

**GENTICALLY MODIFIED  
MOSQUITO WORKSHOP**

**JUNE**

**2020**



# 2020 CALENDAR

January-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

March-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

May-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

July-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

September-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

November-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

February-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

April-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

June-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

August-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

October-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

December-2020						
SUN	MON	TUES	WED	THUR	FRI	SAT
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Holidays

Meetings

Conferences

# **Genetically Modified Mosquito Workshop Agenda**

Florida Keys Mosquito Control District  
Marathon Office  
503 107<sup>TH</sup> Street  
Marathon, FL 33050

**June 23, 2020**

**1:00 PM**

**1. Call to Order**

**2. Invocation and Salute to Flag**

**3. Roll Call**

**4. Approval of Agenda**

**5. Purpose of Workshop:** Chairman Goodman announces that this Workshop has been called for the purpose of discussing Oxitec's 2<sup>nd</sup> Generation Mosquito Technology.

**6. Discussion Agenda:**

- a.) Invited Speakers
- b.) Questions and Answers
- c.) Non-Binding Referendum

**7. Community Input**

The Board adheres to, and conducts each meeting in accordance with Robert's Rules of Order. Presentations to the Board are limited to three (3) minutes for each individual speaker and five (5) minutes for the representative of a designated group. Transfer of time between individuals and/or groups is not permitted. Letters submitted to any Commissioner, the Executive Director, Executive Assistant, or any other District employee during a Board meeting will be placed into the record but will not additionally be read into the record at the meeting.

The Board welcomes public input but also must maintain order. Thus, community input is not a time for open dialogue between the Board and the speaker. Speakers should direct their comments to the Board and not to the District Staff or any other audience members. Speakers should not expect Commissioners or staff to answer or respond to questions during community input. If appropriate, the Board may request the issue be added as a discussion item at a future District Board Meeting.

Any person who wishes to be heard shall complete and provide the supplied community input card or inform the Clerk/Executive Assistant to the Board.

Once community input begins, there will be no further speaker cards or speakers allowed.

**8. Good of the Order**

**9. Meeting Adjourned**

**BACK-UP**

**DOCUMENTATION**

## Table of Contents

- Opening Letter
- Key Oxitec Personnel
- June 23<sup>rd</sup> 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 19<sup>th</sup>, 2020

Board of Commissioners  
Florida Keys Mosquito Control District  
503 107<sup>th</sup> 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 23<sup>rd</sup> 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)
  - 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)
  - 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](http://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,

A handwritten signature in dark ink, appearing to be 'G. Frandsen', with a long, sweeping horizontal stroke extending to the right.

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 2<sup>nd</sup> 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 in 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 2<sup>nd</sup> 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.



OXITEC

# FKMCD Workshop







# Our Mission



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



Like it's mosquito technology, Oxitec's Friendly™ agricultural insects help control crop-destroying pests safely without impacting the environment.

Oxitec is led by passionate individuals from the US, UK, and 13 other countries. The US team includes, among others:



