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

13 November 2024

Summary of Licence Application DIR 207

Oxitec Australia Pty Ltd (Oxitec) has made an application under the *Gene Technology Act 2000* (the Act) for the commercial release of a genetically modified mosquito.

Project Title	Commercial release of a genetically modified (GM) mosquito strain to help prevent dengue outbreaks[1].
Parent organism	Mosquito (*Ae. aegypti*)
Genetic modifications	• Expression of a self-limiting gene to prevent female mosquito larvae from surviving to adulthood. • Expression of a red fluorescent marker allowing for easy identification of the GM mosquito.
Principal purpose	Commercial release of GM mosquitoes for the purpose of decreasing the population of *Ae. aegypti* mosquitoes in Queensland.
Previous releases	• The product is approved and commercially available in Brazil. • Oxitec has conducted field trials in Brazil and in the United States.
Proposed limits	
Proposed location	Queensland
Proposed release size	Ongoing from date of issue of licence

The application

Female *Aedes aegypti* mosquitoes are responsible for biting and transmitting diseases such as dengue, chikungunya and Zika viruses in many countries. These mosquitoes are not native to Australia but arrived over 100 years ago and are currently found in north and central Queensland and parts of southern Queensland, where they have been linked to dengue outbreaks.

Oxitec Australia Pty Ltd (Oxitec) is seeking approval to commercialise a strain of GM mosquito to help control the population of *Ae. aegypti* mosquitoes in Queensland. Eggs of the GM mosquito strain, called OX5034 *Ae. aegypti*, would be produced overseas and imported into Australia. These eggs would be used to prepare mosquito rearing boxes at a dedicated facility in Queensland. The mosquito rearing boxes would be used to release the GM mosquitoes into the environment.

The OX5034 *Ae. aegypti* mosquito strain has been modified for the selective expression of the rTAV-OX5034 protein in female mosquitoes. This protein causes the death of female mosquito larvae, while males survive and develop to adulthood. Additionally, the OX5034 *Ae. aegypti* mosquitoes express a red fluorescent marker, known as DsRed2, which facilitates their identification.

Upon deployment of the mosquito rearing box, only male mosquitoes carrying the modified genes would develop to adulthood and be released into the environment. These male mosquitoes would mate with wild female mosquitoes and the modified genes would be passed on to the offspring. Female offspring carrying at least one copy of the self-limiting gene produce the rTAV-OX5034 protein and so would die during the larval stages, while males would survive to adulthood, continuing the cycle. Male mosquitoes do not bite humans or other animals, and they cannot transmit disease. It is expected that the continuous release of the

[1] Application title as provided by the applicant: Aedes aegypti mosquito strain OX5034 for commercial release in the state of Queensland

GM mosquitoes would reduce the population of *Ae. aegypti* mosquitoes. If the releases stop and in the absence of GM male mosquitoes, the number of GM mosquitoes would gradually reduce, and the wild mosquito population would return to its initial state.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

After seeking advice from prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comments on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **late March 2025**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- 'Questions and Answers' document for this application
- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR 207
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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