



# FKMCD-Oxitec Public Educational Webinar #7

## Human Health and Oxitec: The Safety of Oxitec Technology

27 October 2020



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# Introductions – Panelists With You Today



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**Andrea Leal**  
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FKMCD



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Oxitec

FKMCD and Oxitec are hosting a series of public educational webinars to share information with residents of the Florida Keys and provide forums to answer questions.

- All webinars are open to everyone
- All webinars are recorded and made available for everyone after the event
- All questions will be answered (some in batches if questions are similar)
- If time runs out, we will accept questions in writing via [florida@oxitec.com](mailto:florida@oxitec.com)
- Questions and answers will be published in writing after the event with external or related online resources/references

## Upcoming:

1. **Virtual Tour: Inside Oxitec Labs** – coming in November! *Meet the team that produces mosquitoes for the project and see inside one of Oxitec's production facilities in a virtual tour.*
2. **What's in the Box?: How Oxitec's Just-Add-Water Technology Helps Control the *Aedes aegypti* Population** – coming in December!
3. **Preparing for the FKMCD-Oxitec Pilot Project: Overview of Field Trial Design and Management** – coming in January!



## Welcome to Webinar #7!

### Today's Agenda:

- Why now? Health, economy and the environment.
- Disease transmission by the invasive *Aedes aegypti* mosquito.
- Current options for mosquito control.
- Benefits of Oxitec's targeted biological control solution.
- Safety of Oxitec's OX5034 male mosquitoes.
- Regulatory findings.
- Your questions, answered.

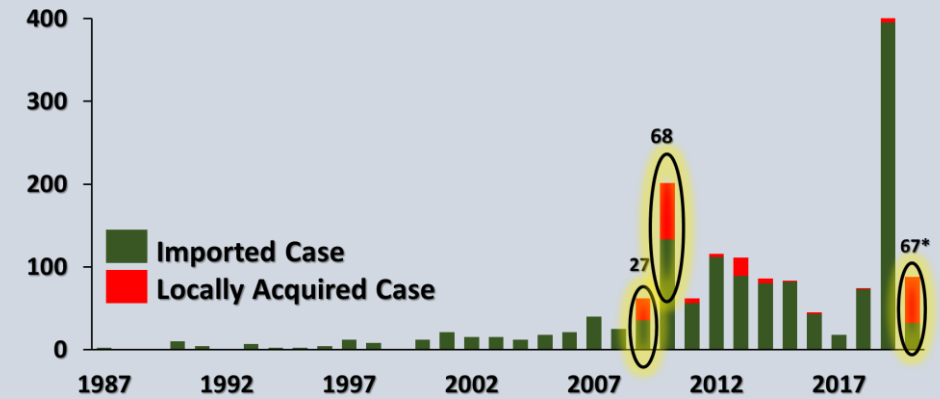


# Why now? – Health and the Environment



- Dengue is an ongoing challenge with over 65 confirmed locally-acquired cases in Monroe County so far in 2020
- The threat of other diseases such as Zika, chikungunya and yellow fever persists
- Insecticide resistance in local mosquitoes
- Need more tools in our toolbox

### Dengue Cases in Florida Since 1987



\*As of 10/27/2020



- Environmental impact is a major consideration, including for human health
- Using species-specific tools minimizes harmful impacts
- Nine national and state agencies concluded Oxitec male mosquitoes pose no risk to human or environmental health
- More than one billion Oxitec mosquitoes have been produced for release worldwide, with no negative impacts