**Grey Frandsen**  
CEO of Oxitec



**Kelly Matzen, PhD**  
Head of R&D



**Meredith Fensom**  
Head of Public Affairs



**Kevin Gorman, PhD**  
Head of Field Operations



**Angela Pickl-Herk, PhD**  
Head of Quality Management

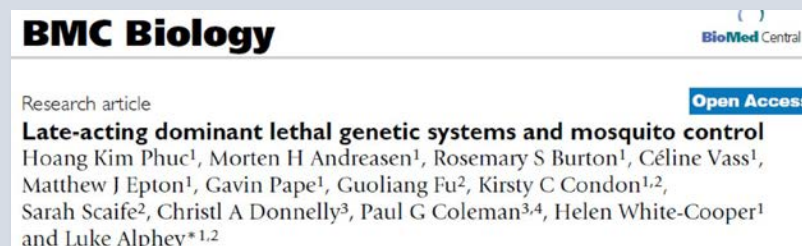
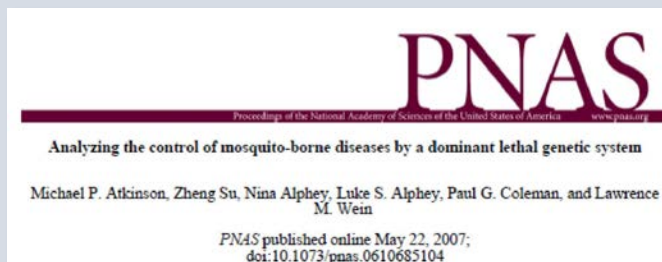
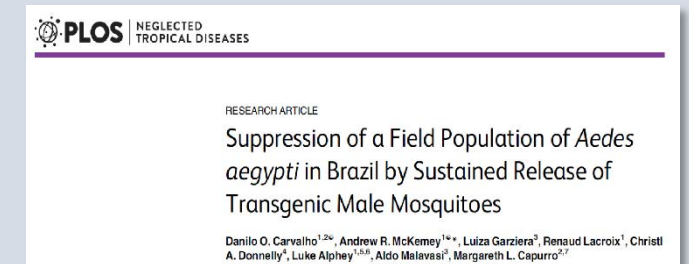
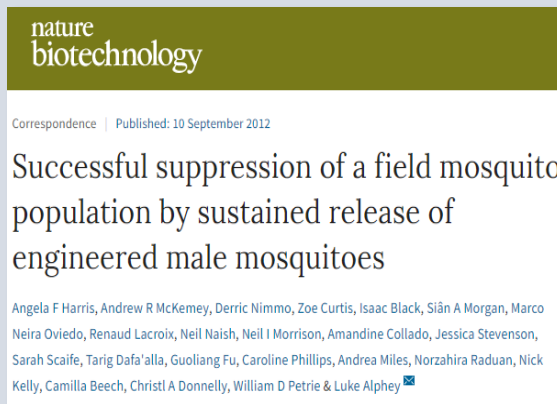
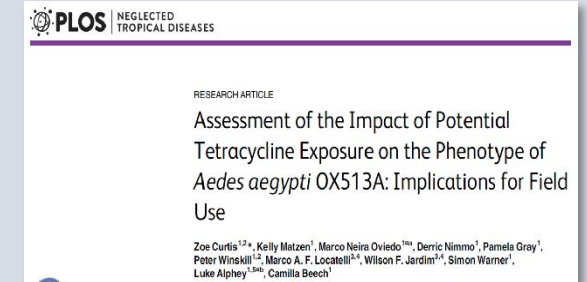
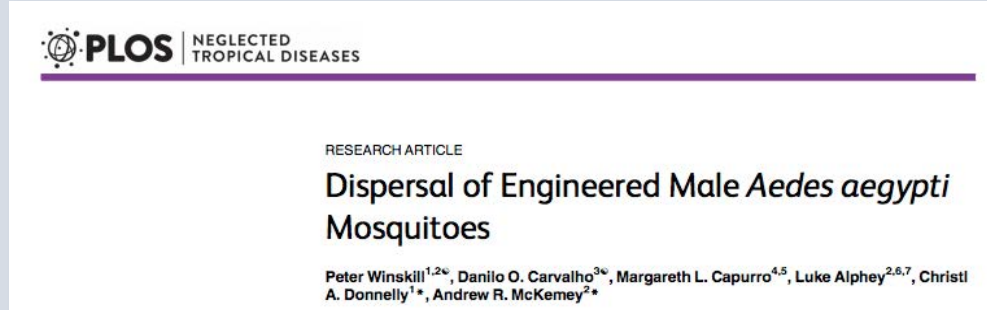


