

Table of Contents

- Opening Letter
- Key Oxitec Personnel
- June 23rd Workshop Presentation (PPT Format)
- Oxitec's U.S. Regulatory Approvals and Supporting Documents
 - a. EUP Approval include all EPA documents, best to PDF with links
 - b. EPA Media Announcement
 - c. EPA Section G
 - d. Human Health and Environmental Risk Assessment
 - e. FDACS Approval
 - f. USDA Diamondback Moth Permit Approval
 - g. CTNBio (Brazil) OX5034 Full Biosafety Approval
- Public Opinion Resources
- Key Press Pieces



June 19th, 2020

Board of Commissioners Florida Keys Mosquito Control District 503 107th Street (Gulf Side) Marathon, FL 33050

Dear Commissioners,

We are thankful for your continued commitment to a collaboration with Oxitec. After more than a decade of working together to shape a pilot project in Monroe County, we're looking forward to ensuring you have the information you need to come to a final decision on this project. Indeed, our efforts together are ground-breaking.

As we progress to the next set of steps formalizing a collaboration for the 2020/2021 time period, and in the spirit of ensuring you have all of the information you need, we wanted to provide you with a number of resources in one package. We'll also be available to provide you with any additional materials, should you need them.

Included in this package are the following:

- > Key Oxitec Personnel a small selection of individuals who will be working with you on this project
- ➤ June 23rd Workshop Presentation Draft this will be updated prior to the meeting, but these slides include the primary themes we will discuss (we may add a few slides to help in adding clarity or for better readability during a live presentation)
 - o Brief Oxitec Overview
 - Brief General Technology Overview high level, but enough to share the nature of the technology
 - Highlights of the EPA's and FDACS EUP Approvals, including:
 - Key findings
 - EPA's technical response to important topics
 - Overview of EPA's responses to specific public comments/inquiries
 - FAQs for topics of interest to Keys residents (this will be condensed for the presentation)
 - o Overview of the trial and its design, developed in collaboration with FKMCD staff
- > Regulatory Approvals Resource Document this includes links to all of the pertinent EPA, FDACS and other regulatory findings, documents, etc., centralized for your convenience
- > Technical Information on Oxitec's OX5034 Strain
- Public Opinion Resources
- > Key Press Clippings



We stand ready to answer any additional questions or requests you may have.

In the case it's helpful, we've created a special project website onto which we will post updates, facts and figures and resource documents so that everyone has access to materials pertinent to this effort. You can view that page at www.oxitec.com/florida.

Again, thank you for taking the time to consider advancing this pilot project together.

If you have any questions at all, please do not hesitate to call me directly. Our team and I stand ready to provide you anything you may need.

Yours sincerely,

Grey Frandsen CEO, Oxitec Ltd.



Oxitec Key Personnel

Updated 19 June 2020

Oxitec is an American-owned company comprised of individuals from 15 countries. Oxitec's team is committed to building trust with its partners and stakeholders and works hard daily to make its technology available to the communities that can benefit most from it.

The following are individuals that will be involved in the pilot project in the Florida Keys. A range of other Oxitec personnel will be involved, but there are some of the faces you'll see routinely.

If you have any questions about our team, our credentials, backgrounds, or other topics, please feel to let us know and we're happy to do our best to answer them.

Grey Frandsen, CEO





Grey Frandsen was appointed the head of Oxitec in December 2017. Prior to this role, Grey served in a number of leadership roles in public and private sectors in the areas of national security and public health. Before and after September 11, 2001, Grey served in the U.S. Government in a range of leadership roles in conflicts and post-conflict stabilization operations around the world. Grey then served on the senior staff of two U.S Secretaries of State as the first Chief of Staff of the U.S. Government's Office of Stabilization Operations. Grey also served as Senior Foreign Policy Advisor in the United States Senate with responsibility for oversight in areas of global public health, diplomacy, counterterrorism, democracy and governance, and international development. After government service, Grey served as the president of Olfactor Laboratories, Inc., a biotech startup developing a range of

novel vector control technologies funded in part by the U.S. National institutes of Health (NIH). In 2016, Grey co-founded a new public-private partnership in the British Virgin Islands to combat the spread of vector-borne diseases. During the Zika crisis in the Western Hemisphere, Grey helped stand up the Puerto Rico Vector Control Unit and was an advisor to the U.S. Centers for Disease Control Dengue Branch. In 2017, Grey developed a new policy and engagement framework for the Caribbean Regional Public Health Agency (CARPHA) designed to bolster government resiliency in combating vector-borne diseases. Grey has served on faculty at the U.S. Department of Defense's Uniformed Services University of Health Science and the University of California San Francisco. Grey received his BA at UCLA and an MA at the Johns Hopkins University School for Advanced International Studies (SAIS). In 2000, during his studies at UCLA, Grey co-founded an American technology company that provides cloud-based services for governments, non-profits, charities, NGOs, international organizations and advocacy organizations.



Kelly Matzen, Head of R&D



Dr. Kelly Matzen is Oxitec's Head of Research, Development and Operations. Kelly is responsible for the R&D division that produces and tests Oxitec's genetically modified insects, delivering new products into the commercial pipeline. Her team develops both the underlying genetics and engineering solutions required to scale insect production. She is also responsible for managing Oxitec's global operations, which includes insect manufacturing and quality in the UK and Brazil.



Kelly has been with Oxitec eight years, during which time she has held a range of leadership roles throughout Oxitec's R&D and operations divisions, giving her a unique perspective and ability to drive the business forward. She was a key member of the team

that brought the OX513A mosquito technology to scale in the world-first GM mosquito factory in Piracicaba, Brazil. She is leading the transition to the 2nd generation technology. Earlier in her career at Oxitec, Kelly served as technical lead during the genesis of a key collaborative partnership in agriculture and remains responsible for establishing scale production of those insects.

Kelly's background is in the technical development of genetically modified insects, which began during her PhD program at the California Institute of Technology where she earned her doctorate in Biochemistry and Molecular Biophysics is 2012. She earned her BS in chemistry at Boston College in 2005. She has published peer reviewed articles and is a named inventor on Oxitec patents.