Photo: Jaret Daniels

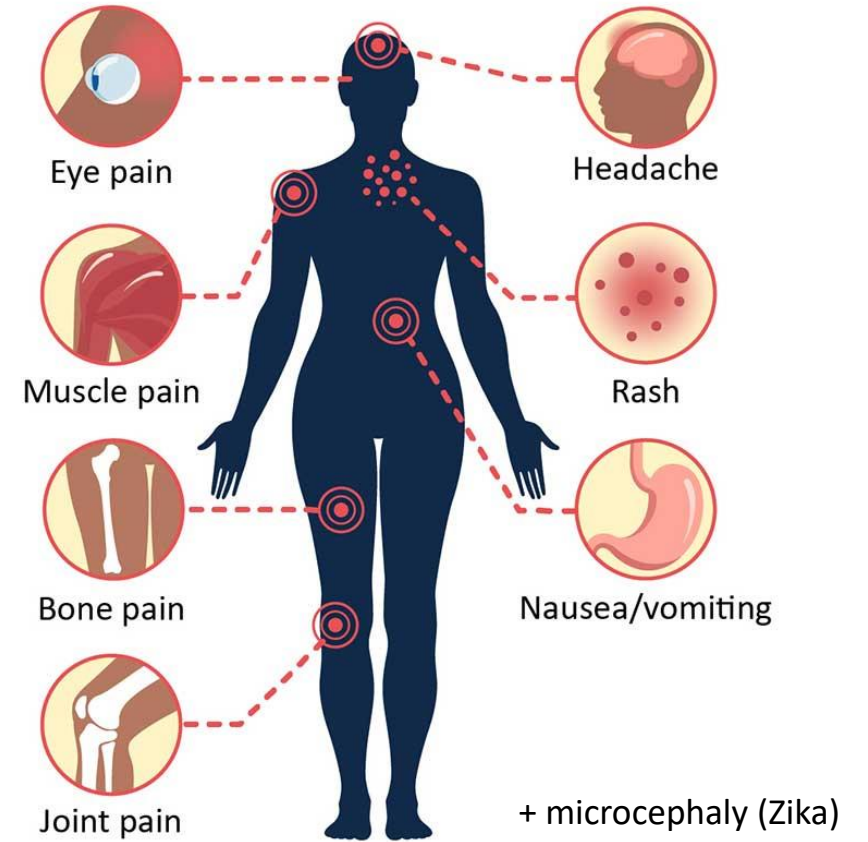
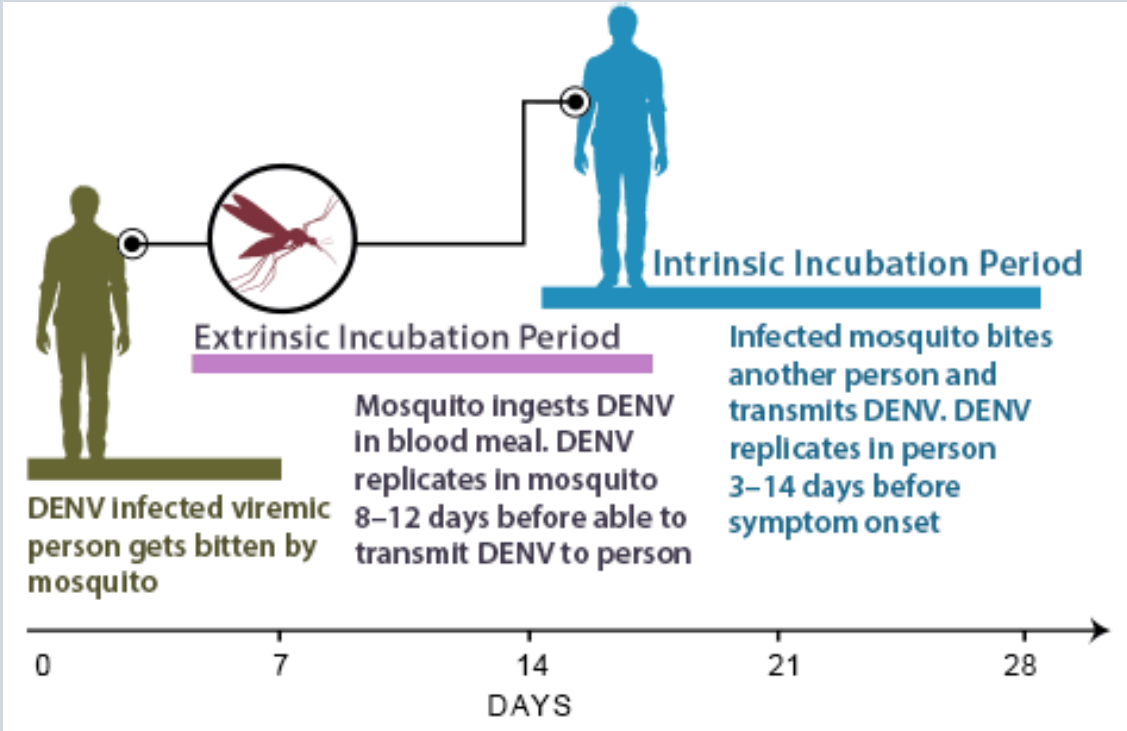
Endangered Schaus' swallowtail butterfly lives where the current dengue outbreak is.