**Benjamin Sperry**  
Field Operations Manager

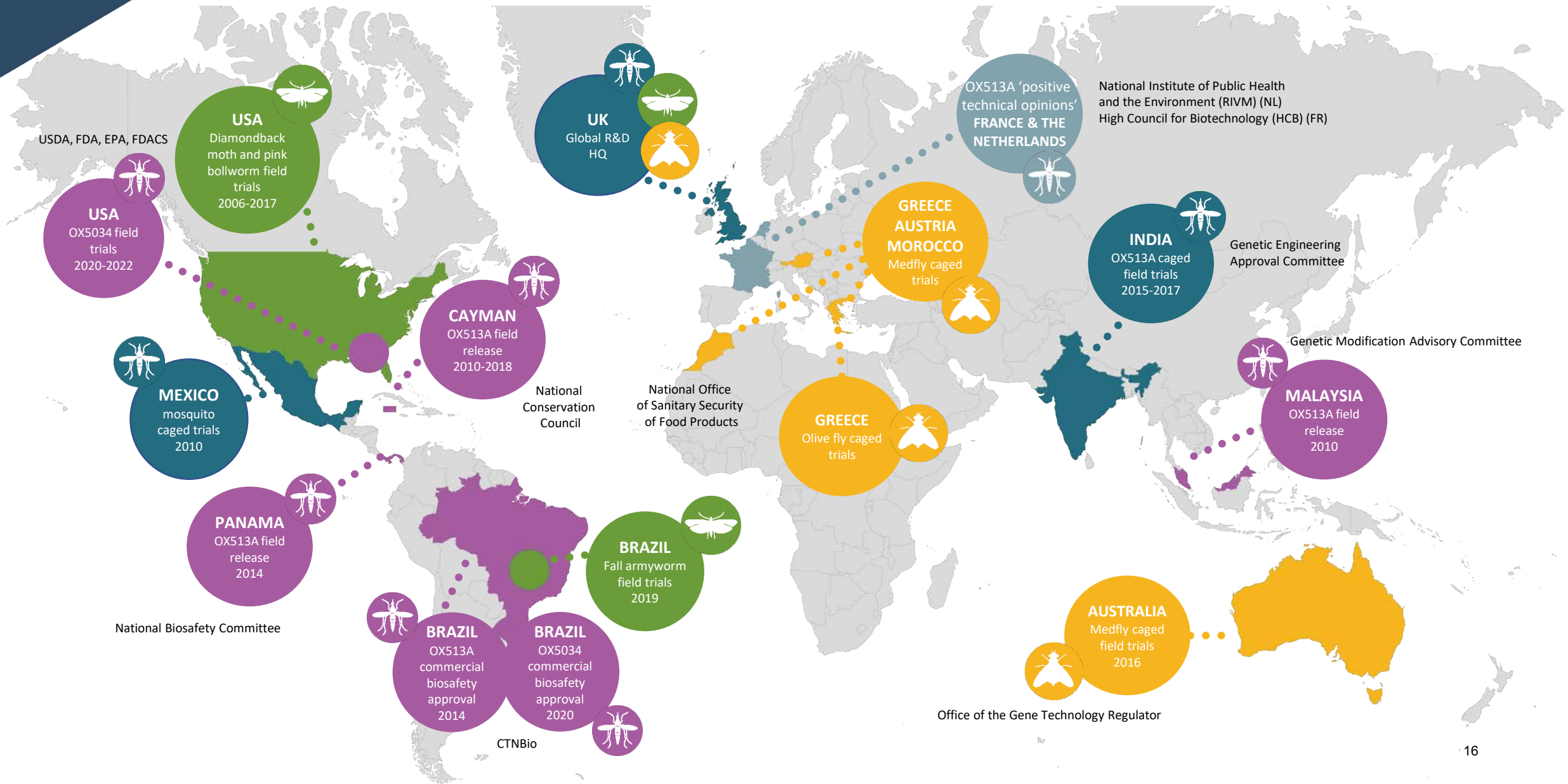




# Scientific Excellence: 100+ Peer-Reviewed Scientific Studies Published











# 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
- Potential synergies with other pest control methods

## OXITEC'S INSECT PROGRAMS

### PUBLIC HEALTH

### PROBLEM



### AGRICULTURE

### PROBLEM



*Aedes aegypti*

Dengue, Zika, chikungunya; current tools are failing



*Aedes albopictus*

Dengue, Zika, chikungunya; current tools are failing



*Anopheles stephensi*

Malaria; invasive, current tools are failing



*Anopheles albimanus*

Malaria; current tools are failing



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

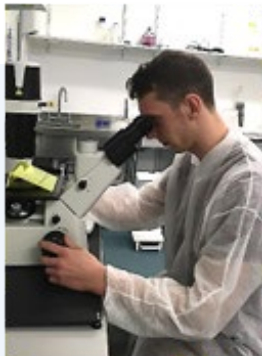


*Drosophila suzukii*

Soft fruits; highly invasive and difficult to control



# Decade of Performance, Safety and Partnerships



## SAMPLE DEPLOYMENT PROGRAMS, 2010 – 2020

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

Juazeiro, Bahia  
2010-2012

93%<sup>1</sup>

Juazeiro, Bahia  
2012-2013

96%<sup>2</sup>

Jacobina, Bahia  
2014

92%<sup>3</sup>

Nuevo Chorrillo, Panama  
2014

93%<sup>3</sup>

Piracicaba, São Paulo  
2015-2019

Successful  
4-Year Pilot

Piracicaba, São Paulo  
2016-2018

Successful  
65,000-  
Person  
Program

First OX5034  
Adult  
Biosafety  
Pilot  
Brazil  
2018-2019

96%<sup>4</sup>

1<sup>st</sup> OX5034  
Product Trial  
Indaiatuba,  
São Paulo  
In progress,  
2019/2020

2021

2020-  
21

US OX5034  
Pilot

OX5034  
Product Pilot  
(10k person)  
Indaiatuba  
2021

1<sup>st</sup> GENERATION *Aedes aegypti*  
DEPLOYMENT PROGRAMS

OX5034 DEPLOYMENT PROGRAMS



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

## OXITEC'S 2<sup>nd</sup> GENERATION *AEDES AEGYPTI*



TARGETED  
SUPPRESSION ✓

MALE-ONLY RELEASES  
(male mosquitoes do not bite) ✓

SAFE, NON-TOXIC,  
NON-ALLERGENIC ✓

TRACEABLE IN  
THE FIELD ✓

## OXITEC'S MALE MOSQUITOES CARRY ONLY TWO SAFE INTRODUCED GENES

1

### 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

#### MANUFACTURING



- Male-only production
- Egg releases and release devices enabled

#### DEPLOYMENT



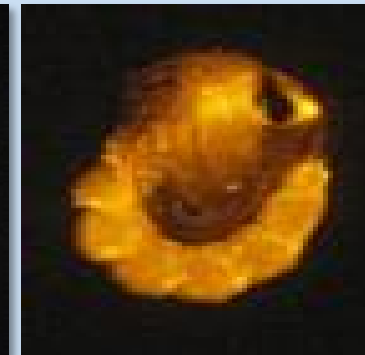
- 'Just-add-water' egg device
- Suppresses target mosquitoes
- Multi-generational suppression potential
- Gene is self-limiting in environment

2

### SIMPLE MARKER GENE

**Easy track-and-trace in the field**

Non-toxic, non-allergenic gene product (DsRed2 protein)

