# Questions & Answers on licence application DIR 207 – Commercial release of a genetically modified (GM) mosquito strain to help prevent dengue outbreaks

## What is this application for?

Oxitec Australia Pty Ltd (Oxitec) is seeking approval for the commercial release of GM mosquitoes in Queensland to reduce the population of *Aedes aegypti* mosquitoes, which carry diseases such as dengue. In Australia, these mosquitoes can be found in north and central Queensland and parts of southern Queensland, where they have been linked to dengue outbreaks (<u>Factsheet – General mosquito information</u>)

### Who is Oxitec Australia?

Oxitec Australia is an Australian private biotechnology company that belongs to a United States-owned company with headquarters and research and development facilities in the United Kingdom. Oxitec develops biological solutions to control pests that can transmit diseases. More information on Oxitec can be found on its <u>website</u>. Oxitec has partnered with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to put forward this application to tackle these disease spreading mosquitoes. More information on this partnership can be found <u>here</u>.

# What is the role of the Office of the Gene Technology Regulator in this application?

The Office of the Gene Technology Regulator (OGTR) works under the *Gene Technology Act 2000* to protect the health and safety of people, and the environment by identifying risks posed by or as a result of gene technology and managing those risks through regulating certain dealings with genetically modified organisms.

The OGTR does not consider the following matters as they fall outside of the remit of the *Gene Technology Act 2000*:

- Risks posed by the wild mosquito.
- Effectiveness of the GM mosquito in reducing the population of Aedes aegypti mosquitoes.
- Any potential trade and market impacts.

These matters would be considered by other agencies described below.

# What other regulatory processes apply to this release?

The applicant will also need separate authorisations from the:

- <u>Australian Pesticides and Veterinary Medicines Authority (APVMA)</u> before this GM mosquito strain can be sold and used.
- <u>Department of Agriculture, Fisheries and Forestry (DAFF)</u> prior to importing the GM mosquitoes into Australia.
- <u>Department of Climate Change, Energy, the Environment and Water (DCCEEW)</u> for the GM mosquito to be included in the live import list.

# (Factsheet – Regulator's infographics)

# What has the OGTR taken into consideration in the assessment of the application?

The following risk considerations have been taken into account in the preparation of the Risk Assessment and Risk Management Plan (RARMP). The OGTR has considered the potential for:

- harm due to accidental exposure of humans and animals to the GM mosquitoes.
- transmission of disease by the GM mosquitoes.
- negative impact on the environment cause by the GM mosquitoes.
- the GM mosquitoes to breed with other species of mosquitoes.

• the GM mosquitoes to reduce the effectiveness of *Wolbachia* as a dengue control strategy.

(Factsheet – Risk Assessment Considerations)

### How will the GM mosquito be used in Australia?

- This application is for the release of GM mosquitoes in Queensland only.
- Dried GM mosquito eggs will be imported into Australia and packed into rearing boxes.
- Water would be added to the rearing boxes at release sites in Queensland where *Ae. aegypti* mosquitoes are present.
- Only male mosquitoes carrying the modified genes would develop to adulthood and fly out from the rearing boxes.

### How has the GM mosquito been modified?

• The *Aedes aegypti* mosquito has been modified by the insertion of genes that prevents the survival of female offspring and to produce a fluorescent protein for identification under specialised light.

### How does the GM male mosquito reduce the wild population of Ae. aegypti mosquitoes?

- GM male mosquitoes would mate with wild female mosquitoes and only produce male offspring that carries the genetic modification (<u>Factsheet Summary of application</u>).
- This cycle continues and will gradually reduce the population of wild mosquitoes due to the lack of females available to mate.
- The GM male mosquitoes disappear within 10 generations if no further GM mosquitoes are released.

### Can the GM male mosquito spread disease or cause harm?

- Only male GM mosquitoes will survive into adulthood. As males do not bite, they are unable to transmit disease.
- The GM mosquitoes are not toxic or allergenic to people or animals.

#### Is the GM mosquito used to spread vaccines?

• No, despite some commentary online, there is no relationship between the GM mosquitoes and any vaccines. The GM male mosquitoes do not bite.

#### Has the GM mosquito been previously tested or used?

- The GM mosquito was approved for commercial release in Brazil in 2020.
- Field trials of the GM mosquitoes have been carried out in Brazil (2018) and the USA (2020).
- No negative impacts were reported from the field trials or commercial release.

#### What controls are proposed for this release?

The licence application proposes an ongoing commercial release in Queensland. The Gene Technology Regulator has prepared a consultation RARMP, which concludes that the proposed commercial release of this GM mosquito poses negligible risk to the health and safety of people or the environment. However, licence conditions would require the licence holder to notify the Regulator of any new information, and to provide an annual update of the release.

#### How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 207 are available on the <u>OGTR</u> <u>website</u>, the <u>consultation hub</u> or via the contacts listed below. You are invited to submit your written comments (via the <u>consultation hub</u> or by email) related to any risks to the health and safety of people or to

the environment from the proposed release. Comments must be received by the close of the consultation period on **7 July 2025**.

Please note that issues such as **quality and efficacy of a biological pest control agent, marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities.

#### What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

# The Office of the Gene Technology Regulator <u>OGTR Website</u> E-mail: ogtr@health.gov.au