# Dengue, Chikungunya, Zika, Yellow Fever



Dengue, Chikungunya, Zika, Yellow Fever and other viruses are all transmitted by female *Aedes aegypti* mosquitoes. Only Yellow Fever has an effective vaccine available.



Symptoms of these viruses range from mild to severe.

- Dengue Hemorrhagic Fever (DHF) is a severe form of dengue that may be life-threatening.
- Zika may result in microcephaly in babies.

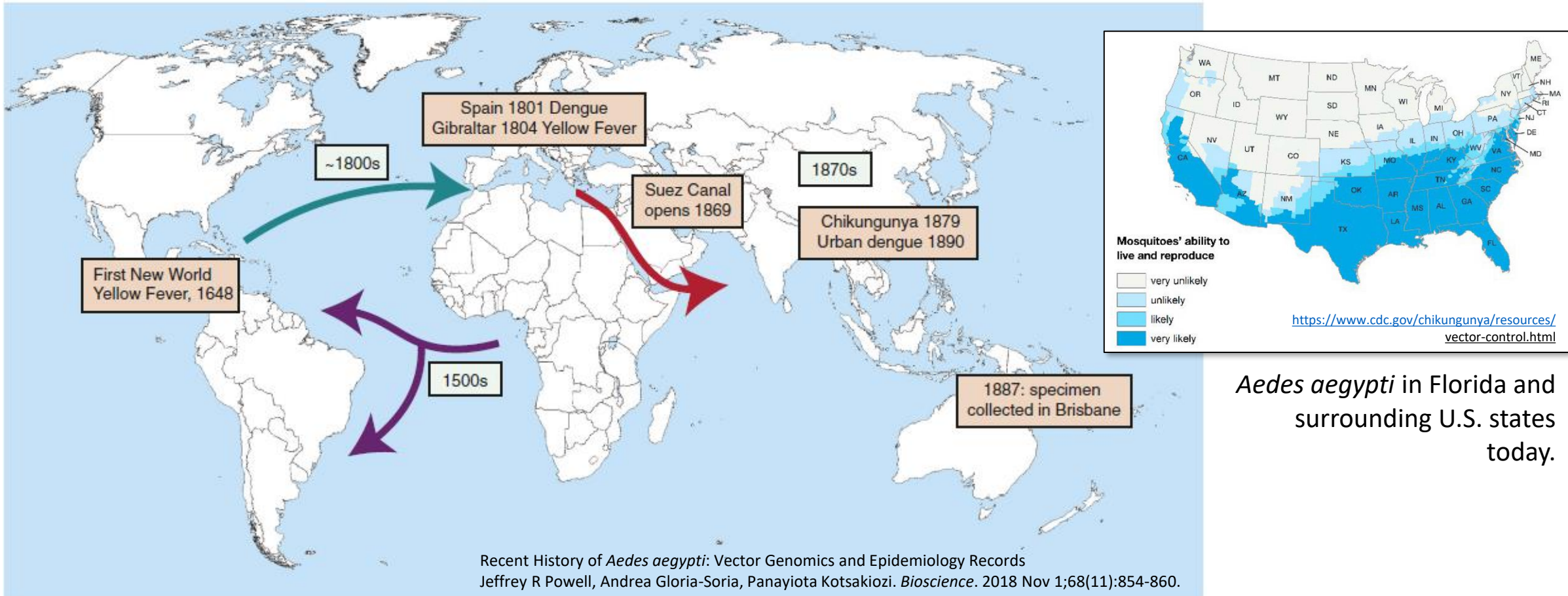




# The *Aedes aegypti* Mosquito: an Invasive Species in Florida



*Aedes aegypti* is not native to the Americas. It was most likely transported from Africa by Portuguese ships sometime in the 16<sup>th</sup> century, bringing viral diseases with it.