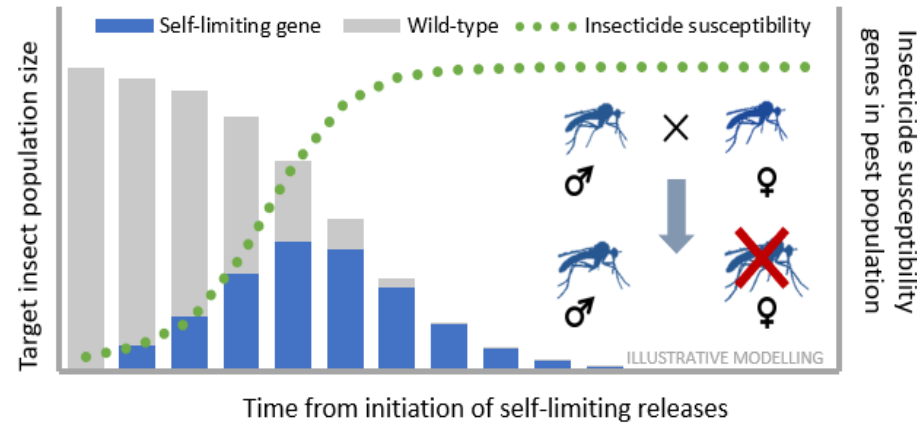




# Key Performance and Operational Benefits of OX5034

## 1 TARGETED PEST SUPPRESSION

- Significant pest suppression
- Multi-generation suppression
- Fully self-limiting
- Proven effective in [pilot study](#)



## 2 ENVIRONMENTALLY FRIENDLY

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

## 3 EFFICIENT MGF PRODUCTION

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



## 4 EASY DEPLOYMENT & SCALABILITY

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

<sup>1</sup>Harris et al. 2012 *Nature Biotech*; Ant et al. 2012 *BMC Biol*; Leftwich et al. 2014 *Proc Roy Soc B*; Carvalho et al. 2015 *PLoS Negl Trop Dis*; Gorman et al. 2016 *Pest Man Sci*.

<sup>2</sup>Harvey-Samuel et al. 2014 *Evol Appl*.

<sup>3</sup>Alphey et al. 2007 & 2009 *J Econ Entomol*.

