



Updated: 20 May 2021

## Fact Sheet

### Florida Keys Mosquito Control District - Oxitec Mosquito Project

#### Quick Facts:

---

US Environmental Protection Agency (EPA)-approved project is examining the use of non-biting male Oxitec-developed mosquitoes as a method of effective mosquito control for the first time in the United States. Oxitec's non-biting male mosquitoes emerge from just-add-water mosquito boxes situated on private property with owner permission.

- Placement of Oxitec's just-add-water mosquito boxes commenced week of April 26<sup>th</sup>
- Oxitec's non-biting male mosquitoes began to emerge the week of May 10<sup>th</sup>
- Project fully approved by the EPA and the State of Florida Department of Agriculture and Consumer Services (FDACS), and supported by an Independent Advisory Board.

#### Quick Links:

---

- [Project website – news, resources, information, events](#)
- [Project images](#) and [Virtual Tour: Inside Oxitec Labs Worldwide](#) (please contact us for available B-roll)
- [YouTube channel](#) with 13+ public webinars relating to a range of project topics
- [Video used during Virtual Press Conference](#)
- [EPA's approval and supporting documents, including scientific rationale and risk assessment](#)
- [Letter from EPA relating to misleading information](#)
- [List of 100+ scientific publications relating to Oxitec's technology](#)

#### Latest News: Landmark Project to Control Potential Disease Carrying Mosquitoes Kicks Off in the Florida Keys

- A collaborative effort between the Florida Keys Mosquito Control District (FKMCD) and Oxitec is evaluating the effectiveness of Oxitec's safe, non-biting male mosquitoes as a potential control method for the invasive, disease vector *Aedes aegypti* mosquito in the Florida Keys;
- The *Aedes aegypti* makes up approximately 4% of the mosquito population in the Keys, but is responsible for virtually all of the mosquito-borne disease transmission to humans;
- *Aedes aegypti* mosquitoes can transmit dengue, Zika and other diseases in people and heartworm and other deadly diseases to pets and animals;
- *Aedes aegypti* mosquitoes in the Florida Keys have consistently shown a developed resistance to EPA approved pesticides.



The groundbreaking project conducted jointly by the FKMCD and Oxitec started the week of April 26<sup>th</sup> after a decade of planning, public engagement and regulatory approvals.

Over the next few months, six locations in the Florida Keys will host Oxitec's male *Aedes aegypti* release boxes that will slowly release their self-limiting, male mosquitoes. Like all male mosquitoes, Oxitec's mosquitoes **DO NOT BITE**. They find and mate with invasive female *Aedes aegypti* mosquitoes, mediating a reduction of the target population as the female offspring of these encounters cannot survive. Oxitec's males are intended to reduce the number of potentially disease-transmitting female *Aedes aegypti*.

This project comes more than a decade after FKMCD first invited Oxitec to pilot its technology in the Keys. The project has received required regulatory approvals from federal and state regulators (U.S. EPA and FDACS respectively). In August 2020, the FKMCD Board of Commissioners formally approved the project. Extensive public consultation, education and engagement has been carried out and community support for the project remains high.

**Andrea Leal, Executive Director Florida Keys Mosquito Control District, said,** "Our primary mission is to protect residents in the Florida Keys from all mosquitoes including the disease-transmitting *Aedes aegypti*. The Florida Keys Mosquito Control District remains committed to seeking out environmentally-friendly and targeted tools to protect our residents and to preserve our wildlife. With full approval from the US EPA and the Florida Department of Agriculture and Consumer Services, as well as support from the US Centers for Disease Control and an independent advisory board, we are now eager to see the project progress over the coming months," she said.

**Grey Frandsen, Oxitec's CEO** said, "We're thankful for the opportunity to demonstrate the effectiveness of Oxitec's technology with such an outstanding partner. The challenges posed by disease-spreading mosquitoes is growing, not shrinking, making this pilot project a major step forward in bringing Oxitec's safe, self-limiting technology to the US."

Oxitec's *Aedes aegypti* technology is part of an expanding line of Oxitec technologies being developed to deliver safe, targeted biological control of pests. Oxitec's self-limiting technology has been deployed successfully around the world against major agricultural and public health pests.

