OXITEC

Myth vs. Fact

The Truth About Oxitec's Technology and Proposed California Project

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Myth: Oxitec's mosquitoes pose significant environmental and public health risks, and no assessments to endangered species assessments or potential human health impacts have been done.

Fact: Oxitec's projects in all territories have received full regulatory approvals which are widely documented. For the Florida project, the U.S. Environmental Protection Agency (EPA), U.S. Centers for Disease Control and Prevention (CDC), and the State of Florida approved the Experimental Use Permit (EUP) following an exhaustive regulatory assessment that included more than 70 scientific and technical documents, 4,500 pages of material, and 25 commissioned scientific studies.

All found that Oxitec's technology poses no risk to humans, animals or the environment, including endangered species. The U.S. EPA also opened a public comment period after which it provided direct, technical answers to each substantive question submitted. Those technical responses can be found here.

Myth: Oxitec released half a billion GE mosquitoes in Florida in 2021.

Fact: The actual number is less than 10 million.

Myth: Hybrid mosquitoes that may be more aggressive, more difficult to eradicate, and may increase the spread of mosquito-borne disease.

Fact: Oxitec's self-limiting genes have been tested for a decade and have demonstrated to disappear from the environment; natural background genes also decline over time. Extensive scientific literature confirms that there is no hybrid vigor or selective mating observed. Claims in an article stating that 'hybrid' mosquitoes might be more aggressive or increase the spread of disease, were discredited when the journal's editors published an Editorial Expression of Concern regarding these scientifically unfounded claims.

Myth: The communities where Oxitec's mosquitoes are to be released have not been consulted have not consented to being part of this open-air genetic experiment.

Fact: Oxitec is not testing on humans and this project is not introducing risk to humans, animals, or the environment, as stated by the EPA and FDA. This project will only be releasing non-biting males that do not bite humans. Further, "EPA does not find that the research involved with Oxitec's release of male OX5034 mosquitoes meets the regulatory definition of research involving human

subjects…therefore the requirements of EPA's human studies rule do not apply to this research proposed by Oxitec" (p134, Response to Comments).

Oxitec works closely with the communities in project areas and relevant authorities to provide information, education and an open line of communication to answer questions from individuals, businesses, conservationists and other stakeholders. There is more demand in the Florida Keys to host Oxitec's boxes and traps than there is availability.

Myth: Oxitec claims the data and results from earlier trials in other countries and in Florida are confidential business information and will not make them available to the public.

Fact: In Florida, data is not available yet. The pilot project is still in operation. We plan to release data at a later date. In Brazil, data has been released and can be found here, among others.

Myth: Oxitec's mosquitoes depend on the presence of tetracycline.

Fact: The use of tetracycline was addressed in detail by the EPA, FDA and Florida regulators, each of which looked at this exhaustively and found no risk. There is no exposure of Oxitec male mosquitoes to tetracycline, either as eggs in the labs in the UK or as adults in the US.

Myth: None of the vector-borne diseases are endemic in California or in the U.S. outside of Puerto Rico.

Fact: It is well documented that the spread of vector-borne diseases is a growing risk in California. *Aedes aegypti* and *Aedes albopictus*, two invasive (non-native) mosquito species have been found in over 300 cities throughout California, and there is a potential for them to spread into other areas of California. According to the California Department of Public Health, "none of these viruses are currently known to be transmitted within California, but thousands of people are infected with these viruses in other parts of the world, including in Mexico, Central and South America, the Caribbean, and Asia. The presence of *Aedes aegypti* mosquitoes in California poses a threat that Zika, dengue, and chikungunya viruses can be transmitted in infested areas from returned infected travelers." See: Aedes aegypti in California for more details. In the Florida Keys, there was a dengue outbreak as recently as last year.

Myth: To date, GE mosquito trials have failed to reduce mosquito populations.

Fact: This statement is false. The first field pilot of Oxitec's 2nd Generation mosquito in Brazil resulted in up to 96 percent suppression of the *Aedes aegypti* mosquito. See: Suppression in Brazil. Previous trials of Oxitec's 1st Generation mosquito in Brazil, Cayman Islands and Panama were all successful in suppressing the invasive mosquito populations, and details are available in peer-reviewed articles here and here.

Myth: Hybrid GE-wild mosquitoes could be created that may be more resistant to pesticides and more aggressive.

Fact: Natural genes carried by Oxitec mosquitoes do not confer increased capacity to transmit disease nor resistance to commonly used insecticides, as confirmed by EPA in the risk assessment for Oxitec's 2nd Generation mosquito.

Myth: *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.