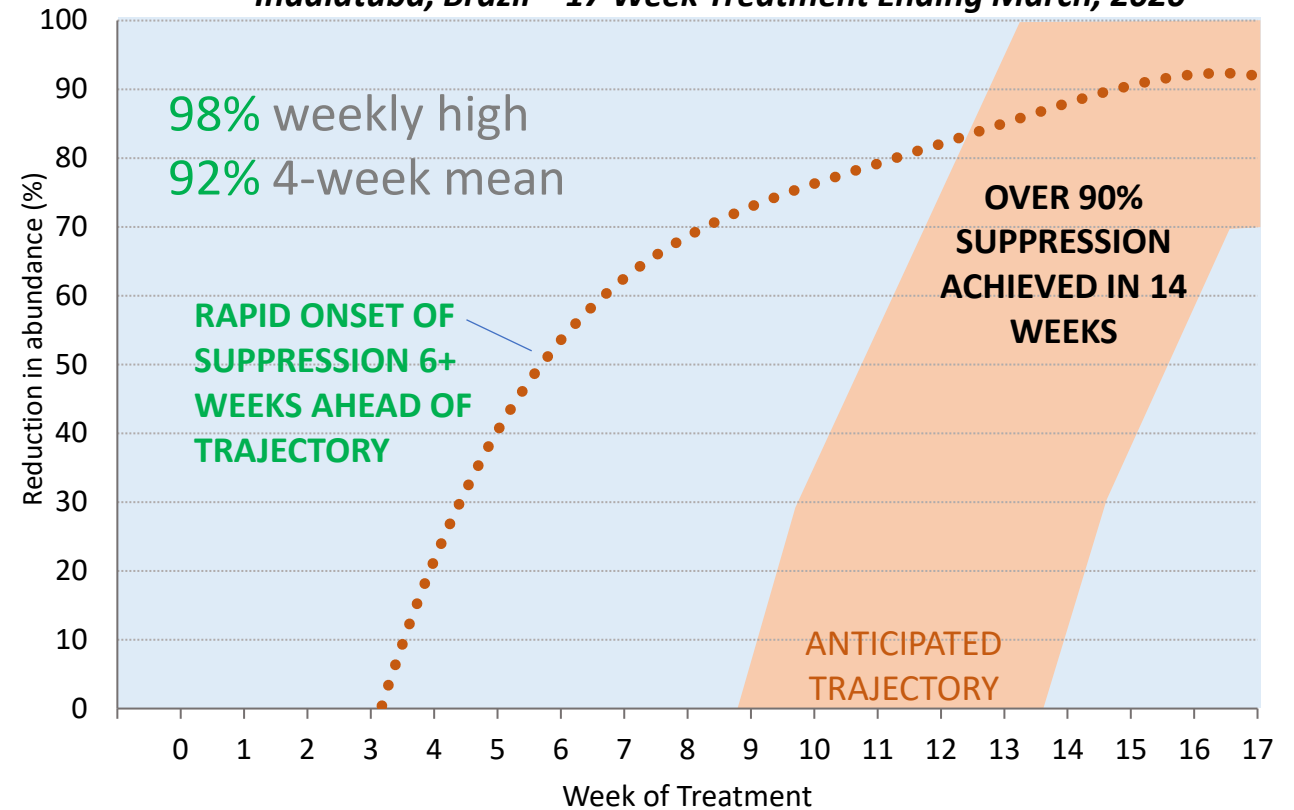




OXITEC

# OX5034 Mini-Capsule Pilot Exceeded Expectations

Field Trial #1 for Mini-Capsule Product – 1,000 Person Area  
Indaiatuba, Brazil – 17 Week Treatment Ending March, 2020



6  
Weeks

Faster to Suppression  
Than OX513A

90%

More Efficient  
Production &  
Deployment



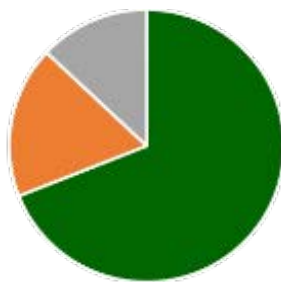
# High Public Acceptance and Strong Community Partnerships



## Oxitec establishes strong, collaborative partnerships with local communities it serves:

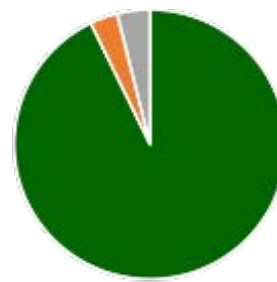
- Works in partnership with local government
- Proactively engages all segments of community
- Respects local social and cultural settings
- Develops multi-stakeholder coalitions
- Communicates openly and with transparency

CAYMAN ISLANDS, 2016



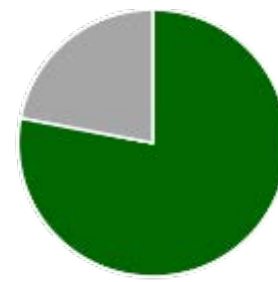
■ Support ■ Neutral ■ Oppose

PIRACICABA, BRAZIL, 2016



■ Support ■ Neutral ■ Oppose

USA, 2016 (PURDUE UNIVERSITY)



■ Support ■ Oppose



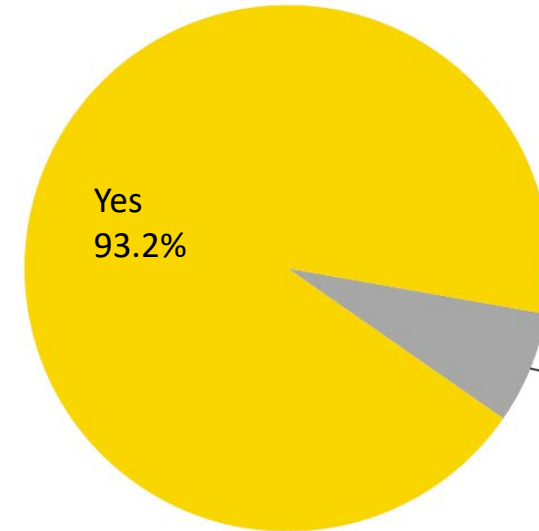
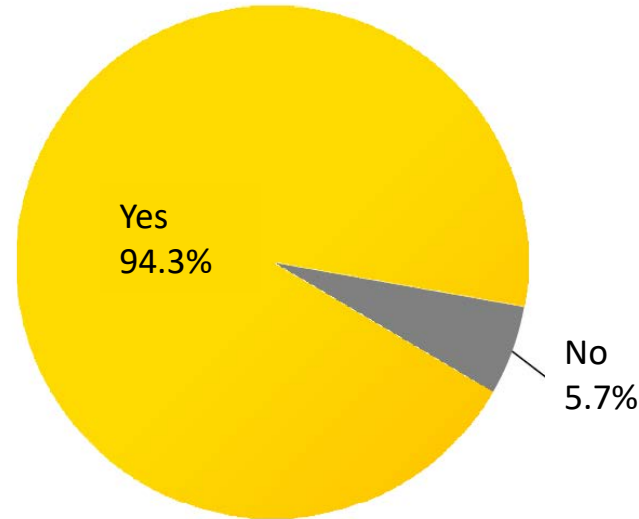


## OX5034 Mosquito Receives High Levels of Public Support

A public survey of 1,000 people carried out in September 2019 in the city of Indaiatuba, where Oxitec's 2<sup>nd</sup> Generation 'Aedes do Bem' had been released for 1 year, showed exceptionally high levels of support for the technology.