Meredith Fensom, Head of Public Affairs



Meredith leads Oxitec's communications, government affairs and stakeholder engagement worldwide. Meredith's positions before joining Oxitec include serving as the Intrexon Corporation (renamed Precigen, Inc. in February 2020) Head of Global Public Affairs, Biotechnology Innovation Organization (BIO) founding Director for International Affairs; manager of an agricultural trade business and policy consulting firm; Special Assistant in the Office of the U.S. Trade Representative's Office of the Americas; and founding Director of the University of Florida's Law & Policy in the Americas Program. Meredith has litigated matters of international law and was a Fulbright Scholar in Santiago, Chile, where she assisted in the design and evaluation of Chile's judicial reform process. She was also awarded CIBER and FLAS Fellowships to

Brazil. She has served as a consultant to various multilateral institutions including the Inter-American Development Bank, the United Nations' International Trade Centre and the World Bank. Meredith received a J.D. from the University of Florida Levin College of Law, a Master's Degree from the University of Florida Center for Latin American Studies, an undergraduate degree from Furman University and is pursuing a Global Executive MBA with INSEAD in France. She is fluent in Spanish, conversant in Portuguese and has a basic understanding of French.



Benjamin Sperry, Field Operations Manager





Benjamin has 20 years' experience in leading community focused initiatives including 15 years in mosquito control in both the public and private sectors. He has a record of driving progress by promoting new technologies, tools and methods. His diverse professional experience in the field, lab, and with community engagement is augmented by a Master's in Public Health from the University of Utah and an MSc in Medical Entomology from the London School of Hygiene and Tropical Medicine. As a Field Operations Manager for Oxitec Ltd. Benjamin will be working in tandem with local partners to ensure technical and community success with Oxitec's 2nd Generation Friendly™ mosquito.

Kevin Gorman, Head of Field Operations



Kevin has over 25 years' experience as an agricultural and public health entomologist, with a career focus on integrated and sustainable pest management practices. Previously a Project Lead for regulatory efficacy trials (ORETO and GEP) and a public-sector academic, he has extensive line management and project management experience. He has been the Technical Lead in Central America and the Indian sub-continent for insect control programs using Oxitec's genetic technologies, with emphasis on the mosquito vectors responsible for transmission of dengue, chikungunya, and Zika viruses. Kevin has regulatory and business development experience, and his current role is Head of Field Operations for Oxitec. He has authored over 70 publications and has served on the editorial board for two leading international journals.

Nathan Rose, Head of Regulatory Affairs





Nathan is responsible for Oxitec's global regulatory efforts and supports Oxitec's R&D, Field and Business Development teams across the Oxitec global portfolio. He joined Oxitec as an R&D group leader in 2016 and, before that, had a career as an academic researcher at the University of Oxford, where he worked on the design of drugs targeting epigenetic enzymes involved in human cancers, where his research led to over 30 scientific publications. He has an MSc in Chemistry from Rhodes University in South Africa, and a DPhil in Chemical Biology from the University of Oxford.



Introductions – Our Team With You Today





Grey Frandsen CEO of Oxitec



Kevin Gorman, PhD Head of Field Operations



Meredith Fensom Head of Public Affairs





Kelly Matzen, PhD Head of R&D



Nathan Rose, PhD Head of Regulatory Affairs



Benjamin Sperry Field Operations Manager



Florida Keys & Oxited

We are pleased to be celebrating 10+ years of collaboration with the FKMCD to introduce Oxitec's mosquitoes to the Florida Keys.

Agenda:

- About Oxitec
- Overview of Oxitec's Technology
- Overview of OX5034
- Overview of Oxitec & Florida Keys Pilot Project
- Regulatory Update (EPA, State of Florida Approvals)
- FAQs
- Closing



Our Mission

To improve lives and livelihoods by developing safe, environmentally sustainable and highly effective solutions to control disease-transmitting and crop-destroying insects.



After spinning out of Oxford University in 2002, development of Oxitec's Friendly™ technology is the result of strong public-private partnerships and collaborations over 18 years in multiple countries.

4 Research Universities
10+ Governments & International Orgs
Global Foundations
200+ Scientists Globally
100+ Scientific Studies
4 Research Institutes
10+ Civil Society Organizations



Oxitec's Technology Platform Overview

PLATFORM FEATURES

- Targeted, precise pest control
- Safe & non-toxic
- Non-allergenic
- Non-persistent
- Environmentally friendly

- Built-in biosecurity
- No effect on non-target species
- Demonstrated field effectiveness
- Potential to reverse resistance to traditional pest control tools
- High levels of public acceptance

- Easy tracking with fluorescent marker
- No impact to crops
- No radiation or introduced bacteria used
- Does not affect grower cultivation practices

PROBLEM

Potential synergies with other pest control methods

OXITEC'S INSECT PROGRAMS

PUBLIC HEALTH		PROBLEM
	Aedes aegypti	Dengue, Zika, chikungunya; current tools are under strain
	Aedes albopictus	Dengue, Zika, chikungunya; current tools are under strain
	Anopheles stephensi	Malaria; invasive, current tools are under strain
	Anopheles albimanus	Malaria; current tools are under strain

AGRICULTURE

7.3331.31.2	
Fall Armyworm	80+ crops; resistance emerging to existing tools
Soybean Looper	Soybean; over-reliance on traditional management tools
Medfly	Citrus/pome/stone fruit; pressure to reduce insecticide applications
Diamondback Moth	Brassica crops; resistant to most insecticides
Pink Bollworm	Cotton; resistant to some biotech cotton
Drosophila suzukii	Soft fruits; highly invasive and difficult

