



**Australian Government**

**Department of Health and Ageing**

**Office of the Gene Technology Regulator**

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

**Licence No.: DIR 098**

**Licence holder: Sanofi-Aventis Australia Pty Ltd**

**Title: Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV™)**

Issued: 19 August 2010

Transferred: 28 September 2010

**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 at <http://www.ogtr.gov.au>, 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 the development and use of 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, National Health and Medical Research Council and Australian Quarantine and Inspection Service. 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.

For this licence the relevant regulatory agencies include the Therapeutic Goods Administration and Australian Quarantine and Inspection Service. Additionally handling and disposal of the GMO is also regulated through relevant state and territory legislation as discussed in the Risk Assessment and Risk Management Plan (RARMP) prepared in connection with the assessment of the application for this licence.

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 B of this licence.

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.

## **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 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 within ninety (90) days of each anniversary of issue of this licence containing all the information required by this licence to be provided in the Annual Report.

**'ARTG'** means the Australian Register of Therapeutic Goods.

**'GM'** means genetically modified.

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

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

**'Personal Information'** means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

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

## **Section 2 Dealings with the GMO**

3. This licence allows the licence holder and all people in Australia to import, transport and dispose of the GMO in all areas of Australia for the purposes of vaccination against Japanese encephalitis.

*Note: The GMO (a live viral vaccine) is also subject to regulation by other federal and state agencies including the Therapeutic Goods Administration and Australian Quarantine and Inspection Service. These other agencies may impose further requirements for, or limitations on, these dealings.*

## **Section 3 General conditions**

### **Duration of Licence**

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

### **Holder of Licence**

5. The holder of this licence ('the licence holder') is Sanofi-Aventis Australia Pty Ltd.

### **Project Supervisor**

6. The Project Supervisor in respect of this licence is a person named in Attachment A of the licence.

7. The licence holder must immediately notify the Regulator in writing if any of the contact details of the Project Supervisor change.

### **GMO covered by this licence**

8. The GMO covered by this licence is the organism genetically modified as described in Attachment B of the licence.

### **No dealings with the GMO except as authorised by this licence**

9. Persons covered by this licence must not deal with the GMO except as expressly permitted by this licence.

*Note: The conditions of this licence do not prohibit any lawful use of the GMO as a vaccine.*

### **Informing people of their obligations**

10. The licence holder must inform any person covered by this licence, to whom a particular condition of this licence applies, of the following:

- (a) the particular condition (including any variations of it);
- (b) the cancellation or suspension of the licence;
- (c) the surrender of the licence.

11. The licence holder must notify the project supervisor and each person to whom a particular condition(s) of this licence applies that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

12. Prior to dealing with the GMOs the licence holder must provide the Regulator with an explanation of how the licence holder has informed, or proposes to inform, each person to whom a particular condition(s) of this licence applies, of the particular condition of the licence, including conditions related to the collection of Personal Information by the licence holder.

13. Where any of the details provided under the immediately preceding condition change, the Licence holder must notify the Regulator of the changes within fourteen (14) days of the change occurring.

14. If a particular condition, including any variation of it, applies to a person with respect to a particular dealing, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

- (a) the person has been informed of the condition, including any variation of it; 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 condition and, when applicable, its variation; and
- ii) has understood and agreed to be bound by the condition, or its variation.

15. The licence holder must provide the Regulator, on the Regulator's request, with copies of the signed and dated statements referred to in the immediately preceding condition.

***Applicant to notify of circumstances that might affect suitability***

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 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;
- (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the holder of this licence to meet the conditions in it.

17. The licence holder must notify the project supervisor and all persons to whom a particular licence condition applies that Personal Information collected by the licence holder which is relevant to the administration and/or enforcement of the licence may be released to the Regulator.

***Licence holder must provide information on matters related to suitability***

18. 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.

***Additional information to be given to the Regulator***

19. It is a condition of this licence that the licence holder informs the Regulator if the licence holder becomes aware of any of the following:

- (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 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, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

20. The licence holder must provide the information required by paragraphs (a), (b) and (c) of the immediately preceding condition to the Regulator as soon as practically and reasonably possible, and must also include the information in the Annual Report.

