

# Genetically Engineered Mosquitoes Proposed for Release in California: Risks and Concerns

California is poised to be the second state where genetically engineered (GE) mosquitoes may be released, unless the public and California's government officials demand otherwise. In March 2022, U.S. EPA approved the experimental release of GE mosquitoes in California and Florida. In 2021, half a billion GE mosquitoes were released in Florida for the first time. Now, Tulare County, in the heart of California's agricultural Central Valley, is targeted for the next release of GE mosquitoes. This open-air genetic experiment poses significant environmental and public health risks.

## Summary of Concerns

Oxitec, a UK-based corporation, is proposing a mass release, even though:

- Assessments of potential human health impacts, like allergenicity, are incomplete;
- This trial could result in invasive mosquitoes that may be more aggressive,
- more difficult to eradicate, and may increase the spread of mosquito-borne disease;
- The communities where the GE mosquitoes could be released have not been consulted and have not consented to being part of this open-air genetic experiment;
- Oxitec has not published data from field trials in Florida ahead of a second release;
- Endangered species assessments were inadequate; and
- California does not have any locally transmitted cases of dengue or zika.



## What is the GE Mosquito?

The proposed experiment is meant to determine whether the mass release of GE mosquitoes can reduce the population of *Aedes aegypti*, one mosquito species that can carry the viruses that cause yellow fever, dengue, chikungunya and Zika.<sup>1</sup> None of these diseases are endemic in California or in the U.S. outside of Puerto Rico.<sup>2</sup> Oxitec has genetically engineered *Aedes aegypti* mosquitoes to depend on the presence of tetracycline, an antibiotic, and for its female offspring to die in its absence. In theory, the GE male mosquitoes would mate with wild females, and their tetracycline-dependent gene would be passed on to their female offspring. The female offspring, when they aren't exposed to tetracycline, are meant to die in the late larval or pupal stage. While limiting the spread of mosquito-borne disease is important, once GE mosquitos are released into the wild, there is no calling them back, and scientists have raised important concerns about the efficacy and potential risks associated with this open-air experiment.



## Scientific Concerns

**To date, GE mosquitoes have not reduced mosquito populations.** Oxitec has conducted GE mosquito field trials in the Cayman Islands, Malaysia, Panama and Brazil. To date, peer reviewed studies on the GE mosquito that show it effectively reduced *Aedes aegypti* mosquito populations have not been published.<sup>3</sup> Also, there is no publicly available data from the 2021 field trials in Florida, neither from Oxitec nor the Monroe County (Florida Keys) mosquito control district, to support Oxitec's claims that their GE mosquitoes reduced local *Aedes aegypti* populations.

**Hybrid GE-wild mosquitoes could be created that may be more resistant to pesticides and more aggressive.** Data from a trial in Brazil found genetic material from Oxitec's GE mosquitoes in wild mosquitoes, creating hybrid mosquitoes.<sup>4</sup> The researchers named that hybrid wild GE mosquitoes could result in increased mosquito populations and flagged for research whether hybrid mosquitoes could potentially contribute to the spread of viral diseases like Zika, West Nile and Dengue.<sup>5</sup> A study highlighted that these hybrid mosquitoes may be more resistant to insecticides and even more aggressive than their wild counterparts. Wild hybrids may also be able to transmit viruses more easily.<sup>6</sup>

**Reduction in populations of one type of mosquito could result in an increase in others.** *Aedes aegypti* mosquitoes are only one of several species of mosquitoes that can carry diseases. If the experiment succeeded in reducing populations of *Aedes aegypti*, other varieties, such as the *Aedes albopictus* (Asian tiger), which also transmit dengue and other similar viruses, could increase in number to fill the ecological niche.<sup>7,8,9</sup>

**Female GE mosquitoes could survive and spread disease.** Oxitec's trial application states that female offspring — which bite and spread disease — will die before they mature into adults, and therefore exposure to biting female mosquitoes is not anticipated. However, females have been inadvertently released in Oxitec's experiments.<sup>10,11</sup> Data also show that females may survive in the presence of tetracycline — an antibiotic that is widely used in California agriculture and therefore is likely present in the environment. Because of the very large numbers of GE mosquitoes proposed for release (up to 30,000 mosquitoes per acre, per week or up to 1.6 million per acre per year),<sup>12</sup> even a small percentage of surviving biting female GE mosquitoes may lead to a significant number of females in the environment. This could lead to an increased mosquito population in in Tulare County, California where mosquitoes are proposed for release.