Oxitec 2020

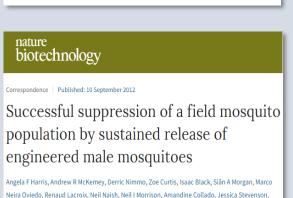
to control



Scientific Excellence: 100+ Peer-Reviewed Scientific Studies Published

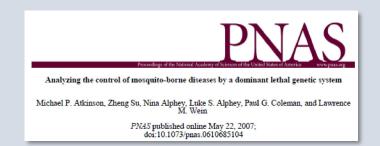


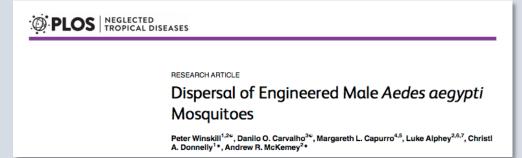
Kevin Gorman, ^{a*} Josué Young, ^b Lleysa Pineda, ^b Ricardo Márquez, ^b Nestor Sosa, ^b Damaris Bernal, ^b Rolando Torres, ^b Yamilitzel Soto, ^b Renaud Lacroix, ^a Neil Naish, ^a Paul Kaiser, ^a Karla Tepedino, ^a Gwilym Philips, ^a Cecilia Kosmann ^a and Lorenzo Cáceres ^b

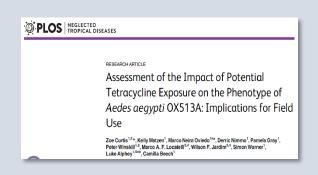


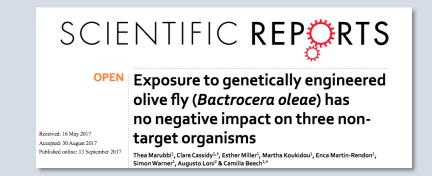
Sarah Scaife, Tarig Dafa'alla, Guoliang Fu, Caroline Phillips, Andrea Miles, Norzahira Raduan, Nick

Kelly, Camilla Beech, Christl A Donnelly, William D Petrie & Luke Alphey

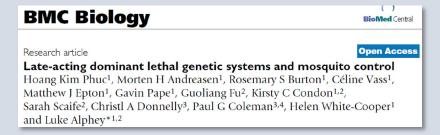








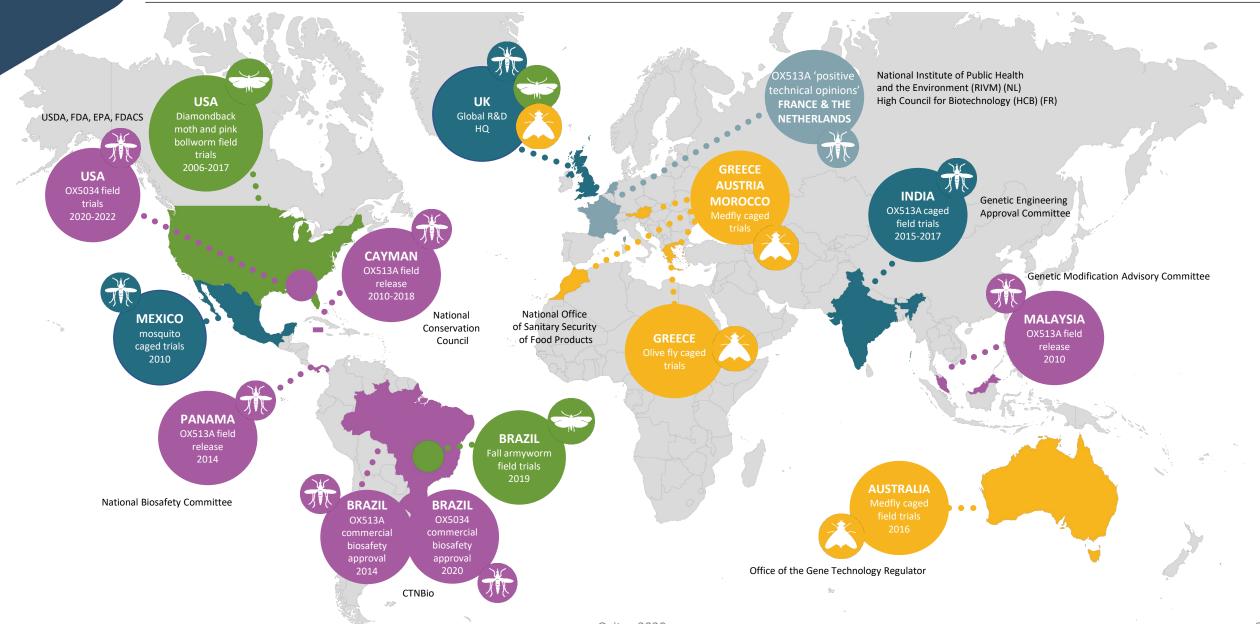








Global Regulatory Approvals, Trials and Positive Technical Opinions



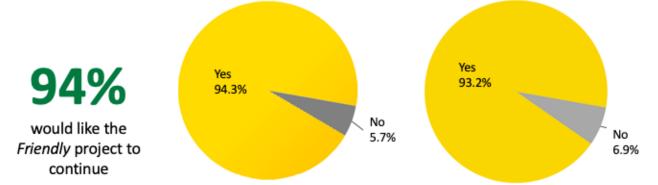


Long History of Strong Public Acceptance and Community Partnerships

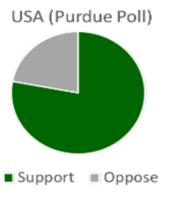


2019 Survey on OX5034 in Brazil

US National Survey on Oxitec Mosquitoes



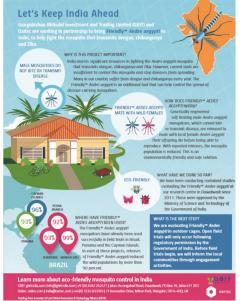
93% would like to see the project expanded





We Work to Build Genuine Partnerships with Communities











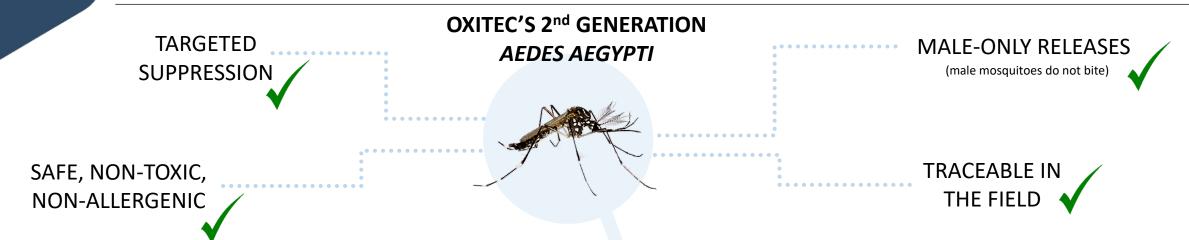




Technology Overview



Oxitec's Aedes aegypti Mosquito Technology ("OX5034")