21. 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 19(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 19(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 19(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.

22. If the Regulator invites the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant the progress of the GMO, the licence holder may make such a submission to the Regulator within thirty (30) days of receipt of the invitation.

#### ***People dealing with GMOs must allow auditing and monitoring of the dealing***

23. 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.

#### ***Remaining an Accredited organisation***

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

#### ***Notices***

25. The licence holder must provide all notices to the Regulator required to be given by this licence and each notice must be provided in the manner required by Section 3 of this licence.

### ***Section 4 Reporting and Documentation Conditions***

#### ***Notice of amendment to the ARTG registration***

26. Amendments to the conditions of the ARTG registration involving the pattern of usage, handling, storage, transport or disposal of the GMO must be notified to the Regulator in writing fourteen (14) days of the change occurring.

### ***Annual Report***

27. The licence holder must provide an Annual Report to the Regulator. An Annual Report must include the following:

- (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 GMO or material from the GMO; and
- (b) the number of doses of GM vaccine distributed within Australia during the preceding twelve (12) months.

### ***Testing methodology***

28. The licence holder must provide written document to the Regulator describing an experimental method that is capable of reliably detecting the presence of the GMO and the presence of the genetic modifications described in this licence (for details see Attachment B of the licence) in a recipient organism. The detection method should be capable of reliably distinguishing between GMO described in this licence and the parent organisms. The document must be provided within 30 days of the issuing of this licence.

## ATTACHMENT A

**DIR No: 098**

**\*Full Title:** Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV™<sup>1</sup>)

### **Organisation Details**

**Postal address:** \* Sanofi-Aventis Australia Pty Ltd  
Locked Bag 2227  
North Ryde BC 1670

**Phone No:** 1800 829 468

### **Project Supervisor Details**

**Surname:** [*Personal Information Redacted*]

**First Name:** [*Personal Information Redacted*]

**Title:** [*Personal Information Redacted*]

**Phone No:** [*Personal Information Redacted*]

**Fax:** [*Personal Information Redacted*]

**Email Address:** [*Personal Information Redacted*]

**Position:** [*Personal Information Redacted*]

**Organisation:** Sanofi-Aventis Australia Pty Ltd

**Postal Address:** \* Sanofi-Aventis Australia Pty Ltd  
Locked Bag 2227  
North Ryde BC 1670

### **IBC Details**

**IBC Name:** IBC 1033 (Queensland Clinical Trials Network Institutional Biosafety Committee)

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<sup>1</sup> As IMOJEV™ has been registered by the TGA, it is expected to be marketed as IMOJEV®.

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

The genetically modified (GM) live viral vaccine known as IMOJEV™ (formerly known as ChimeriVax JE™)

**\*Parent Organism**

Common Name: *Yellow fever virus*

Scientific Name: *Yellow fever virus* vaccine strain 17D

**\*Modified Traits:**

Categories:       antigen expression  
                          attenuation

**Description:**

The YF 17D parent virus has been modified to remove the endogenous envelope (E) and pre-membrane (prM) proteins that make up the outer surface of the viral particle and replace them with the equivalent proteins from *Japanese encephalitis virus* (JEV) vaccine strain JE SA14 14 2.

**\*Genes Responsible for Conferring the Modified Traits:**

Gene	Function of protein	Source	Intended purpose
Envelope (E)	envelope protein is the major component of the outer surface of virus particle, mediates fusion of the viral particle with the host cell membrane	JEV SA-14-14-2	Elicit an immune antibody response against JEV
pre-Membrane (prM)	membrane protein is the minor component of the outer surface of virus particle, mediates processing and folding of E protein	JEV SA-14-14-2	Elicit an immune antibody response against JEV

**Purpose of the Dealings with the GMO**

Sanofi Pasteur Pty Ltd has applied for a commercial release of a live attenuated GM viral vaccine in Australia as a prescription medicine. The release involves the commercial release of GM vaccine known as IMOJEV™. The commercial release will occur in medical facilities throughout Australia. The vaccine is intended for people travelling to areas where JEV is endemic and would be prescribed by registered medical practitioners to persons over 12 months of age.

\* Information that must be included in the Record of GM Products and GMO dealings.