are trained in handling and decontamination of the GMOs as documented in the Compliance Management Plan provided under Condition 44.

20. The licence holder must:

- (a) inform the persons covered by this licence to whom a particular condition applies that any personal information relevant to the administration and/or enforcement of the licence may be released to the Regulator; and
- (b) provide the Regulator, if requested, with copies of the signed and dated statements referred to in Condition 18.

### **Provision of new information to the Regulator**

*Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment and risk management plan is communicated to the Regulator.*

21. The licence holder must inform the Regulator if the licence holder becomes aware of:

- (a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; 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: The Act requires, for the purposes of the above condition, that:*

- (a) the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 21(a) if he or she was reckless as to whether such information existed; and*
- (b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 21(b) or 21(c), 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.*

22. If the licence holder is required to inform the Regulator under the immediately preceding condition, the Regulator must be informed without delay.

*Note: An example of informing 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.*

23. If the licence holder informs the Regulator under the immediately preceding condition and the Regulator requests further information, such information must be provided in a manner, and within the time period, stipulated by the Regulator.

### **Obligations of persons covered by the licence**

24. Persons covered by this licence engaged in the field trial must not deal with the GMOs except as expressly permitted by this licence.

25. If a person is authorised by this licence to deal with the GMO and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

## **Section 3 Limits and control measures**

*Note: This licence does not expressly authorise or prohibit any dealings or storage in facilities certified by the Regulator. Under the Act it is not an offence to deal with a GMO if the dealing is otherwise licenced or if it is a notifiable low risk dealing (NLRD) or an exempt dealing and complies with all relevant statutory requirements.*

### **Limits on the release**

*The following licence conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be released, and on other activities that can be undertaken.*

26. Inoculation and housing of GMO-inoculated crocodiles may only occur at Darwin Crocodile Farm and Janamba Crocodile Farm in the local government area of Litchfield Council, Northern Territory; or at the LAH at Berrimah Farm, in the Northern Territory Rates Act Area.

27. GMO stocks and Samples may only be stored at a Trial area within a Participating farm or at the BVL.

28. Only juvenile crocodiles, up to 9 months of age, may be inoculated with the GMOs.

29. A cumulative maximum of 2,800 crocodiles may be inoculated with the GMOs.

30. Inoculation of crocodiles and storage of GMO stock must be completed by May 2023.
31. If experimentation and analysis with the GMOs, GMO-inoculated crocodiles or Samples, is not conducted in accordance with NLRD requirements, such activities may only be undertaken within a Trial area or at the BVL.

### **Controls on the release**

*The following licence conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs, and apply to dealings on Participating farms and transport to and from these farms.*

#### ***Practices at Participating farms***

32. The licence holder must ensure that a copy of the licence is available and readily accessible to persons conducting dealings at Trial area.
33. Access to Trial areas must be restricted to only persons authorised by the Licence holder.
34. Signs indicating the presence of the GMOs must be displayed at all entrances to Trial areas.
35. Inoculation of crocodiles with the GMOs must only occur inside a Pen.
36. Persons preparing or administering the GMOs must be appropriately trained as detailed in the Compliance Management Plan.
37. Persons preparing or administering the GMOs must wear personal protective equipment, including gloves. Puncture-resistant gloves must be used when there is a risk of sharps injury during these procedures (as detailed in the Compliance Management Plan).
38. Crocodiles must be inoculated with the GMOs by subcutaneous or intramuscular injection into the tail.
39. At least 20% of each batch of GMO-inoculated crocodiles must be tested for the presence of the GMOs within 4 weeks of their final inoculation, and periodically thereafter (as specified in the Compliance Management Plan), until no GMO is detectable.
40. GMO-inoculated crocodiles must be kept on the Participating farm, and segregated from all non-inoculated crocodiles, up to and including 4 weeks after their last GMO inoculation and until the testing required by condition 39 indicates that the GMOs are no longer present.
41. Mosquitoes and non-inoculated crocodiles on the Participating farms must be sampled and tested for the presence of GMOs over the period of the trial (as specified in the Compliance Management Plan).
42. The licence holder must ensure that only persons holding an *environment protection licence* or a *best practice licence* under the *Waste Management and Pollution Control Act (NT)(WMPC Act)* for conduct of activities specified in clause 2 and 3 of Part 2 of Schedule 2 WMPC Act are engaged for disposal of waste potentially contaminated with the GMOs, other than at a Trial area or at the BVL.

*Note: Condition 42 does not impose licence conditions on persons engaged to conduct waste disposal, however the licence holder is responsible for ensuring only people who are appropriately authorised for waste disposal in the NT are permitted to conduct the disposal.*

#### ***Transport and storage of GMO stock and Samples***

43. Transport and storage of the GMO stock or Samples must be in accordance with requirements for Physical Containment level 1 GM micro-organisms of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* in force at the time of transport or storage.