OXITEC'S MALE MOSQUITOES CARRY ONLY TWO SAFE INTRODUCED GENES

MALE-SELECTING SELF-LIMITING GENE

Non-toxic, non-allergenic gene product (tTAV protein)

After Oxitec males mate with wild-type females, the progeny receive a copy of a self-limiting gene that prevents females from developing into adults **DEPLOYMENT**

MANUFACTURING



- **Efficient production**
- No sex sorting
- Male-only production
- Egg releases and release devices enabled



- 'Just-add-water' egg device
- Suppresses target mosquitoes
- Multi-generational suppression
- Gene is self-limiting in environment

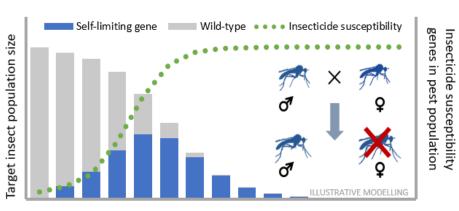
SIMPLE MARKER GENE Easy track-and-trace in the field Non-toxic, non-allergenic gene product (DsRed2 protein)



Key Performance and Operational Benefits of OX5034

1 TARGETED PEST SUPPRESSION

- Significant pest suppression
- Multi-generation suppression
- Fully self-limiting
- Proven effective in pilot studies



Time from initiation of self-limiting releases

2 ENVIRONMENTALLY FRIENDLY

- Safe, non-toxic
- No impact on environment
- No impact on off-target species
- No persistence in environment

3 EFFICIENT MFG PRODUCTION

- Male-only field release
- No sex-sorting required
- No factories required
- No female release
- No complex adult releases





EASY DEPLOYMENT & SCALABILITY

- Easy deployment
- Just-add-water
- No special tools
- Rapid placement
- 3-month shelf-life
- Easy shipping/distribution

13

³Alphey et al. 2007 & 2009 *J Econ Entomol*.

Oxitec 2020



Decade of Performance, Partnerships & Demonstrated Safety







Aedes aegypti peak suppression measured in each program compared to control sites





Juazeiro, **Bahia** 2010-2012

93%

Juazeiro, **Bahia** 2012-2013

96%

Jacobina, **Bahia** 2014

92%

Nuevo Chorrillo, **Panama** 2014

93%

Piracicaba, São Paulo 2015-2019

SAMPLE DEPLOYMENT PROGRAMS, 2010 – 2020

Successful 4-Year Pilot Piracicaba, São Paulo 2016-2018

> Successful 65,000-Person Program

First OX5034 Adult **Biosafety Pilot** Brazil 2018-2019

96%⁴

US OX5034 Pilot

1st OX5034 **Product Pilot** Indaiatuba, São Paulo

95%

In progress, 2019/2020

OX5034 **Product Pilot** (10k person) Indaiatuba 2021

OX5034 DEPLOYMENT PROGRAMS

1st GENERATION AEDES AEGYPTI **DEPLOYMENT PROGRAMS**

Oxitec 2020

14



High-level Summary of Differences Between Oxitec & Other Novel Approaches

There are a number of promising new technologies to combat *Aedes aegypti*. Oxitec's technology has unique advantages relating to performance, scalability and cost-effectiveness.

Feature	Benefit	Wolbachia Suppression	Sterile Insect Technique	Oxitec's 2 nd Generation (OX5034)
100% male-only releases (biosafety)	Biosafety / no biting	•	•	
Multi-generational performance	Cost effectiveness per mosquito			
Mini-capsule egg-based deployment	Major cost reductions & simplicity of operations	•		
Potential to restore efficacy of insecticides	Supports other tools			

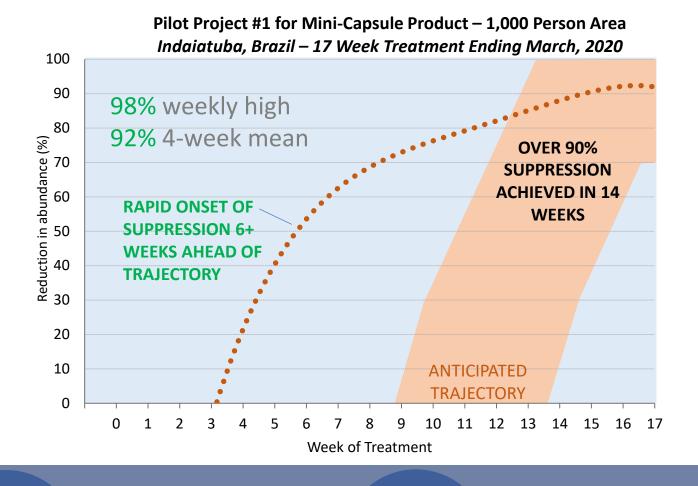


OX5034 Mini-Capsule Pilot Successful

Results:

- ✓ 100% safe no unintended impacts
- √ 100% males no female release
- ✓ 100% self-limiting no persistence
- ✓ Significant suppression (see graph)
- √ 90% reduction in operations
- ✓ 94%+ public acceptance





Faster to Suppression than OX513A

90%

More Efficient Production & Deployment

Proposed Small Pilot Project with FKMCD

With FKMCD, FDACS and EPA approval, Oxitec will carry out a small pilot project to demonstrate performance and safety of Oxitec's OX5034 *Aedes aegypti* technology in the Keys.



Illustrative design similar to what will be piloted.