*Aedes aegypti* in Florida and surrounding U.S. states today.





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# Current Options for *Aedes aegypti* Control



- Insecticides (pyrethroids, organophosphates), with resistance an increasing problem
- Aerial *Bti* spraying
- Breeding site disruption/removal

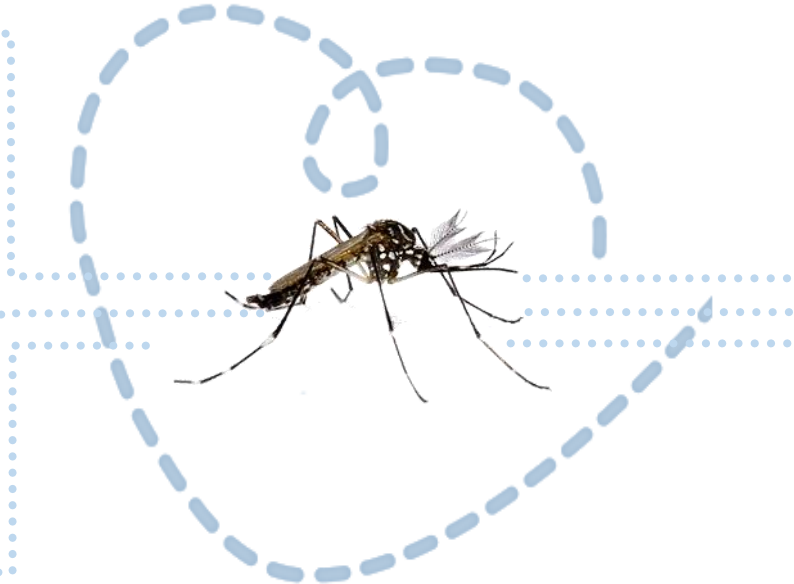


## OXITEC'S *Aedes Aegypti*

✓ TARGETED SUPPRESSION

✓ SAFE, NON-TOXIC, NON-ALLERGENIC

✓ PROVEN EFFECTIVENESS



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

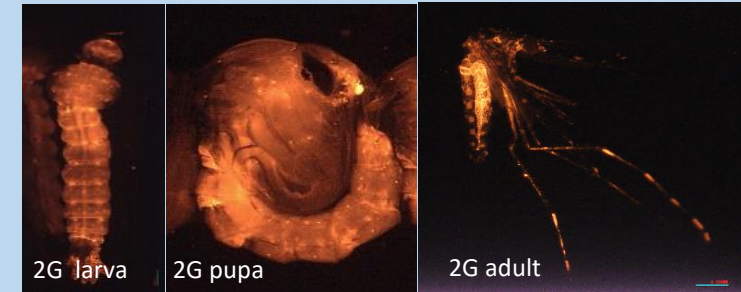
TRACEABLE IN THE FIELD ✓

SELF-LIMITING IN THE ENVIRONMENT ✓

- No females produced
- Low-tech, egg-based devices enabled



- Easy track-and-trace in the field
- Non-toxic, non-allergenic



# Do Oxitec Mosquitoes Bite?



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# No.

## Oxitec mosquitoes do not bite.

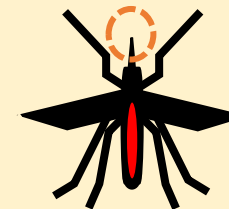
Only female mosquitoes bite.

There will be no Oxitec female mosquitoes.

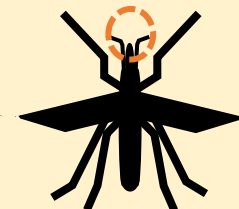
Oxitec male mosquitoes are safe and non-toxic.

### MALE MOSQUITOES CANNOT BITE

**FEMALE:**  
Biting  
mouthparts



**MALE:**  
Non-biting  
mouthparts



The mouthparts of males mean they are physically unable to bite people





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# How Does the Self-Limiting Gene Work?