## Section 4 Reporting and Documentation

*Note: Attachment B provides a checklist of documents that must be provided to the Regulator under conditions this licence, to aid compliance with reporting conditions.*

### Compliance management and Contingency plans

44. At least 14 days prior to inoculating crocodiles with the GMO at each Participating farm, a written Compliance Management Plan must be submitted to the Regulator, detailing:

- (a) procedures for the use of sharps, handling of the GMOs during preparation and administration, decontamination of the GMOs and waste disposal;
- (b) personal protective equipment to be used when preparing the GMO for inoculation, administering the GMO and taking samples from GMO-inoculated crocodiles (including details of situations for which the use of puncture resistant gloves are appropriate);
- (c) a plan for the testing for the presence of GMOs in GMO-inoculated crocodiles at each Participating farm, including criteria for selection of crocodiles, types of the samples to be collected, and timing of sample collection (as required by Condition 39);
- (d) a plan for the testing for the presence of the GMOs in non-inoculated crocodiles and mosquitoes at each Participating farm, including details of type of samples to be collected and, for each sample type, criteria for determining where, when and how many samples are to be collected.

*Note: A Compliance Management Plan may be applicable to more than one Participating farm.*

45. At least 14 days prior to inoculating crocodiles with the GMO at each Participating farm, a written Contingency Plan must be submitted to the Regulator detailing measures to be taken in the event of:

- (a) the GMO being detected in GMO-inoculated crocodiles later than 4 weeks post-inoculation;
- (b) a GMO being detected in a Sample from crocodile other than a GMO-inoculated crocodile or mosquito;
- (c) a person receives a needle stick/sharps injury during GMO preparation, inoculation or sample collection from an inoculated crocodile;
- (d) a spill or unintended release of GMO (i.e. during transport between Trial areas or during inoculation);
- (e) escape or loss of a GMO-inoculated crocodile that is required to be segregated from non-inoculated crocodiles according to Condition 40 from its Pen.

*Note: A Contingency Plan may be applicable to more than one Participating farm.*

46. The Contingency Plans must include details of procedures to:

- (a) ensure the Regulator is notified as soon as reasonably possible after the licence holder becomes aware of the event;
- (b) if GMOs are detected in GMO-inoculated crocodiles later than 4 weeks post inoculation or in non-inoculated crocodiles or mosquitoes, implement measures to minimise further persistence and dispersal of the GMO in the environment;
- (c) if exposure through needle stick/sharps injury is suspected or confirmed, provide appropriate medical attention to affected persons as necessary;
- (d) in the event of a spill or unintended release of GMO, procedures to contain and decontaminate the GMO;

- (e) in the event of an escape or loss of a GMO-inoculated crocodile that is required to be segregated from non-inoculated crocodiles according to Condition 40, procedures to locate the animal and return it to containment.

47. If any of the events described in Condition 45 occur, the appropriate procedure(s) from the Contingency Plan must be implemented.

### **Notices of commencement and completion of inoculations**

48. At least 14 days prior to commencing dealings with the GMO at a Participating farm, the licence holder must provide the Regulator with a detailed diagram or map of the farm, including the proposed Trial areas, the Pens and any other buildings, and what each structure is used for.

49. The licence holder must notify the Regulator in writing at least 7 days before inoculation of each batch of crocodiles with the GMOs at each Participating farm, and must include the following details:

- (a) expected dates of inoculation with the GMO;
- (b) number and age of crocodiles to be inoculated with the GMO;
- (c) identification of the particular Pens where the GMO-inoculated crocodiles will be kept.

*Note: The notices required by conditions 48 and 49 may be combined for the first inoculation at a particular Participating farm, and a notice under condition 49 may cover more than one batch of crocodiles if the relevant details for each batch can be accurately provided.*

50. Any changes to the details provided under Condition 49 must be provided to the Regulator within 7 days.

51. For each Participating Farm, the Licence Holder must notify the Regulator of the following:

- (a) for the first batch of GMO-inoculated crocodiles, at least 14 days prior to the expected date, the intention to release the GMO-inoculated crocodiles into the General crocodile population, along with a summary of the testing data (as required under Condition 39) supporting the release;
- (b) for all other batches of GMO-inoculated crocodiles, their release into the General crocodile population within 7 days of the event. If there are no further GMO-inoculated crocodiles to be released, and no further inoculations to be conducted, this information must be included in the notification.