Four Project Components

- 1. Community Engagement
- 2. Mark-Release-Recapture
- 3. Project A: Single-point Releases
- 4. Project B: Area-wide Releases

Safe & Non-Toxic

~130

Boxes

Placed

~28
Weeks

Females Released



Pilot Project Design in Collaboration with FKMCD

Project Design Elements

- Single-point release with capture of males and offspring;
- 2. Multi-point release with capture of offspring;
- 3. Replicated and compared to untreated areas.
- 4. Locations TBD with FKMCD
- 5. Timing: 2020-2021

Evaluation Elements

- Male dispersal and longevity;
- Residual activity (persistence);
- Multi-point release with capture of offspring and evaluation of cryptic breeding sites;
- 4. Efficacy and coverage



PROJECT A: Single-Point Releases

Low rate High rate

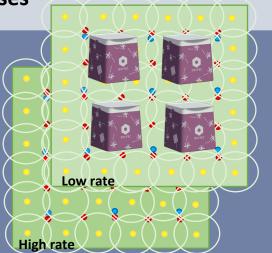
Project A:

- ~12 weeks
- Single-point releases
- Evaluate release rates
- Demonstrate effectiveness in small areas

PROJECT B: Area-wide Releases

Project B:

- ~16 weeks
- Area-based releases
- Evaluate release rates
- Demonstrate effectiveness area-wide





Florida Keys Community Engagement

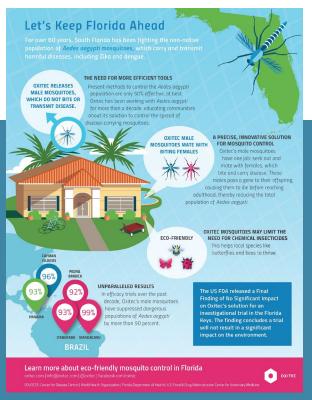
Hand-in-hand with the FKMCD, Oxitec has been engaging and communicating openly with communities in the Florida Keys for more than 10 years.



- Full coordination with FKMCD
- Transparency and robust information sharing
- Listening and learning from communities and stakeholders
- Inclusive engagement programs specific to stakeholder groups
- Broad view of stakeholders citizens, communities, businesses, experts
- Multiple avenues for anyone to contact and engage with us



KEYSWEEKLY





Regulatory Approvals Overview



U.S. Approvals and Endorsements of Oxitec Technology

Exhaustive review by five U.S. government agencies over 14 years











		USG Changes Federal Jurisdiction		
2006	2017 •	2016 •	2020	2020 •
Arizona	New York			
Approvals for a	agricultural insects	FDA issues Finding of No Significant Impact for OX513A	EPA approves EUP including U.S. CDC Scientific Review for OX5034	FDACS approves Deployment Permit for OX5034



Approval of Oxitec's EUP

"...after extensive evaluation of the best available science and public input, the U.S. Environmental Protection Agency (EPA) has granted an experimental use permit (EUP) to Oxitec Ltd." (OPP Update)



"EPA anticipates that this could be an effective tool to combat the spread of certain mosquito-borne diseases like the Zika virus in light of growing resistance to current insecticides."

"...only male mosquitoes will be released into the environment and as they do not bite people, they will not pose a risk to people."

"It is also anticipated that there would be no adverse effects to animals, such as bats and fish, in the environment."



Overview of EPA's Review & Approval

Key Elements:

- 14-month in-depth process
- Exhaustive scientific review
- Risk assessment
- Multi-agency support
- Public comment responses

By the Numbers:

- 70+ documents submitted
- 25 commissioned studies
- 4,500+ pages, including 2,500+ pages of scientific peer-reviewed literature



Data Requirements Fulfilled by Oxitec (partial list)

Environmental Assessments:

- Fish
- Birds
- Mammals
- Plants
- Aquatic Invertebrates
- Insects
- Endangered Species

Health Assessments:

- Trait Penetrance
- Oral Toxicity
- Inhalation Toxicity
- Ocular Toxicity
- Dermal Toxicity
- Allergenicity
- Vector Competence

Mosquito Characterization and Performance:

- Insecticide Susceptibility
- Trait Penetrance
- Tetracycline Response
- Stability of Genetic Traits
- Trait Persistence
- Field Data (Brazil)

- Protein Stability
- Arbovirus Screening
- Introgression Analysis
- Complete SOPs
- AnalyticalMethodologies



State of Florida Departments/Bureaus Unanimously Approve Permit









EUP Approved By:

- ✓ Florida Department of Agriculture and Consumer Services
- Florida Department of Environmental Protection (FDEP)
- ✓ Florida Fish and Wildlife Conservation Commission (FWC)
- ✓ Bureau of Inspection and Incident Response (BIIR)
- ✓ Florida Department of Health (DOH)
- ✓ Bureau of Agricultural Environmental Laboratories (BAEL)
- ✓ Bureau of Chemical Residue Laboratories (BCRL)
- ✓ Bureau of Scientific Evaluation and Technical Assistance, Scientific Evaluation Section (SES)

EPA – Key Takeaways

<u>Topic</u>	EPA's Findings
☐ Human Health	✓ No risk to human health from OX5034 male mosquitoes. (EPA Human Health and Environmental Risk Assessment: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0359)
☐ Environment	✓ No risk to the environment, including endangered species. (EPA Human Health and Environmental Risk Assessment: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0359)
☐ Trial Scope	✓ Two years of releases authorized, with weekly monitoring system in place. (EPA EUP Issuance Letter: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0353)



EPA Responds to Keys Residents' Questions

<u>Topic</u>	PA's Response	
☐ Tetracycline	"negligible risk that testing of OX5034 mosquitoes would spread antibiotic resistant bacteria in the US environment"	
	(p75-76, Response to Comments)	s)
☐ Off-target Impacts	"no adverse effects are anticipated for nontarget organisms as a result of the experimental permit to release OX5034 mosquitoes"	
	(p 49, EPA Human Health and Environmental Risk Assessment	t)
☐ Endangered Species	"a 'No Effect' determination is also made for direct and indirect effects to federally listed endangered and threatened species, and for their designated critical habitats"	
	(p 49, EPA Human Health and Environmental Risk Assessment	t)
☐ GM mosquito survival in the environment	"introgression of OX5034 strain genetics into the local wild Ae. aegypti mosquito population is likely to occur during releases of OX5034; however, the risk resulting from such introgression is negligible" (p134, Response to Comments	s)
	(p134, response to comments	21