Oxitec's just-add-water *Aedes aegypti* technology was successfully proven in the State of São Paulo, Brazil in 2019, where after just 13 weeks of treatment, the technology suppressed up to 95% of *Aedes aegypti*. In May 2020, Oxitec received full biosafety approval for this technology from Brazil's national biosafety regulatory authority CTNBio after demonstrating the technology's full safety to human health and the environment. Independent research found community support for the project was overwhelmingly high, with 94% of residents surveyed in favor of Oxitec's mosquito technology and its use in their neighborhoods.

#### **About the *Aedes aegypti*:**

The *Aedes aegypti* mosquito is an increasingly global threat, now living alongside half of the world's population. After decades of effort, there is still no cure or specific treatment for many diseases transmitted by the *Aedes aegypti*, and public health agencies are trying to stop these devastating diseases at their common source: by controlling the *Aedes aegypti* mosquito itself.



Unfortunately, existing methods of controlling *Aedes aegypti*, such as spraying or fogging using chemical insecticides, have failed to prevent the spread of disease. This is partly because *Aedes aegypti* has developed resistance to insecticides, rendering many common chemicals less effective at controlling the mosquito.

### **Why this Project is Important:**

- Oxitec's mosquitoes are a safe tool to combat invasive *Aedes aegypti* mosquitoes that are known to transmit dengue, Zika, chikungunya and other diseases;
- Oxitec's non-biting male mosquitoes do not produce female offspring. They find and mate with invasive female mosquitoes, mediating a reduction of the target population as the female offspring of these encounters cannot survive;
- This technology is designed to give governments and communities a powerful tool that can scale effectively without the need for complex infrastructure and serve as a stand-alone solution or as a valuable component of integrated vector management programs. To do so in the U.S., a commercial approval for the product from the EPA would be required. The data obtained under this Experimental Use Permit will contribute to any subsequent registration package that Oxitec submits to the EPA for consideration.

### **Highlights from Regulatory Agency Approvals:**

- EPA's exhaustive study determined that there will be no unreasonable adverse effect to humans or the environment as a result of the permit to release Oxitec's male mosquitoes;
- Oxitec is pleased that the EPA has completed such a rigorous assessment of the data provided for the OX5034 mosquito, and that a finding has been made of no unreasonable adverse effect to humans or the environment. EPA considered extensive data relating to human health and potential impacts on the environment, non-target organisms and endangered species. Additional opinion was provided by mosquito-borne disease experts at the U.S. Centers for Disease Control (CDC);
- EPA also reviewed over 30,000 public comments in its determinations and responded in detail to all substantive comments made during the public consultation period for this application. Responses to comments are available in the EPA docket.

*EPA's OX5034 docket can be found [here](#).*

- Following EPA's approval, the project was also approved by the Florida Department of Agriculture and Consumer Services, incorporating reviews from other Florida agencies including the Florida Department of Environmental Protection (FDEP), the Florida Fish and Wildlife Conservation Commission (FWC), the Florida



Department of Health (DOH), the Bureau of Agricultural Environmental Laboratories (BAEL) and the Bureau of Scientific Evaluation and Technical Assistance, Scientific Evaluation Section (SES).

#### **Key Findings Include:**

- No unreasonable adverse effects for humans or the environment due to introduction of background strain genetics into the local *Aedes aegypti* population;
- No unreasonable adverse effects for non-target organisms (bats, invertebrates, amphibians, etc.), either due to consumption of OX5034 males or due to decreases in the invasive mosquito population;
- EPA has made a “no effect” finding as to threatened or endangered species under the Endangered Species Act;
- EPA concluded negligible risk of OX5034 mosquitoes spreading antibiotic-resistant bacteria in the U.S. environment.
- Careful Monitoring and Surveillance: EPA approved Oxitec’s robust monitoring program for the trial, to track the mosquito releases and their impact. Releases include buffer zones, so they do not occur in the vicinity of potential environmental tetracycline sources, such as citrus orchards or sewage treatment plants. EPA acknowledges that these are extremely unlikely to be *Aedes aegypti* breeding sites;

#### **Project Locations:**

This technology is likely to have the most impact in U.S. locations that are most threatened by this invasive species, such as Monroe County, Florida.

**This project is being carried by the Florida Keys Mosquito Control District and Oxitec, with mosquito releases for the first phase of the project in Cudjoe Key, Ramrod Key and Vaca Key.**

Untreated comparison sites will be monitored with mosquito traps on Key Colony Beach, Little Torch Key, and Summerland Key. Throughout all release locations less than 12,000 mosquitoes are expected to emerge each week for approximately 12 weeks.