## SELF-LIMITING FEATURES:

- Females cannot survive
- Male OX5034 mosquitoes are unaffected:
  - Male-only production;
  - Egg release devices;
  - Suppression of wild mosquito populations, as female offspring cannot survive.

Zero OX5034 females released  
Males are unaffected



**20 million**

male OX5034 mosquitoes released in Brazil

**1 billion**

OX513A mosquitoes produced for release globally

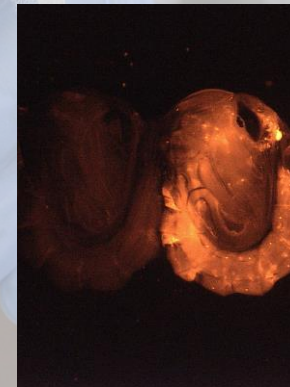
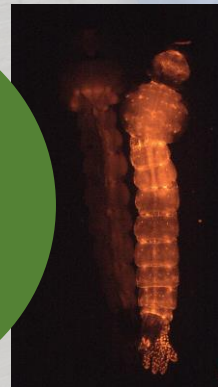
**Zero Negative Impact**



## THE DSRED2 PROTEIN:

- Allows us to track Oxitec mosquitoes after release
- Widely used in biology for 20 years
- Produced in OX5034 mosquitoes at all life stages
- Male OX5034 mosquitoes can pass on the gene to their offspring

Non-toxic,  
non-allergenic  
protein that is  
visible under  
special filters





# Background Genetic Introgression

The EPA and CDC reviewed the impact of ‘introgressing’ background genes, concluding there was no risk to human health or the environment and no risk of “hybrid vigor”.



Regulatory Agencies Confirmed

- + NO HYBRID VIGOR
- + NO INSECTICIDE RESISTANCE
- + NO ADDED VECTORIAL CAPACITY



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Beer



Cotton Textiles



Medicines



Vaccines



Fruit

Biotechnology is Everywhere  
in Public Health and  
Everyday Life

Vegetables  
and Grain





## 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

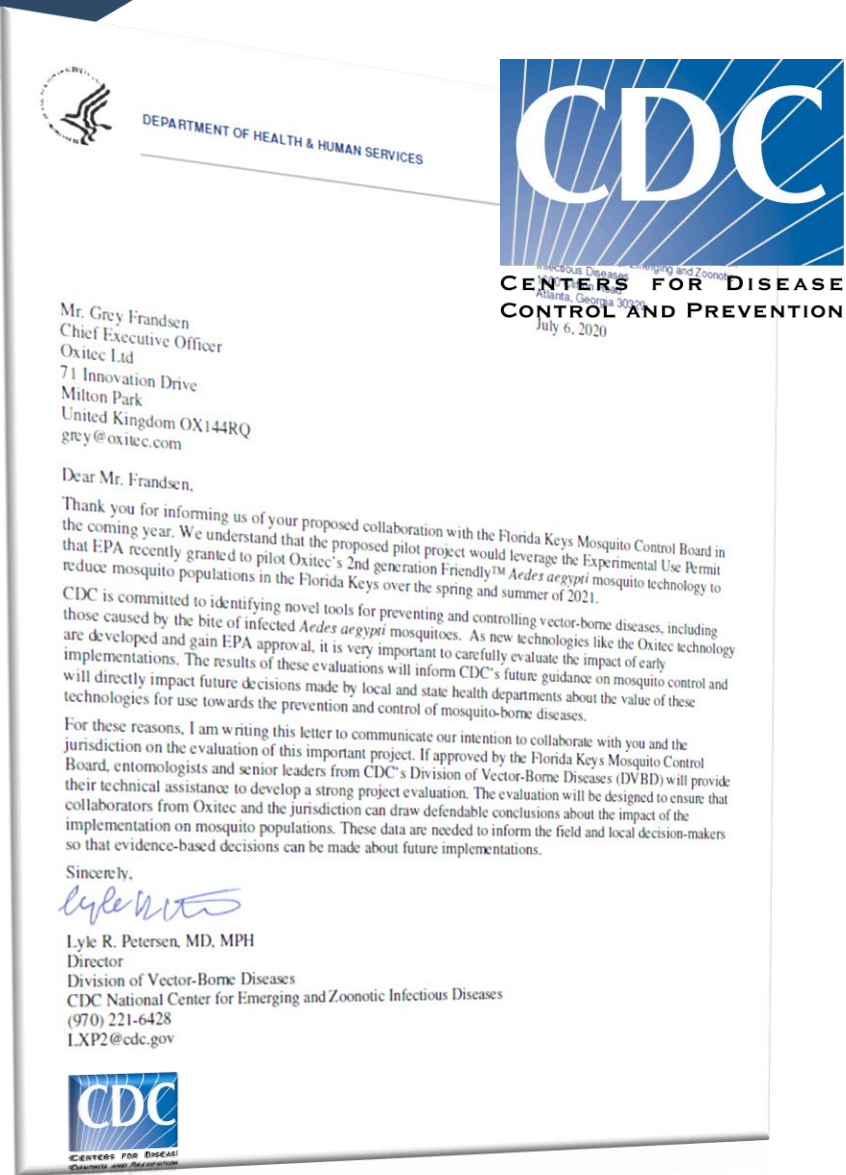
### Mosquito Characterization and Performance:

- Insecticide Susceptibility
- Trait Penetrance
- Tetracycline Response
- Stability of Genetic Traits
- Trait Persistence
- Field Data (Brazil)
- Protein Stability
- Arbovirus Screening
- Introgression Analysis
- Complete SOPs
- Analytical Methodologies

\*see September Webinar for details



# We Continue to Invite Comprehensive Independent Reviews



## CDC confirms participation:

*“...I am writing this letter to communicate our intention to collaborate with you and the jurisdiction on the evaluation of this important project.*

***...entomologists and senior leaders from CDC’s Division of Vector-Borne Diseases (DVBD) will provide their technical assistance to develop a strong project evaluation.”***

Lyle Petersen, MD, MPH  
Director of Division of Vector-Borne Diseases  
Centers for Disease Control and Prevention

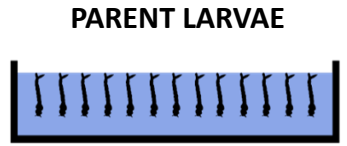


# How Are OX5034 Mosquitoes Produced in the UK?



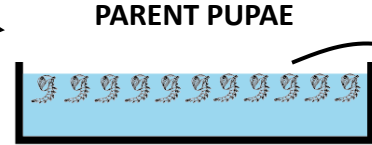
1

Eggs hatch into larvae. Small amount of tetracycline is added to larval water so females can survive.



No tetracycline used beyond this point

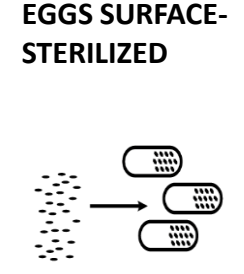
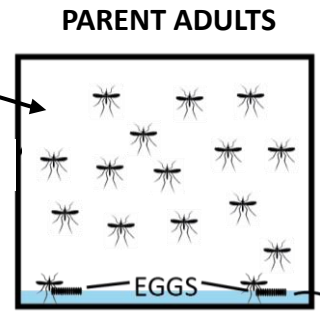
2



Once larvae pupate, they are washed and moved to clean water.

- ✓ EPA compliant quality control at every step
- ✓ Egg surfaces sterilized with sanitizer 4x stronger than hospital-grade disinfectant

3



4

**Tetracycline**  
Is used only in the UK to produce female OX5034 to lay eggs

To produce all the eggs required for this project, Oxitec will use less tetracycline than sugar in a 5g packet

**Quality Control**  
on every batch of eggs to check self-limiting gene function and male performance

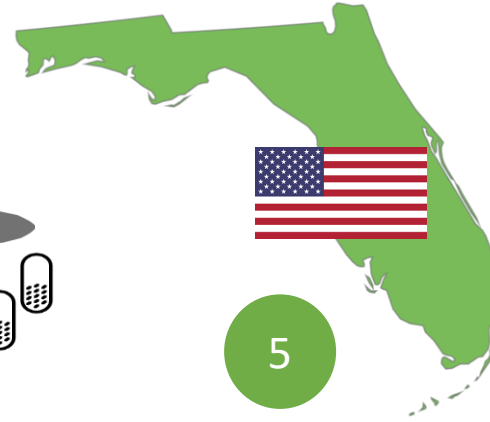
# How Are OX5034 Mosquitoes Delivered to the Keys?