Common Misconceptions

<u>Misconceptions</u>	<u>Documented Facts</u>		
Spread of tetracycline- resistant bacteria	✓ Tetracycline will not be used to rear OX5034 male mosquitoes in Florida, and EPA and FL state agencies found negligible risk of spreading antibiotic-resistant bacteria. (p75-76, EPA Response to Comments)		
Oxitec's OX513A EUP application rejected	✓ The EPA did not reject any Oxitec application; Oxitec withdrew its OX513A application to focus on the 2 nd Generation <i>Aedes aegypti</i> , OX5034.		
☐ FKMCD rejected OX513A project in 2016	✓ Not true. FKMCD approved an investigational agreement 2016 http://keysmosquito.org/wp-content/uploads/2017/01/FKMCD-Board-Approves-Oxitec-Investigational-Agreement.pdf		
☐ "Hybrid vigor"	✓ "there is no indication that matings between OX5034 mosquitoes and local mosquitoes would result in hybrid vigor" (p 41, EPA Human Health and Environmental Risk Assessment)		

FAQs



FAQ About Oxitec's OX5034 Mosquitoes

What are the risks if a female Oxitec mosquito bites someone?

0%.

There will be no Oxitec female mosquitoes and thus no risk.

We release only male mosquitoes because the Self-Limiting gene prevents females from surviving in the pre-release production stage.

Oxitec male mosquitoes are safe and non-toxic.





FAQ About Oxitec's OX5034 Mosquitoes

Are Self-Limiting mosquitoes an environmentally sustainable control tool?

Yes.

Self-Limiting mosquitoes work by finding and mating with wild *Aedes aegypti* females and the suppression effect is specifically targeted to this species of mosquito. This specificity leaves non-target species, such as bees and butterflies, unharmed.





Will Oxitec mosquitoes harm birds, bees, bats, fish, turtles, or other wildlife?

No.

The EPA and State of Florida confirmed this, and Oxitec has carried out exhaustive research (part of submissions made available to the EPA) on this topic.





Has Oxitec's OX5034 been deployed elsewhere?

Yes.

Building on a decade of deploying OX513A, OX5034 has now been successfully and safely deployed for more than two years in Brazil, and has received full, nationwide biosafety approval from Brazil's regulatory authorities.





PRESS RELEASE - 19 May 2020

Just Add Water: Oxitec's New Friendly™ Mosquito Mini-Capsule Technology Rapidly Suppresses 95% of Disease-Spreading Aedes aegypti in Brazil Trial

- Successful 13-week field trial demonstrated effectiveness and safety of Oxitec's new just-addwater Friendly™ mini-capsule mosquito product in dengue-impacted city
- Friendly™ mini-capsules are designed to equip governments and communities of all sizes with a highly-effective and economically sustainable Aedes aegypti control solution
- Product eliminates costly adult mosquito production facilities, complex rearing systems, need for expert staff, vehicle-based deployment, and female releases 94% of city residents supported Oxitec's Friendly™ technology

Oxford, UK – May 2020 – Oxitec Ltd., a leading developer of safe and targeted biological solutions to control insects that transmit disease and destroy crops, today announced the preliminary results of a successful trial for new Friendly™ Aedes aegypti mini-capsule technology. Implemented in close partnership with the City of Indaiatuba, Brazil, the Friendly™ mini-capsule product method suppressed up to 95%¹ of disease-carrying Aedes aegypti in urban, dengue-prone environments following just 13 weeks

Treatment involved the placement of small Friendly™ mini-capsule products in residential properties once per week, with no special tools or handling. The effort generated rapid suppression over an area of approximately 1,000 people and demonstrated 100% effectiveness of the female larvae-killing feature



Is Oxitec seeking payment from taxpayers for this project?

No.

Oxitec is fully funding this project.



Is Oxitec going to be using tetracycline in Florida?

No.

Tetracycline is only used in our facilities in the UK in very small amounts to produce the eggs used in Florida. The *total* amount used to produce the eggs in the UK is less than three normal therapeutic doses in humans – *for the entire project*. This is roughly equivalent to the contents of a single sugar packet.





Will this technology be expensive compared to others?

No.

The benefits of egg-releases and in-built sexing offer dramatic reductions in production and delivery costs. This will ensure affordability and in conjunction with the benefits of improved and sustainable mosquito management at cost-effective levels.



Will OX5034 replace insecticides and other control measures?

No.

Insecticides are a valuable option available to mosquito control authorities and consumers for a broad range of mosquito species, but they have limitations. Over-reliance on them has led to the development of resistance to insecticides.

Integrated pest management approaches rely on a suite of technologies to optimize protection against disease-carrying mosquitoes and maximize sustainability. Oxitec mosquitoes are intended to be one of these valuable tools and offer the potential to reverse insecticide resistance.



Thank you for your time and interest.

We will remain available for any further questions.

Oxitec 2020 3





Oxitec's US Regulatory Approvals and Supporting Documents

Updated 19 June 2020

OX5034 EUP Documents Issued by EPA:

Office of Pesticide Programs (OPP) Update:

https://content.govdelivery.com/accounts/USAEPAOPPT/bulletins/2896a76

Permit Issuance Letter: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0353

Human Health and Ecological Risk Assessment: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0359

Draft Label: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0357

Response to Comments: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0354 (Explanatory Memorandum) and https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0355 (Response to Comments)

Section G Field Protocol: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0358

Reviews of Section G Field Protocol: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0356 (26 Mar 2020) and

https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0352 (addendum 30 Apr 2020)

Joint Memorandum with CDC on Introgression and Vectorial Capacity: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0351

<u>Florida Department of Agriculture and Consumer Services (FDACS) Authorization</u>, which includes unanimous approval from:

- Florida Department of Environmental Protection (FDEP).
- Florida Fish and Wildlife Conservation Commission (FWC).
- Florida Department of Health (DOH).
- Florida Bureau of Inspection and Incident Response (BIIR).
- Florida Bureau of Scientific Evaluation and Technical Assistance.
- Florida Bureau of Agricultural Environmental Laboratories (BAEL).
- Florida Bureau of Chemical Residue Laboratories (BCRL).