Fact: There is no scientific evidence of this. In fact, in previous trials of Oxitec's 1st Generation mosquitoes in Panama, the company demonstrated that there was no increase in *Aedes albopictus* following suppression of the *Aedes aegypti* population (Gorman et al, 2016).

Myth: Female GE mosquitoes could survive and spread disease.

Fact: Oxitec only releases self-limiting and non-biting male mosquitoes. There are no female mosquitoes released in any pilot of Oxitec's 2nd Generation mosquito.

Myth: In 2019, Yale University conducted a field study in Brazil, found that GE mosquitoes' genetic alterations had spread into the wild population.

Fact: The study's data in Scientific Reports paper does not identify negative, deleterious or unanticipated effect on people or the environment from the release of Oxitec's 1st Generation (OX513A) mosquitoes. The paper's authors made speculative statements and selectively ignored body of critical peer-reviewed evidence, including their own, describing safety and effectiveness of technology. Oxitec's OX513A self-limiting genes have been tested for a decade and have demonstrated to disappear from the environment; natural background genes also decline over time. Data in this paper and other scientific literature confirm that there is no hybrid vigor or selective mating observed. The paper was later subject to an Editorial Expression of Concern which dismissed many of the speculative and unfounded statements made by the authors.

Myth: There are significant levels of tetracycline in California, an antibiotic used in agriculture that can trigger the survival of female GE mosquitoes. The data on this environmental phenomenon has been redacted by Oxitec, so it is not possible for the public to properly assess this risk in California.

Fact: In the unlikely event of a female bred with OX5034 laying eggs in an environment with tetracycline present, then female OX5034 mosquitoes could survive if the growth conditions were appropriate and if the tetracycline concentration were high enough. However, EPA assessed this possibility in their risk assessment for Florida:

"*Several lines of evidence including a survey of environmental levels of tetracycline, tetracycline dose-response testing of OX5034 females, and oviposition behavior of Ae. aegypti, indicate that the risk of hemizygous OX5034 female mosquitoes emerging in the environment due to high levels of tetracycline is low. Trial site location restrictions using known Ae. aegypti dispersal distances to limit exposure to locations with higher probabilities of containing tetracycline would further reduce the likelihood of OX5034 females in the environment to*

the point where the risk would be considered negligible." This is a summary of a much more extensive discussion of this issue, which is available on p31-34 of the Human Health and Environmental Risk Assessment.

It is anticipated that EPA will carry out a similar risk assessment ahead of any approval of mosquito releases in California.

Myth: There is the possibility that the dengue virus will evolve, rather than be eradicated when introduced to GE mosquitoes. The Aedes aegypti could become more virulent, and exacerbate the presence of the dengue virus in the United States.

Fact: Oxitec will be releasing male mosquitoes only, which do not bite, cannot acquire dengue virus from human hosts, and cannot transmit disease to other humans.

Myth: GE mosquitoes may inject novel proteins into humans and other animals.

Fact: Since no female mosquitoes are released, there is no way for these mosquitoes to bite humans. EPA's exhaustive study determined that there will be no unreasonable adverse effect to humans or the environment as a result of the experimental permit to release Oxitec's OX5034 male mosquito.

Myth: Thousands of comments opposing the Oxitec release in California were submitted.

Fact: There are many credible third-party experts who have expressed their support for Oxitec's technology including the National Association of County and City Health Officials (NACCHO), Marian Wilson Butterfly Garden, Mosquito Control Association of California, American Mosquito Control Association, Entomological Society of America, Society for Vector Ecology, Biotechnology Innovation Organization, the Reason Foundation and more. Many of the comments in opposition to Oxitec's application to amend its EUP contained false information based on misleading information campaigns.

Myth: The reduction of *Aedes aegypti* mosquitoes will impact the food chain.

Fact: *Aedes aegypti* is an invasive species, which has only recently been detected in California. It is not a critical part of the native species food chain, which has evolved over long periods of time. Further, EPA has assessed the likely impact of reducing *Aedes aegypti* populations and found that this would cause no unreasonable adverse effects to the environment.

Myth: Oxitec's pilot project in California will include the releases of hundreds of billions of GM mosquitoes over large acreage.

Fact: The number of mosquitoes, acreage, and time period stated in the EUP are not the amounts intended for pilot deployments. These figures represent the proposed (not yet approved) state-wide limits to be set by the EPA. If approved by both federal and state regulators, relatively small pilot projects would likely be conducted in just one or two counties, releasing just a fraction of the state-wide limits that the regulatory agencies approve.

Myth: Zika virus is transmitted by the Culex mosquito, an entirely different breed than the mosquito being prepped for release in California.

Fact: Zika, dengue, chikungunya viruses are all transmitted by the *Aedes aegypti* mosquito, not Culex.