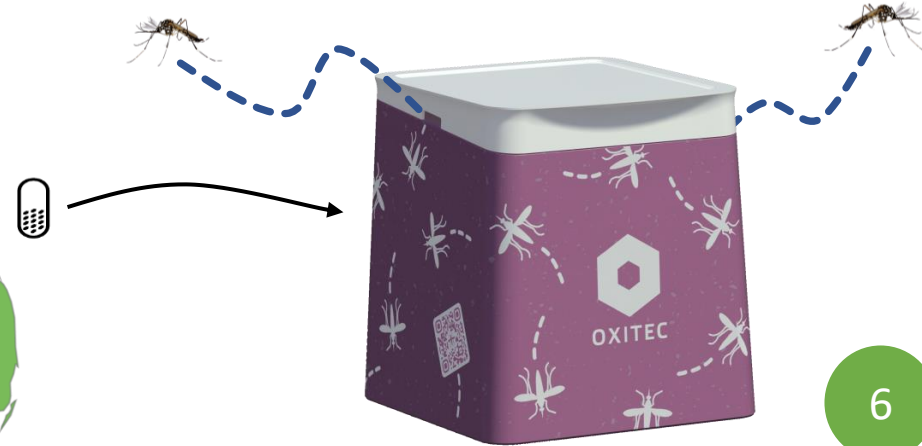
EGGS PACKAGED IN  
MINI CAPSULES



4



5



6

BOXES ARE PLACED BY FKMCD/OXITEC OPERATORS



7

- ✓ No female release & no biting
- ✓ Only male adults in the box
- ✓ **No tetracycline in the box**
- ✓ **No tetracycline in Florida**
- ✓ Boxes will be placed in out-of-the-way areas





EPA has concluded that *“there is negligible risk that testing of OX5034 mosquitoes would spread antibiotic resistant bacteria in the US environment”*



FDA has previously concluded that *“the likelihood of the adverse effects associated with development of anti-microbial resistance is extremely low.”*

- + **Eggs shipped to Florida have never been in contact with tetracycline**
- + To produce all the eggs required for this project in the UK, **Oxitec will use less tetracycline than sugar in a packet, equivalent to two human therapeutic courses**



## In the USA, every year:

- Doctors' offices and emergency departments prescribe about 47 million antibiotic courses for infections that don't need antibiotics ([CDC](#))
- Nearly 4,000 tons supplied to livestock and pets ([FDA](#))

## In Florida:

- Up to 388,000 lbs of oxytetracycline approved for spraying each year on 300,000+ acres of citrus farms since 2015 ([EPA](#))
- Use of tetracyclines on farms and in human medicine is linked to resistant bacteria in waterways and coastal waters<sup>1</sup>, and marine wildlife<sup>2</sup>

<sup>1</sup><https://www.mdpi.com/2079-6382/9/3/118/htm>

<sup>2</sup>Schaefer et al, 2009 *Ecohealth* 6: 33–41.