# 94%

would like the  
*Aedes do Bem!*<sup>™</sup> project  
to continue



# 93%

would like to see the  
project extended to other  
neighbourhoods

**METHOD:** Interviews  
**WHO:** >16 years old citizens of Indaiatuba, SP  
**HOW MANY:** 1000 interviews  
**DISTRICTS:** 17  
**WHEN:** September 2019





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# Oxitec Works Directly With Local Communities







Illustrative design similar to what will be piloted.

## Four Project Components

Community Engagement  
Mark-Release-Recapture  
Project A: Single-point Releases  
Project B: Area-wide Releases

**Safe &  
Non-Toxic**

**~130**  
Boxes  
Placed

**~28**  
Weeks

**0**  
Females  
Released





# Pilot Project Design in Collaboration with FKMCD

## Project Design Elements

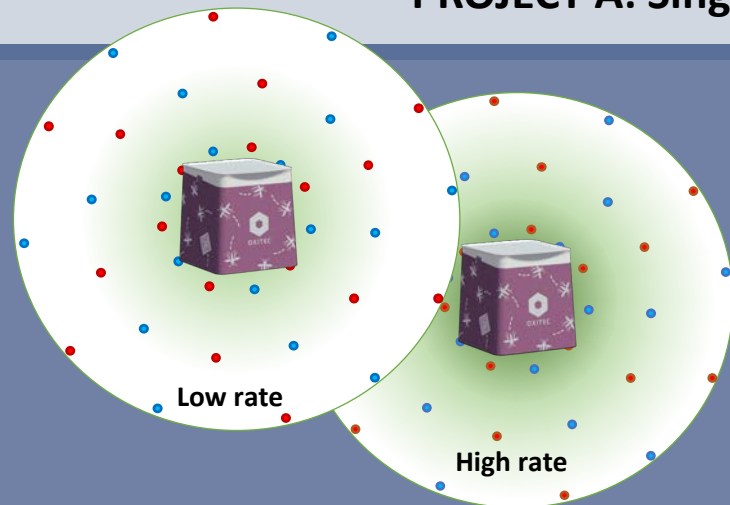
1. Single-point release with capture of males and offspring;
2. Multi-point release with capture of offspring;
3. Replicated and compared to untreated areas.
4. Locations TBD w/ FKMCD
5. Timing: 2020-2021

## Evaluation Elements

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



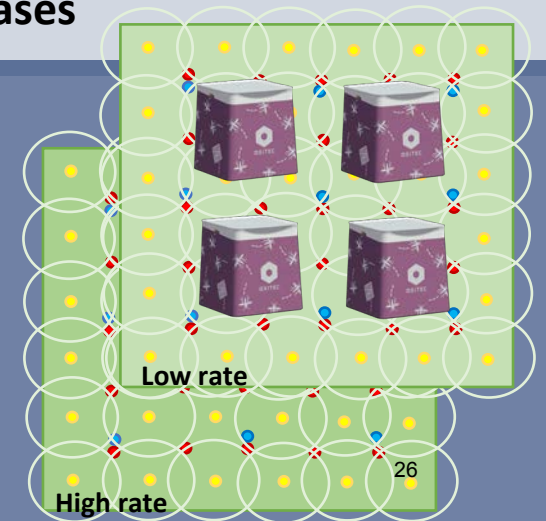
## PROJECT A: Single-Point Releases



### 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



# U.S. Approvals and Endorsements of Oxitec Technology

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

**OXITEC MOSQUITOES ARE SAFE.**



2006 ●

Approvals for agricultural insects

2017 ●

New York

2016 ●

FDA issues Finding of No Significant Impact for OX513A

2020 ●

EPA approves EUP including U.S. CDC Scientific Review for OX5034

2020 ●

FDACS approves Deployment Permit for OX5034



*“...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.”*

“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.”



## Full List

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)





## Highlights of EPA's Findings

<u>Topic</u>	<u>EPA's Response</u>
❑ Human Health	✓ No risk to human health from OX5034 male mosquitoes.
❑ Environment	✓ No risk to the environment, including endangered species.
❑ Trial Scope	✓ Two years of releases authorized, with weekly monitoring, and restrictions on proximity to sewage treatment plants and citrus groves.



## Topic

## EPA's Response

- |  |   |
|--|---|
| <input type="checkbox"/> Tetracycline                            | ✓ <i>“<b>negligible risk</b> that testing of OX5034 mosquitoes would spread antibiotic resistant bacteria in the US environment” (p75-76, Response to Comments)</i>   |
| <input type="checkbox"/> GM mosquito survival in the environment | ✓ <i>“introgression of OX5034 strain genetics into the local wild <i>Ae. aegypti</i> mosquito population is likely to occur during releases of OX5034; however, the <b>risk resulting from such introgression is negligible</b>” (p134, Response to Comments)</i> |
| <input type="checkbox"/> Informed Consent                        | ✓ <i>“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 “... (p134-137, Response to Comments)</i>   |



## Misconceptions

- ❑ Spread of tetracycline-resistant bacteria
- ❑ Oxitec's OX513A EUP application rejected
- ❑ FKMCD rejected OX513A project in 2016

## Documented Facts

- ✓ 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.
- ✓ The EPA did not reject any Oxitec application; Oxitec withdrew its OX513A application to focus on the 2<sup>nd</sup> Generation *Aedes aegypti*, OX5034.
- ✓ Not true. FKMCD approved an investigational agreement 2016





## **Q: How does this 2<sup>nd</sup> Generation Friendly technology work?**

A: We use genetics to provide two useful traits in our insects. A Self-Limiting gene allows us to release male-only cohorts of 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 allows for easy and effective monitoring of performance.

