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 to reduce the population of *Aedes aegypti* mosquitoes and help to prevent dengue outbreaks. Female *Ae. aegypti* mosquitoes are responsible for biting and transmitting diseases such as dengue, chikungunya and Zika viruses in many countries. 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. Eggs of the GM mosquitoes would be packed into mosquito rearing boxes and would be available for sale to pest control professionals, businesses and the general public in Queensland.

What other regulatory processes apply to this commercial product?

The applicant will need to separately apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for approval before this GM mosquito strain can be sold and used. They will also require approval from the Department of Agriculture, Fisheries and Forestry (DAFF) prior to importing the GM mosquitoes into Australia. In addition, the applicant may require approval by the Queensland government.

How has the GM mosquito strain been modified?

The GM mosquito strain, called OX5034 *Ae. aegypti,* has been modified for the selective expression of a self-limiting gene. Female mosquitoes carrying at least one copy of this gene die during the larval stages, while males survive and develop to adulthood. These mosquitoes also express a red fluorescent marker, which facilitate their identification.

How the GM mosquitoes would be used?

Eggs of the GM mosquito strain would be produced overseas and imported into Australia. Mosquito rearing boxes would be assembled in a dedicated facility in Queensland. Only male mosquitoes carrying the modified genes would develop to adulthood and be released from the mosquito rearing boxes. These male mosquitoes would mate with wild female mosquitoes and the modified genes would be passed on to the offspring. Female offspring carrying the self-limiting gene would not survive, while males would develop to adulthood and continue the cycle. Male mosquitoes do not bite humans or other animals and they cannot transmit disease. If the releases stop, the number of GM mosquitoes would gradually reduce over time and the wild mosquito population would return to its normal state.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised taking into account submissions received, and inform the Regulator's decision whether or not to issue a licence.

How can I comment on this application?

The comprehensive RARMP for this application is expected to be released for public comment in **March 2025**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 207. A summary of the application is available on the OGTR website or by contacting the OGTR.

The Office of the Gene Technology Regulator
Tel: 1800 181 030 E-mail: ogtr@health.gov.au
OGTR website