#### **Related milestones:**

**2006-2007:** Oxitec first released genetically-modified pink bollworm (possessing the marker gene only) as part of efforts to eradicate this pest from cotton crops in Arizona, with approvals from USDA



**2016:** FDA granted approval for small-scale project with Oxitec's first-generation mosquito, OX513A, in the Florida Keys

**2017:** Oxitec released genetically-modified diamondback moth in New York State as part of a project to evaluate its use in protecting field crops like broccoli, with approvals from USDA

**2017:** FDA transferred jurisdiction over GM insects to EPA

**2019:** Oxitec applied to EPA for an Experimental Use Permit (EUP) for its second-generation mosquito OX5034

**2020:** EPA granted the EUP for pilot projects of OX5034 in Florida and Texas

**2020:** Florida state authorities also authorized the EUP for OX5034 releases in Monroe County, Florida

**2020:** The Florida Keys Mosquito Control Board of Commissioners approved the project in the Florida Keys.

**2021:** First releases of OX5034 mosquitoes in the Florida Keys to evaluate the effectiveness of this control tool for *Aedes aegypti*



## FAQ

### **Q: Why target the *Aedes aegypti* mosquito?**

The *Aedes aegypti* mosquito makes up approximately four percent of the mosquito population in the Keys but is responsible for virtually all mosquito-borne diseases transmitted to humans. This species of mosquito transmits dengue, Zika, yellow fever and other human diseases, and can transmit heartworm and other potentially deadly diseases to pets and animals.

### **Q: How does the Oxitec technology work?**

We use genetics to provide two useful traits in our insects. A self-limiting gene allows us to release male-only adult mosquitoes into the environment, which mate with pest females, and the self-limiting gene prevents female offspring from surviving. With sustained releases of self-limiting males the number of pest females in the population declines, and the target pest population declines. Our insects also carry a fluorescent marker gene which, in traps from the field, allows us to distinguish the self-limiting insects from wild counterparts, for effective monitoring.

### **Q. Why do only female offspring die?**

Oxitec's mosquitoes carry a self-limiting gene that is only active in females, therefore preventing females from surviving; males are not affected by this gene, so can survive as normal. This is Oxitec's '2<sup>nd</sup> Generation' technology, which is designed to prevent survival of female offspring to allow for production of male-only cohorts of mosquitoes. In the field, it is female *Aedes aegypti* that bite humans and transmit diseases such as dengue and Zika viruses.

### **Q. What are the risks if a female Oxitec mosquito bites someone?**

We release only male mosquitoes because the self-limiting gene prevents females from surviving. However, even if someone were to be bitten by a female Oxitec mosquito, for example in our mosquito production facility, the bite of a female Oxitec mosquito is the same as the bite of a wild *Aedes aegypti*. The proteins of the two introduced genes are not expressed in the mosquito saliva, so a person bitten by a female mosquito would not be exposed to these proteins. In addition, these proteins are non-toxic and non-allergenic.

### **Q. Are self-limiting mosquitoes an environmentally sustainable vector control tool?**

Yes - because self-limiting mosquitoes work by finding and mating with wild females, the suppression effect is highly targeted to this species of mosquito. This specificity leaves non-target species, such as beneficial insects like bees and butterflies, unharmed.

### **Q. Why do you still need trials if everything is already proven safe?**

The EUP approved by the EPA and FDACS is not intended to demonstrate safety; that has already been done as part of the application and risk assessment process. The EUP is aimed at assessing efficacy and performance of the



OX5034 male mosquito in the US environment, as part of the process towards registration of the new biopesticide under FIFRA.

**Q. Why haven't you sought consent from residents for this project?**

The EPA ruled clearly on this subject: "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 is not testing on humans and this project is not introducing risk to humans, animals, or the environment, as stated by the EPA. This project will only be releasing non-biting males that do not bite humans. Oxitec is demonstrating the efficacy of its mosquito technology to control *Aedes aegypti* mosquitoes. This is analogous to other control products evaluated for use against mosquitoes like pesticides.

Oxitec has received outstanding support from Keys residents. Oxitec has obtained consent from residents hosting boxes and traps. Oxitec's technology received support in 31 of 33 Monroe County precincts in a 2016 referendum, highlighting a broad base of support that far surpassed any political candidate on the ballot.

The real risks to human health are the diseases (dengue, Zika, chikungunya, etc.) that are spread by the invasive *Aedes aegypti* mosquito, which this technology is designed to control.