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

A: 2<sup>nd</sup> Generation Friendly *Aedes aegypti* 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?**

**A: 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.

### **Q. Are Self-Limiting mosquitoes an environmentally sustainable vector control tool?**

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

### **Q. Will Oxitec mosquitoes harm birds, bees, bats, fish, turtles, or other sensitive wildlife?**

**A: No, not at all.** The EPA and State of Florida confirmed this.



### **Q. Are Oxitec mosquitoes safe?**

**A: Yes.** The EPA confirmed that Oxitec mosquitoes pose no risk to humans, animals or the environment. In 2016, the FDA confirmed its “Finding of No Significant Impact” to humans, animals or the environment.

### **Q. Has Oxitec’s OX5034 been tested elsewhere?**

**A: Yes.** OX5034 has now been successfully deployed for more than two years in Brazil.

### **Q. Is Oxitec seeking payment from tax payers for this project?**

**A: No.** Oxitec is funding this project.



# FAQ About Oxitec's OX5034 Mosquitoes

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## Q. Why not just use insecticides?

A: 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. 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.

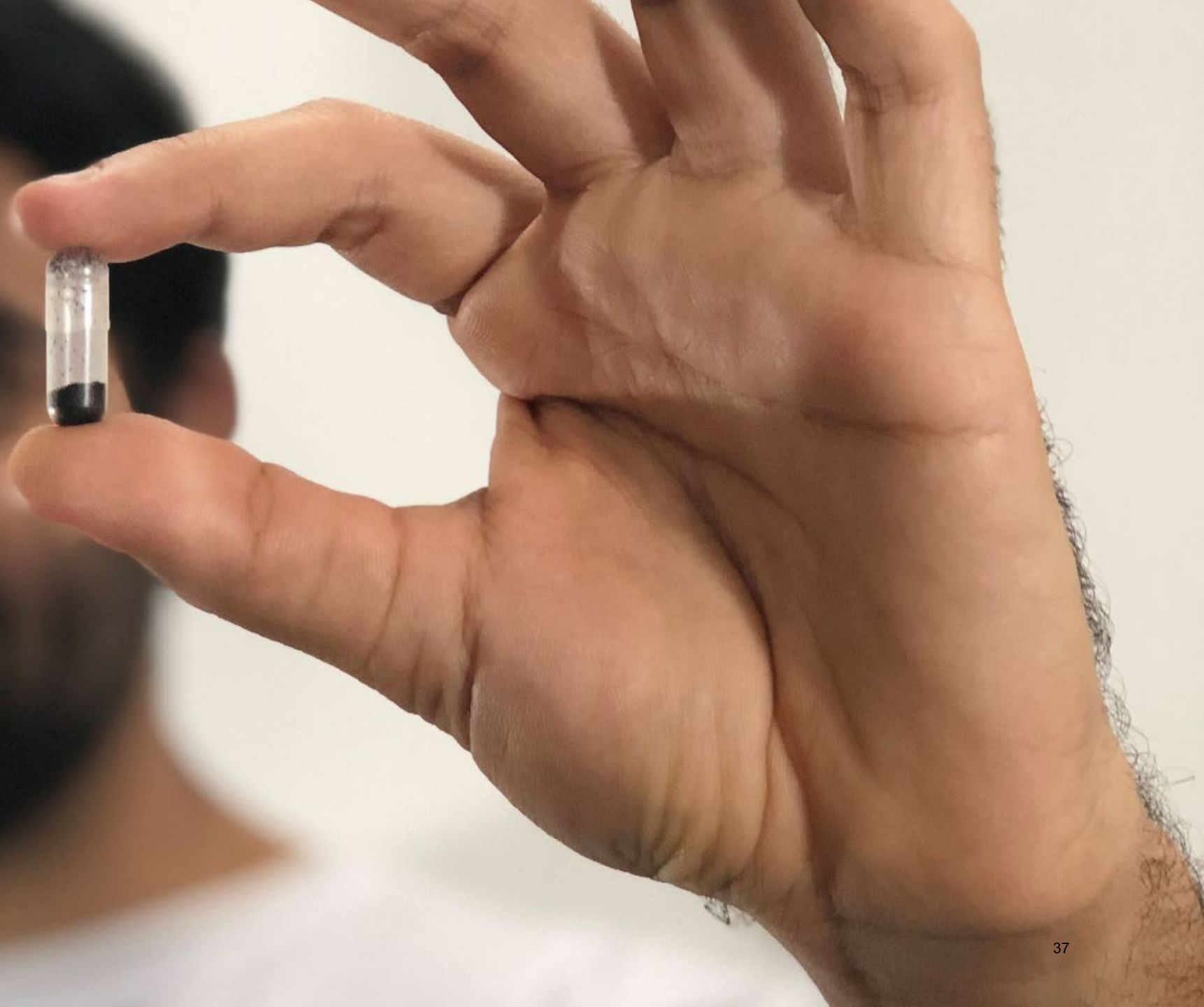
## Q. What about the news headlines last year relating to hybrid GM mosquitoes?

