



**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 174**

**Licence holder: Bioclect Pty Ltd**

**Commercial supply of a genetically modified cholera vaccine,  
Vaxchora®**

Issued: 17 February 2021

### **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 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 genetically modified organisms into the Australian environment.

Other agencies that also regulate genetically modified organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction 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.

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 174**

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.

## Section 1 Interpretations and Definitions

1. In this licence:

- (a) unless defined otherwise in the licence, words and phrases used in this licence have the same meaning as they do in the Act and the Gene Technology Regulations 2001 (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 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 the end of September each year containing all the information required by this licence to be provided in the Annual Report.

**'ARTG'** means the Australian Register of Therapeutic Goods maintained in accordance with the *Therapeutic Goods Act 1989*.

**'GM'** means genetically modified.

**'GMO'** means the genetically modified organism that is 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.

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

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

## Section 2 Licence conditions and obligations

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

4. The licence holder is Bioelect Pty Ltd.

5. Any person, including the licence holder, may conduct any permitted dealing(s) with the GMO.

6. The dealings authorised by this licence are:

- a) import of the GMOs;
- b) transport of the GMOs;
- c) disposal of the GMOs;

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

*Note: Use of the GMO for therapeutic purposes is not covered by the Gene Technology Act 2000 and therefore this licence is not required to authorise such use. The GMOs are also subject to regulation by other federal and state departments and agencies, including the Therapeutic Goods Administration and the Department of Agriculture, Water and the Environment. These other departments and agencies may impose further requirements for, or limitations on, the use of the GMO or these dealings.*

7. This licence does not apply to dealings with the GMOs conducted as a Notifiable Low Risk Dealing (NLRD) or pursuant to another authorisation under the Act.
8. Dealings with the GMO authorised by this licence may be conducted in all areas of Australia.
9. The licence authorises dealings with the GMO described in **Attachment A**.

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

10. The licence holder must immediately notify the Regulator if any of its contact details change.

*Note: Please address correspondence to OGTR.M&C@health.gov.au.*

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

11. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.
12. The licence holder must:
  - (a) inform the Regulator immediately in writing, of:
    - i. any relevant conviction of the licence holder; 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 that would affect the capacity of the licence holder 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.

13. 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.

## **2.2 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 is communicated to the Regulator.*

14. 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 14 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 14, 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.*

15. If the licence holder is required to inform the Regulator under condition 14, the Regulator must be informed without delay.

*Note: An example of informing without delay is contact made at the time 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.*

16. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:

- (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, whether or not the licence holder has provided information to the Regulator under condition 14(a);
- (b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 14(b);
- (c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 14(c);
- (d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;
- (e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period;
- (f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

*Note: The Regulator may invite the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant to the progress of the dealings with the GMO.*

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

17. 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 Reporting and Documentation Requirements**

#### **3.1 Notification of Authorisation by the Therapeutic Goods Administration**

18. If the GMOs are included on the ARTG, the licence holder must notify the Regulator in writing within 14 days of registration.

19. The licence holder must notify the Regulator in writing of any subsequent amendments to the conditions of the ARTG registration involving the pattern of usage, handling, storage, transport or disposal of the GMOs, within 14 days of the change occurring.

#### **3.2 Annual Report**

20. The licence holder must provide an Annual Report to the Regulator by the end of September each year covering the previous financial year. An Annual Report must include:

- (a) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs; and
- (b) information about the numbers of the GM vaccine doses imported and distributed to each State and Territory.

#### **3.3 Testing methodology**

21. At least 14 days prior to conducting any dealings with the GMO, the licence holder must provide to the Regulator a written methodology to reliably detect the GMO, and the presence of the genetic modifications described in **Attachment A** in a recipient organism or environmental sample. The detection method(s) must be capable of identifying, to the satisfaction of the Regulator, the GMO described in **Attachment A**.

*Note: Please address correspondence to [OGTR.M&C@health.gov.au](mailto:OGTR.M&C@health.gov.au)*

**DIR No: 174****Full Title:** Commercial supply of a genetically modified cholera vaccine, Vaxchora®**Organisation Details**

Postal address: Bioelect Pty Ltd  
 Suite 5.02, Level 5, 139 Macquarie Street  
 Sydney NSW 2000 Australia

Phone No: 1300 907 411

Accreditation No: Accr 253

**GMO Description****GMOs covered by this licence**

*Vibrio cholerae* is genetically modified by the deletion of gene encoding cholera toxin A subunit (leading to attenuation); inactivation of the gene encoding haemolysin A (also leading to attenuation); and insertion of a mercury resistance operon from *Shigella flexneri* (as a selectable marker). The resultant strain is *V. cholerae* CVD 103-HgR which is used in the cholera vaccine.

**Parent Organism**

Common Name: Cholera bacterium

Scientific Name: *Vibrio cholerae* strain 569B**Modified traits**

Category: Loss of toxin expression - Vaccine attenuation

Gene inactivation - Vaccine attenuation

Selectable marker expression

Description: The GMO consists of a live-attenuated bacterium *V. cholerae* strain CVD 103-HgR which is not able to cause cholera disease. The genes responsible for modified traits are listed in Table 1.

**Table 1: Genetic elements responsible for conferring the modified traits.**

| Gene              | Source organism                                 | Modification   | Intended purpose    |
|-------------------|---|--|---------------------|
| <i>ctxA</i>       | <i>Vibrio cholera</i> 395<br>(Classical Ogawa ) | Deletion of cholera toxin A subunit gene ( <i>ctxA</i> )   | Vaccine attenuation |
| <i>hlyA</i>       | <i>Vibrio cholerae</i> N16961<br>(El Tor Inaba) | Inactivation of haemolysin A gene ( <i>hlyA</i> )          | Vaccine attenuation |
| <i>Mer operon</i> | <i>Shigella flexneri</i> NRI                    | Insertion of <i>mer</i> operon (Confer mercury resistance) | Selectable marker   |

**Purpose of the dealings with the GMO**

The purpose of the dealings is commercial supply of the GM cholera vaccine, Vaxchora® for use as human vaccine Australia-wide for travellers. The permitted dealings under the licence are import, transport, storage and disposal of the GM vaccines. The licence does not authorise the manufacture of the GM cholera vaccine, Vaxchora® in Australia.