PSGR

Physicians & Scientists for Global Responsibility

June 16, 2025.

Submission

Consultation on the commercial release of a genetically modified (GM) mosquito strain (DIR 207)

Submitted to the:

OGTR/Australian Government, Department of Health, Disability and Ageing.

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PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) works to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

PSGR express alarm at the evidence that the Office of the Gene Technology Regulator (OGTR) to requires so little evidence before proposing to release a genetically modified (GM) mosquito strain to help prevent dengue outbreaks (DIR 207).

DIR-207

- Risk Assessment and Risk Management Plan (Consultation version)
- Questions & Answers on licence application DIR 207
- Summary of Application Commercial release of a genetically modified mosquito strain to help prevent dengue outbreaks (application under assessment).
- Risk assessment considerations

It is concerning that the OGTR are unable or unwilling to evaluate or demand evaluations of broader risks, including the efficacy of these GM (Genetically Manipulated) *Aedes aegypti* and *Aedes albopictus* mosquito strains.

The GM mosquito has been modified to express two proteins, the DsRed and the tTAV proteins. The proposed modification involves altering the mosquitoes' genes to ensure that female larvae do not survive to adulthood. Additionally, these mosquitoes are engineered to express a red fluorescent marker to make them easy to identify in the wild.

However, for some other reason other unintentional transgenes that are present, do not have to be declared.

The Australian Government seems to believe that the approval for release in Brazil, and corporate data on field trials in Brazil and the USA are sufficient for Australian purposes.

The public data that has been supplied is unfit for any purpose of risk analysis and assessment and would fall outside the scope of good regulatory practice.

There is no evidence that the OGTR have required that the applicant conduct a screening evaluation to identify other potential transgenes. The GM mosquitoes could be contaminated with site-directed nucleus guide fragments or from ingredients and reagents used in the process. Therefore, the GM mosquitoes may have more modifications – and hence more transgenes - than the two expressed proteins.

Therefore, the risk is that not only are there declared transgenes, but undeclared mutations and/or unintentional transgenes may promote resistance to insecticides or result in any other unintended change.

Gene flow between species within the Culicidae family is a recognised phenomenon. Insecticide resistance is an ever-present threat. Screening for all transgenes to identify mutations known to be associated with resistance is critical.

As a result, more transgenes than those expressed could spread into surrounding populations and alter the susceptibility of mosquitoes to existing controls (including insecticidal control).

There is no evidence that the OGTR has demanded an assessment of these risks.

The OGTR Risk Assessment and Risk Management Plan Consultation version) suggests that the increasing sophistication and use of instrumentation used by corporations, has not stretched into the

regulatory environment, to ensure that regulatory agencies keep pace with the speed and pace of development in the corporate sector.

The effect is a decline in regulatory standards, due to the asymmetrical escalation in advancement in corporate development. Over time, it will become increasingly untenable for the OGTR to uphold public confidence and trust due to this substantial erosion of good process.

The OGTR notes 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.

The *object* of the Gene Technology Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The OGTR are tasked with protecting the health and safety of people and the environment by identifying risks.

The efficacy of this organism is *of the essence*, - it is directly dependent to its capacity to be safely released as there is an assurance that it will reduce mosquito populations. Therefore, the modified *Aedes aegypti* and *Aedes albopictus* strains would ultimately 'die out'.

The OGTR have an obligation to assess the risks involved, and to publicly disclose the efficacy of this organism, if they are to uphold the purpose of the Act that gives the OGTR powers. Simply deferring to the ACVMA is insufficient to uphold public confidence.

Furthermore, the Summary of the Risk Assessment and Risk Management Plan additionally fails to take into account the existing dengue fever control programme and any potential off-target (i.e., unintended) impact on domestic mosquito populations.

The existing control programme harnesses the bacterium Wolbachia to render mosquitoes immune to certain diseases, including dengue fever virus. The programme has been exceptionally successful.

The OGTR have not addressed the cumulative uncertainty in any transparent cost-benefit analysis. There has been no appraisal of the capacity for a high rate of transmission of the introduced gene to induce death in the female offspring of Australian species, in combination with an already successful control programme.

It is evident that the Australian Government, because of funding parcels directed to the CSIRO, have a demonstrable conflict-of-interest in the GM-mosquito release. The proposed commercial sale and release of imported GM (Genetically Manipulated) *Aedes aegypti* and *Aedes albopictus* mosquitoes is an arrangement between **Oxitec UK and CSIRO** (jointly Oxitec Australia).

This collaboration may have prompted this proposal, where Australia would be an early-adopter of this technology. We ask that the OGTR step away from this release due to the absence of suitable data on the safety of such a programme.