A: News headlines last year highlighted a paper which contained inaccurate, 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, interpretations of the data, and speculations. It also validated claims that some of the named authors had not approved the final version that was submitted for publication.

**Important Update:** Scientific Report editors publish [Editorial Expression of Concern](#) for Evans et al., 2020.



OXITEC



THANK YOU!

## 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/USAEPAPPT/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>

**Florida Department of Agriculture and Consumer Services (FDACS) Authorization, 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](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](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](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](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 31 out of 33 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 [issuing its 2016 findings](#) 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. [This research article](#) and [press release](#) about the survey are publicly available.

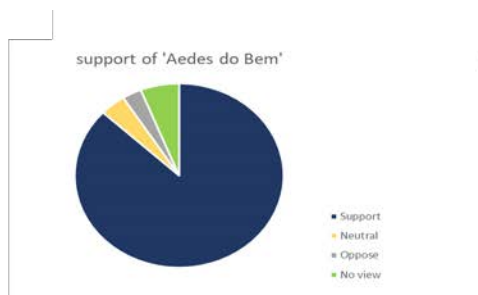
Oxitec's technology has since received unanimous approval from the following U.S.-based agencies:

- [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. [This FDACS authorization](#) includes approvals from:
  - 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)

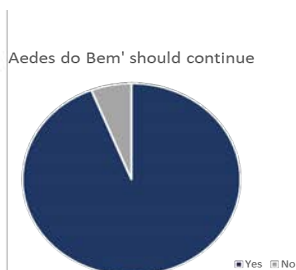


### OX5034 “Aedes do Bem” Project in Indaiatuba, Brazil

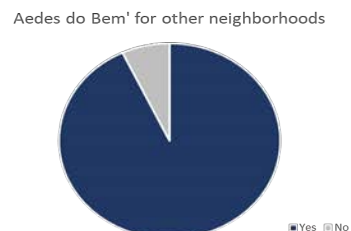
*Survey conducted in September 2019*



**87%** fully support  
'Aedes do Bem'  
project



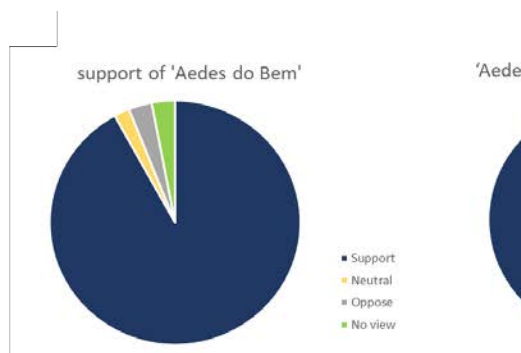
**94%** would like the  
'Aedes do Bem'  
project to continue



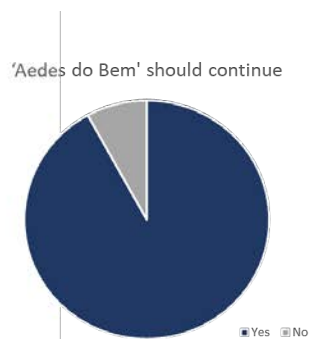
**93%** would like to see  
the Project  
extended to other  
neighbourhoods

### OX513A “Aedes do Bem” Project in Piracicaba, Brazil

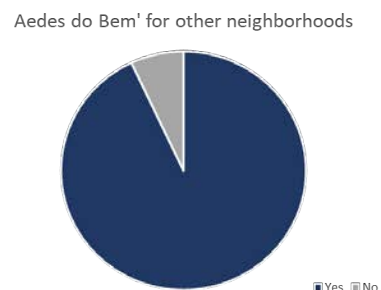
*Survey conducted in May 2019.*



**92%** fully support  
'Aedes do Bem'  
project



**93%** would like the  
'Aedes do Bem'  
project to continue



**94%** would like to see  
the Project  
extended to other  
neighbourhoods

### **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" [said Dr. Pedro Mello, Piracicaba's Secretary of Health.](#)

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* mini-capsule technology. Implemented in close partnership with the City of Indaiatuba, Brazil, the Friendly™ mini-capsule 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

#### **EPA Approves Experimental Use Permit for Field Testing of Genetically Modified Aedes aegypti Mosquitos**

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**

#### **'Just Add Water' GM Mosquitoes Suppress Wild Population by 95%**

Biotech News

#### **'Just Add Water' GM Mosquitoes Suppress Wild Population by 95%**

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 Females](#)

Newsweek

[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