**Q. What about risks associated with the presence of tetracycline antibiotics in the environment?**

EPA assessed this possibility:

"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.

EPA has also included guidelines on the project locations: releases will not be carried out within 500 m of citrus groves (where oxytetracycline could potentially be used for control of citrus greening) or within 500 m of municipal wastewater treatment plants (where pharmaceutical-use doxycycline might be present in effluent) (see EPA's approval of Oxitec's proposed pilot project).



### Q. Why not just use insecticides?

Insecticides are a valuable option available to mosquito control authorities and consumers for a broad range of mosquito species, but they aren't a complete solution. Over-reliance on this vector control method is not sustainable and has led to the development of resistance to insecticides. Insects are also more likely to develop resistance against a single mode of action versus multiple modes of action. There is an increasing trend amongst vector control agencies and consumers to employ an integrated pest management approach that relies on a suite of management options to optimize protection against disease-carrying mosquitoes and maximize sustainability.

### Q. What about the news headlines in 2019 relating to hybrid GM mosquitoes?

News headlines in 2019 highlighted a paper which contained inaccurate, false, unverified and misleading information about Oxitec's 1<sup>st</sup>-generation mosquito. **The publishers, Nature and Scientific Reports, issued an Editorial Expression of Concern for this Article**, which validated Oxitec's misgivings in a number of areas, including the authors' claims, interpretation of the data, and speculation. It also validated claims that some of the named authors had not approved the final version that was submitted for publication.

Scientific Report's [Editorial Expression of Concern](#) for Evans et al., 2020.

### About FKMCD:

The Florida Keys Mosquito Control District is an special purpose district authorized to control the presence of mosquitoes within Monroe County. By using necessary maintenance and improvements to help support the health, comfort, welfare, and prosperity of the people thereof, the FKMCD has been established for public health and other public purposes.

An important part of FKMCD's mission is to protect residents in the Florida Keys from the disease-transmitting mosquito, *Aedes aegypti*. The FKMCD have monitored the presence of the *Aedes aegypti* closely and have seen a development of resistance to some of the current control methods. The FKMCD partnered with Oxitec due to the need for new tools to combat this mosquito. And given the unique ecosystem in the Florida Keys, those tools need to be safe, environmentally friendly, and targeted. FKMCD is collaborating with Oxitec on this project, which has full approval from the US EPA and the Florida Department of Agriculture and Consumer Services.

### About Oxitec:

Oxitec is an impact-driven company comprised of passionate people who share a mission to develop safe, effective solutions to enable communities to control disease-carrying and crop-destroying insects at scale. Oxitec's insect technology has been deployed for 15 years around the world with strong support from governments, foundations, international organizations and communities alike. In the US, Oxitec has previously deployed agricultural insects with the approval of the U.S. Department of Agriculture (USDA), demonstrating safety, efficacy and high levels of public acceptance. With more than 100 peer-reviewed scientific publications focused on its technology, and with high





approval ratings from communities across countries and deployments, Oxitec's technology is one of the most studied and tested insect-based technologies globally.

Oxitec is strongly committed to transparency, quality, and safety. Oxitec has made available on its [website](#) a large selection of the 100+ scientific studies and peer-reviewed articles relating to Oxitec's technology and its performance, safety, deployment methods, genetics, and other features. In all of its work worldwide, Oxitec operates in close partnerships with local governments and communities, prioritizing transparency, open communications and information-sharing with all stakeholders.

**Additional resources:**

- The U.S. EPA's [approval](#) of and complete [risk assessment](#) of the pilot project;
- The U.S. EPA's [responses to public comments](#);
- The U.S. EPA/U.S. CDC [memorandum](#) on vectorial capacity of Oxitec's technology;
- The U.S. CDC's [letter](#) confirming their support for the project (COVID prevented CDC from sending personnel to the Keys, so their participation is advisory in nature);
- The State of Florida's [approval](#) of the pilot project;
- 100+ independent peer-reviewed [scientific publications](#) on Oxitec technology.

**FKMCD – Oxitec Mosquito Project Information:**

[florida@oxitec.com](mailto:florida@oxitec.com); [questions@keysmosquito.org](mailto:questions@keysmosquito.org)

+1-888-308-1859

[keysmosquitoproject.com](http://keysmosquitoproject.com)

**Press Inquiries:**

+1-202-792-3080

[press@oxitec.com](mailto:press@oxitec.com)