**GE mosquitoes may inject novel proteins into humans and other animals.** Biting female GE mosquitoes may inject a novel engineered protein into humans and other animals.<sup>13</sup> Oxitec has yet to show that these novel proteins would not harm humans or other animals. However, EPA did not do a full risk assessment for the allergenic or toxic effects of the genes inserted into the mosquitoes.<sup>14</sup>

**Insufficient studies have been completed to assess risks to endangered species.** The Tulare Basin is home to endangered, threatened, and sensitive animal species, some endemic to Tulare.<sup>15</sup> Yet, EPA's endangered species assessments prior to the release of GE mosquitoes are inadequate. Feeding trials for key mammals and birds could provide important insights about what impacts the GE mosquitoes may have on endangered or threatened species. However, no feeding trials have been done using mammals or birds, they just used "aquatic invertebrates (crayfish)" and guppies.<sup>16</sup>

## **Lack of Transparency**

Oxitec's proposal has not undergone independent scientific review, and EPA has not convened a Scientific Review Panel as it has done for other new pesticides. Neither the full proposal nor data from the 2021 releases in Florida are publicly available. In addition, Oxitec's community engagement has not been transparent. In 2021, Oxitec released GE mosquitoes as part of an experimental trial in Monroe County, Florida. Neither the mosquito control board nor Oxitec informed community residents about the locations of release until three days beforehand. Residents were not given advance warning about the exact date the release was set to occur and there was no free and prior informed consent by affected community members — a fundamental tenet of any research involving human subjects.

## **Lack of Regulations Specific to GE Insects**

Currently, there are no regulations in the U.S. specific to GE insects. EPA regulates GE mosquitoes as biopesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), but because of their potential impacts on the environment and human health,<sup>17</sup> critics have named the need for full environmental and health assessment and oversight.<sup>18</sup> Prior to any further consideration of a release in California, CEQA (California Environmental Quality Act) analysis, as well as regulations specific to GE insects, must be in place. In addition, government agencies must not solely rely upon company self-assessment of risks and must require third-party peer-reviewed public health and environmental assessments.

For More Information: <https://foe.org/projects/gmo-animals/>  
Contact: [melias@foe.org](mailto:melias@foe.org)