USDA-APHIS Documents for Oxitec Diamondback Moth EUP (2017):

USDA Announcement: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2017 brs news/final diamondback moth

Diamondback Moth Environmental Assessment: https://www.aphis.usda.gov/brs/aphisdocs/16 076101r fea.pdf

Diamondback Moth Finding of No Significant Impact (FONSI): https://www.aphis.usda.gov/brs/aphisdocs/16 076101r fonsi.pdf

Diamondback Moth Federal Register Notice: https://www.aphis.usda.gov/brs/fedregister/BRS 20170707.pdf

CTNBio (Brazil) OX5034 Full Biosafety Approval



Oxitec Public Opinion Resources

Updated 19 June 2020

Florida Keys Resources

In 2016, a public referendum on Oxitec's mosquito technology received support in <u>31 out of 33</u> Monroe County precincts and the Florida Keys Mosquito Control District approved the field trial. The precinct results are included as part of this package. This followed the U.S. FDA <u>issuing its 2016 findings</u> that Oxitec's technology would have no negative impacts on human, environmental or animal health. The trial was delayed due to a transfer of jurisdiction from FDA to the EPA, after which Oxitec reapplied with its next generation Friendly™ mosquito, OX5034.

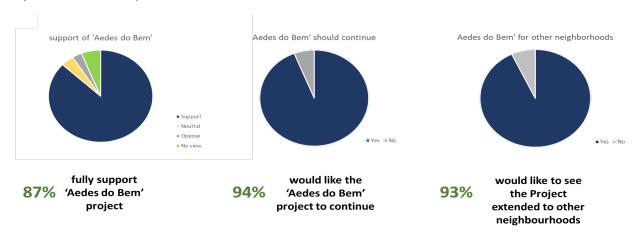
A 2016 survey carried out by Purdue University found 78% of over 900 surveyed U.S. residents supported the use of mosquitoes like Oxitec's to help control the spread of the Zika virus. <u>This research article</u> and <u>press release</u> about the survey are publicly available.

Oxitec's technology has since received unanimous approval from the following U.S.-based agencies:

- U.S. EPA, with scientific endorsement from U.S. Centers for Disease Control (CDC)
- The State of Florida has accepted Oxitec's Experimental Use Permit. <u>This FDACS authorization</u> includes approvals from:
 - Florida Department of Environmental Protection (FDEP)
 - Florida Fish and Wildlife Conservation Commission (FWC)
 - Bureau of Inspection and Incident Response (BIIR)
 - o Florida Department of Health (DOH)
 - Bureau of Agricultural Environmental Laboratories (BAEL)
 - Bureau of Chemical Residue Laboratories (BCRL)
 - Bureau of Scientific Evaluation and Technical Assistance, Scientific Evaluation Section (SES)

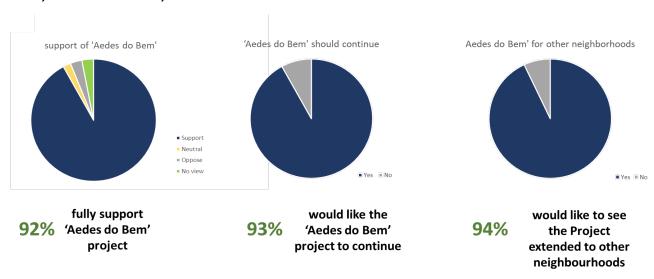
OX5034 "Aedes do Bem" Project in Indaiatuba, Brazil

Survey conducted in September 2019



OX513A "Aedes do Bem" Project in Piracicaba, Brazil

Survey conducted in May 2019.



Brazil Projects Quotes

Nov 2019 - "The work that we have here, together with the Aedes do Bem, had an influence on not letting the epidemic spread throughout the city. With this new phase, and methodology, we hope it will be as effective as in the first phase or even more" said Ulisses Bernardinetti, coordinator of the Aedes aegypti Control Program of Indaiatuba.

Oct 2019 – "In addition to reducing the cost of laboratory production and logistics for the distribution of adult mosquitoes, with the use of Aedes do Bem™ eggs, it will be possible to reach more distant places," said the Municipal Administrator of Indaiatuba.

Sept 2019 - "We trust this technology; genetically modified mosquitoes are male."

"This second generation should eliminate dengue with fewer releases of mosquitoes. In addition, a new strain offers economic and economic cost advantages, which simplifies the production process" said the Municipal Administrator of Indaiatuba.

2016 - "We always have to look for new alternatives and 'Aedes do Bem!', more than a bet, proved to be a great success for this administration" <u>said Dr. Pedro Mello, Piracicaba's Secretary of Health</u>.

Precinct	Precinct_name	YES	NO
1	1-Jaycee Clubhouse	50.56%	49.44%
2	2-KW High School	51.95%	48.05%
3	3-KW High School	52.84%	47.16%
4	4-MLK Pool	49.33%	50.67%
5	5-Old City Hall	60.26%	39.74%
6	6-Gato Building	52.33%	47.67%
7	7-Moose Club	54.96%	45.04%
8	8-Glad Tidings Tabernacle	54.45%	45.55%
9	9-Sr Citizen Plaza	51.43%	48.57%
10	10-Sr Citizens Plaza	51.43%	48.57%
11	11-Stock Island Fire Station	49.47%	50.57%
12	12-BC Fire Station	53.17%	46.83%
13	13-Sugarloaf Baptist Ch	61.40%	38.60%
14	14-Sugarloaf Baptist Ch	67.78%	32.22%
15	15-Boy Scouts of America	67.73%	32.27%
16	16-BPK First Baptist Church	67.73%	32.27%
17	17-BPK Comm Park	63.71%	36.29%
18	18-American Legion Marathon	61.84%	38.16%
19	19-Marathon First Baptist Church	62.90%	37.10%
20	20-Presbyterian Kirk of the Keys	56.23%	43.77%
21	21-Marathon Moose Lodge	58.83%	41.17%
22	22-KCB City Hall	72.64%	27.36%
23	23-Marathon Moose Lodge	63.51%	36.49%
24	24-Islamorada Library	59.23%	40.77%
25	25-PK Courtroom B	57.54%	42.46%
26	26-Immanuel Lutheran Church	52.70%	47.30%
27	27-Elks Club	51.20%	48.80%
28	28-KL Civic Club	57.33%	42.67%
29	29-KL Civic Club	52.25%	47.75%
30	30-Monroe County Library	52.92%	47.08%
31	31-Monroe County Library	50.85%	49.15%
32	32-KL Baptist Church	54.13%	45.87%
33	33-Academy at Ocean Reef	84.03%	15.97%