### **Annual Report**

52. By 30 September each year, the licence holder must provide to the Regulator an Annual Report for the preceding financial year, including for the period:

- (a) the number of crocodiles inoculated with the GMO at each Participating farm;
- (b) the number of GMO-inoculated crocodiles released into the General crocodile population at each Participating farm; and
- (c) a summary of the results of testing for the GMO in GMO-inoculated crocodiles, non-inoculated crocodiles and mosquitoes (as required under Condition 39 and according to the Compliance Management Plan provided under Condition 44);

### **Records to be maintained**

53. The following records must be made and kept for the life of this licence, and made available to the Regulator on request:

- (a) measures taken to ensure that Pens, Trial areas and Participating farm fencing keep crocodiles securely enclosed, including inspection and maintenance activities, as applicable;
- (b) details of each batch of crocodiles inoculated with the GMO as notified to the Regulator under Condition 49;
- (c) details of each release of GMO-inoculated crocodiles to the General crocodile population;
- (d) monitoring and testing data as required under Conditions 39 and 41, and according to the Compliance Management Plan provided under Condition 44.

**DIR No: 159**

**Full Title:** Limited and controlled release of genetically modified insect-specific viruses as vaccines against Kunjin virus infection in farmed crocodiles

### **Organisation Details**

Postal address: The University of Queensland  
St Lucia  
Queensland 4072

Phone No: (07) 3365 1111

### **IBC Details**

IBC Name: The University of Queensland Institutional Biosafety Committee

### **GMO Description**

#### **GMOs covered by this licence:**

Insect-specific flaviviruses genetically modified by introduction of only the genetic elements listed below.

#### **Parent Organisms:**

Common Name: Insect-specific flaviviruses (ISFs)

Scientific Name: Insect-specific flaviviruses (ISFs) [Specific details of the parent organisms have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.]

#### **Modified traits and introduced genetic material:**

Trait categories: Vaccine – altered antigen expression

Description: Insect-specific flaviviruses have been genetically modified to contain two genes that encode virion proteins from either of two naturally attenuated, Australian isolates of the Kunjin virus (KUNV, a member of the WNV group of flaviviruses), in place of the corresponding ISF genes.  
[Specific details relating to the genetic modifications, including the Kunjin virus genes, corresponding proteins and their function, have been declared as Confidential Commercial Information (CCI) under section 185 of the Act.]

#### **Purpose of the dealings with the GMOs:**

The GMOs will be administered to juvenile crocodiles by subcutaneous or intramuscular injection, to assess their safety and efficacy as vaccines against Kunjin virus infection.

## ATTACHMENT B

### Checklist of documents that must be sent to the Regulator:

When	What	Condition	Timeframe of reporting
Prior to conducting any dealings	Details of persons covered	15 (a)	
	Plan to inform people covered by the licence	15 (b)	
	Plan to ensure control and access to the Site	15 (c)	
	Detection methodology	15 (d)	
Prior to inoculation	Compliance management plan	44	At least 14 days prior to any inoculation
	Contingency plan	45	At least 14 days prior to any inoculation
	Details of farm	48	At least 14 days prior to any inoculation
	Intention to inoculate and details about the inoculation	49	At least 7 days prior to inoculation
	Changes to inoculation details as required by condition 49	50	Within 7 days of the change
	For each Participating farm, intention to release the 1 <sup>st</sup> batch of GMO-inoculated crocodiles into the General crocodile population and their GMO test results (Condition 39)	51 (a)	At least 14 days prior to the expected moving date
Prior to or following release of crocodiles to the General crocodile population	Following release of other batches of GMO-inoculated crocodiles	51 (b)	Within 7 days of moving date
	The number of crocodiles inoculated at each Participating farm; the number of inoculated crocodiles released into the General crocodile population at each farm; and a summary of rest results (Conditions 39 and 44)	52	30 September each year
Annual report for each financial year	Any changes of the project supervisor contact details	10	As soon as practicable
Any time after issue of the licence	Copy of any permit issued by the APVMA, or changes to permit conditions	11	Within 14 days of the issue or changes
	Any relevant conviction, any revocation, suspension or cancellation of a relevant permit or any circumstances that may affect compliance with licence conditions	13 (a)	Immediately, if occurs
	Any information relevant to on-going suitability	13 (b)	If and when requested

<b>When</b>	<b>What</b>	<b>Condition</b>	<b>Timeframe of reporting</b>
	Any changes to details provided under conditions 15 (a-d)	16	Within 14 days of the changes
	Signed statements from persons covered under the licence	20 (b)	If and when requested
	Any additional information regarding health and safety of people and the environment, contraventions of this licence or any unintended effects of the dealings authorised by the licence	21	Without delay, after becoming aware (Condition 22)
	Further information relating to condition 21	23	If and when requested
	Measures taken to secure crocodiles, including inspection and monitoring	53 (a)	If and when requested
	Details of each batch of crocodiles inoculated	53 (b)	If and when requested
	Details of each release of inoculated crocodiles to the General crocodile population	53 (c)	If and when requested
	Monitoring and testing data	53 (d)	If and when requested