## Endnotes

- 1 Friends of the Earth. (2020). Genetically Engineered mosquitoes Issue Brief. [https://1bps6437gq8c169i0y1drt\\_gz-wpengine.netdna-ssl.com/wp-content/uploads/2020/07/FOE\\_GE-Mosquitoes\\_issue\\_brief.pdf](https://1bps6437gq8c169i0y1drt_gz-wpengine.netdna-ssl.com/wp-content/uploads/2020/07/FOE_GE-Mosquitoes_issue_brief.pdf).
- 2 Centers for Disease Control and Prevention. (2020) Dengue in the US States and Territories. <https://www.cdc.gov/dengue/areaswithrisk/in-the-us.html>
- 3 GeneWatch UK comments on docket identification (ID) number EPA-HQ-OPP-2019-0274-0001: New Active ingredient for Oxitec OX5034 *Aedes aegypti* mosquitoes. (2019) GeneWatch UK. [http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatch\\_EPA\\_Oxitec\\_consul19\\_fin.pdf](http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatch_EPA_Oxitec_consul19_fin.pdf)
- 4 Evans, B.R., Kotsakiozi, P., Costa-da-Silva, A.L. et al. Transgenic *Aedes aegypti* Mosquitoes Transfer Genes into a Natural Population. *Sci Rep* 9, 13047 (2019). <https://doi.org/10.1038/s41598-019-49660-6>.
- 5 Ibid
- 6 Ibid
- 7 "100 of the World's Worst Invasive Alien Species." Global Invasive Species Database. Invasive Species Specialist Group, Nov. 2004. Web. <http://www.issg.org/database/species/search.asp?st=100ss>.
- 8 CDC (2017) Estimated potential range of *Aedes aegypti* and *Aedes albopictus* in the United States, 2017. <https://www.cdc.gov/zika/vector/range.html>
- 9 Zhong, D., Lo, E., Hu, R., Metzger, M. E., Cummings, R., Bonizzoni, M., Fujioka, K. K., Sorvillo, T. E., Kluh, S., Healy, S. P., Fredregill, C., Kramer, V. L., Chen, X., & Yan, G. (2013). Genetic Analysis of Invasive *Aedes albopictus* Populations in Los Angeles County, California and Its Potential Public Health Impact. *PLOS ONE*, 8(7), e68586. <https://doi.org/10.1371/journal.pone.0068586>
- 10 Evans, B.R., Kotsakiozi, P., Costa-da-Silva, A.L. et al. Transgenic *Aedes aegypti* Mosquitoes Transfer Genes into a Natural Population. *Sci Rep* 9, 13047 (2019). <https://doi.org/10.1038/s41598-019-49660-6>.
- 11 Section G- Proposed Experimental Program. <https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0467>
- 12 Environmental Protection Agency (2021). Application: pesticide Experimental Use Permit. <https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0363>
- 13 GeneWatch UK comments on docket identification (ID) number EPA-HQ-OPP-2019-0274-0001: New Active ingredient for Oxitec OX5034 *Aedes aegypti* mosquitoes. (2019) GeneWatch UK. Benedict et al., Defining Environmental Risk Assessment Criteria for Genetically Modified Insects to be Placed on the EU Market, Scientific/technical report submitted to EFSA (EFSA-Q-2009-01081), at 97-99 and 135 (Sept. 10, 2010), <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2010.EN-71>
- 14 Environmental Protection Agency (2022). Human Health and Environmental Risk Assessment of OX5034 *Aedes aegypti* Containing Tetracycline-Repressible Transactivator Protein Variant (tTAV-OX5034, New Active Ingredient), DsRed2-OX5034 Protein (new inert ingredient), and the Genetic Material Necessary (Vector pOX5034) for Production of the Proteins in vivo. Data and Information Provided in Support of an Extension and Amendment to a FIFRA. <https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0465>
- 15 California Department of Fish and Wildlife. (2021). State and Federally Listed Endangered and Threatened Animals of California. [https://nrm.dfg.ca.gov/FileHandler.ashx?DocumentID=109405&inline:Tulare Basin Watershed Partnership. Wildlife of the Tulare Basin](https://nrm.dfg.ca.gov/FileHandler.ashx?DocumentID=109405&inline=Tulare+Basin+Watershed+Partnership+Wildlife+of+the+Tulare+Basin). <https://www.tularebasinwatershedpartnership.org/wildlife.html>
- 16 Environmental Protection Agency (2022). Human Health and Environmental Risk Assessment of OX5034 *Aedes aegypti* Containing Tetracycline-Repressible Transactivator Protein Variant (tTAV-OX5034, New Active Ingredient), DsRed2-OX5034 Protein (new inert ingredient), and the Genetic Material Necessary (Vector pOX5034) for Production of the Proteins in vivo. Data and Information Provided in Support of an Extension and Amendment to a FIFRA. <https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0465>
- 17 EPA Approves Experimental Use Permit to Test Innovative Biopesticide Tool to Better Protect Public Health. (2020) U.S. Environmental Protection Agency. <https://www.epa.gov/pesticides/epa-approves-experimental-use-permit-test-innovativebiopesticide-tool-better-protect>
- 18 Kofler, N., Kuzma, J. (2020) Before genetically modified mosquitoes are released, we need a better EPA. <https://www.bostonglobe.com/2020/06/22/opinion/before-genetically-modified-mosquitoes-are-released-we-need-better-epa/>.