Recent Oxitec Press Highlights

Prepared 19 June 2020

Oxitec Press Release Highlights

Unanimous Decisions by U.S. EPA, State of Florida Approve Environmentally Sustainable Oxitec Friendly™ Mosquitoes for Pilot Project

16 June 2020

Oxitec, a US-owned company developing safe, sustainable biological control tools, is pleased to announce the State of Florida yesterday issued its approval for an Experimental Use Permit (EUP), paving the way for a pilot project of Oxitec's Friendly™ *Aedes aegypti* mosquito technology ("OX5034") in the Florida Keys.

###

Oxitec Successfully Completes First Field Deployment of 2nd Generation Friendly™ Aedes Aegypti
Technology

3 June 2020

Oxitec today announced the successful completion of the first field trial in Brazil of its 2nd Generation Friendly™ *Aedes aegypti* technology. In partnership with the municipal vector control authorities in the city of Indaiatuba, the pilot project demonstrated the new strain's effectiveness in suppressing populations of the *Aedes aegypti* mosquito – the primary vector of dengue, Zika, chikungunya and yellow fever – in four densely populated urban communities across the city.

###

Oxitec's New Friendly™ Aedes aegypti Mosquito Technology Receives Full Biosafety Approval in Brazil

27 May 2020

Oxitec today celebrates receiving full biosafety approval to release its new Friendly™ *Aedes aegypti* mosquito technology, granted by CTNBio, Brazil's biosafety regulatory authority. The approval is the result of an in-depth and rigorous scientific review process that included an expansive assessment of the technology and its safety for humans and the environment.



The approval was granted without exception and authorizes releases of the technology throughout Brazil. CTNBio's full biosafety review found no risk to human health or the environment, further validating positive regulatory decisions and technical opinions of regulatory authorities around the world.

###

Just Add Water: Oxitec's New Friendly™ Mosquito Mini-Capsule Technology Rapidly Suppresses 95% of Disease-Spreading Aedes aegypti in Brazil Trial

19 May 2020

Oxitec today announced the preliminary results of a successful trial for new Friendly™ *Aedes aegypti* minicapsule technology. Implemented in close partnership with the City of Indaiatuba, Brazil, the Friendly™ minicapsule product method suppressed up to 95% of disease-carrying *Aedes aegypti* in urban, dengue-prone environments following just 13 weeks of treatment, as compared to untreated control sites in the same city.

Treatment involved the placement of small Friendly™ mini-capsule products in residential properties once per week, with no special tools or handling. The effort generated rapid suppression over an area of approximately 1,000 people and demonstrated 100% effectiveness of the female larvae-killing feature while validating its full biosafety.

###

Oxitec's Friendly™ Mosquito Technology Receives U.S. EPA Approval for Pilot Projects in U.S.

1 May 2020

We are delighted with the U.S. Environmental Protection Agency's (EPA) decision to grant Oxitec an Experimental Use Permit (EUP) for piloting our 2nd Generation Friendly™ *Aedes aegypti* mosquito technology, the result of an in-depth and rigorous scientific review process that included technical support from the U.S. Centers for Disease Control (CDC) and an expansive assessment of the technology and its safety for humans and the environment.

Link to the EPA's media release.

###



First Release of Oxitec's Genetically Engineered Moth Heralds New Era of Crop Protection

January 2020

A newly published study reports a successful, first-ever open-field release of a self-limiting, genetically engineered diamondback moth, stating that it paves the way for an effective and sustainable approach to pest control.

This new strain of diamondback moth, developed by Oxitec, is modified to control the diamondback moth pest in a targeted manner. The study showed the engineered strain had similar field behaviors to unmodified diamondback moths, with results offering promise for future protection of farmers' brassica crops.

Link to the original research article.

###

Oxitec Press Coverage Highlights

EPA EUP Approval

US EPA green-lights genetically modified mosquito

Chemical & Engineering News

<u>EPA Approves Experimental Use Permit for Field Testing of Genetically Modified Aedes aegypti</u>
<u>Mosquitos</u>

The National Law Review

EPA Approves Genetically Modified Mosquito Trial for Florida Keys

WGCU - PBS & NPR for Southwest Florida

'Just Add Water' Mini-Capsule Results

<u>'Just Add Water' GM Mosquitoes Suppress Wild Population by 95%</u>
Biotech News

<u>'Just Add Water' GM Mosquitoes Suppress Wild Population by 95%</u> Labiotech.eu

Mini-capsule technology controls mosquitoes without insecticides



Alliance for Science

Minicapsules with transgenic mosquitoes reduce Aedes population by 95% in Indaiatuba
Time 24

General Coverage

Interview: Oxitec CEO on US field trials and the dengue fight in a new world Break Dengue

GM Mosquitoes Closer to Release in U.S.

The Scientist

Accelerating the Elimination of Malaria, Dengue and Other Vector-borne Diseases Will Require Trust.

Blog by Grey Frandsen, CEO of Oxitec

Diamondback Moths

First release of genetically engineered moth could herald new era of crop protection Frontiers Magazine

Male moths genetically modified to kill females released in the wild New Scientist

Genetically Engineered Male Moths Released into Wild to Wipe Out FemalesNewsweek

Genetically engineered moths can knock down crop pests, but will they take off? Science Magazine

Genetically engineered moths have been released into the wild to wipe out pests CNN