# Success in the Field: Decade of Performance, Lessons & Proof-points

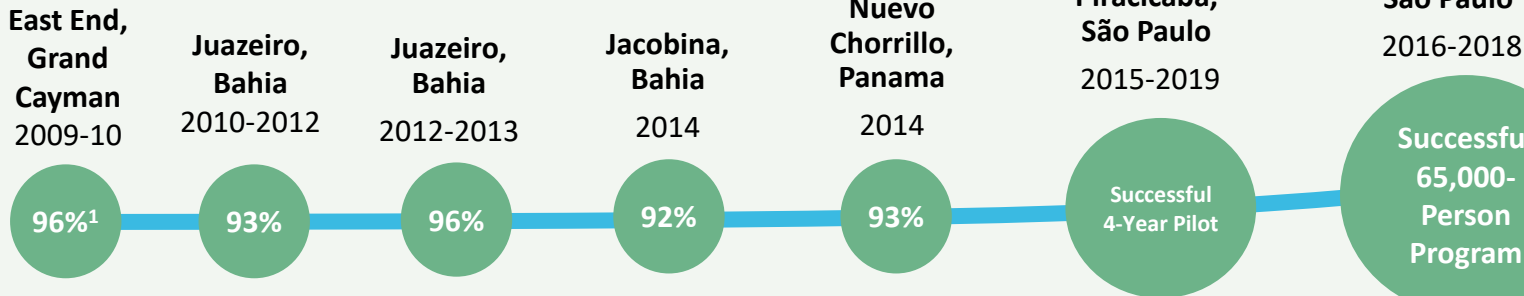


- Published **peak suppression performance of wild-type *Aedes aegypti* ranging from 92% to 96%** as compared to control sites (see below)
- 1Bn+ Oxitec mosquitoes produced for release with no adverse effect on humans or the environment**
- Deployments ranged from small-scale to **coverage of 65K people**
- Successful suppression of target *Aedes aegypti* populations in range of deployments**
- Demonstrated **safe with no lasting impact on the environment, humans or animals**
- Multiple pilot approvals** from biosafety regulators

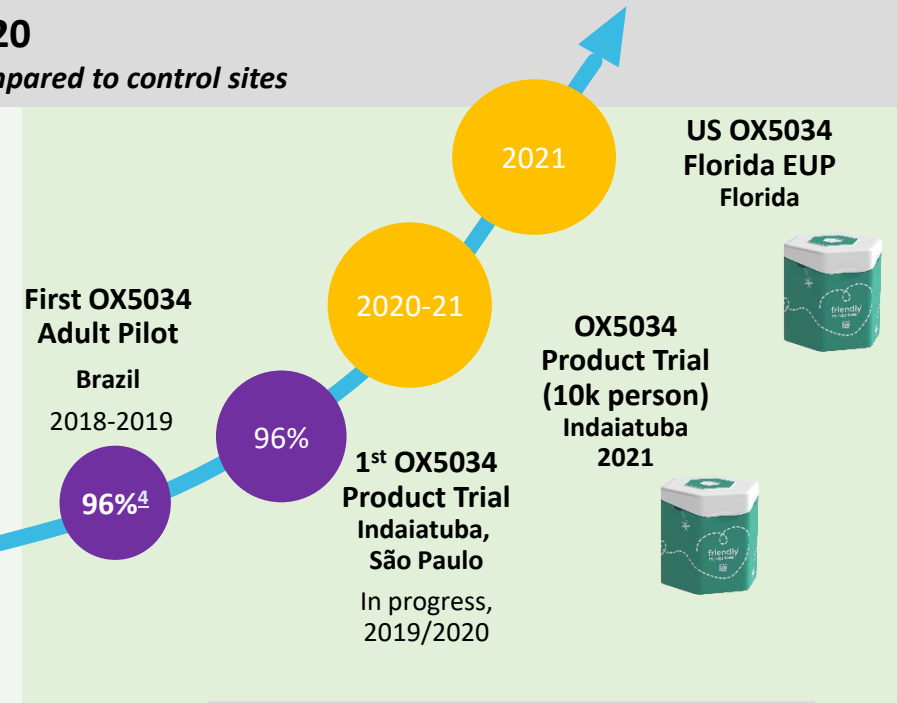


## SELECTED DEPLOYMENT PROGRAMS, 2010 – 2020

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



**BRAZIL 1<sup>st</sup> GENERATION Aedes Aegypti DEPLOYMENT PROGRAMS**



**OX5034 DEPLOYMENT PROGRAMS**





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# EPA and State of Florida Departments/Bureaus Unanimously Approved Permit



## EUP Approved By:

- ✓ US Federal EPA (with CDC expert reviews)
- ✓ 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)

## Further endorsement:



In 2016, following the declaration of a public health emergency of international concern, the World Health Organization recommended Oxitec mosquitoes for pilot deployment to fight the growing threat posed by the Zika virus

- An increasing disease threat is evident.
- Protecting against an invasive species is important.
- Oxitec's non-biting male mosquitoes pose no risks to human health.
  - *Male mosquitoes are harmless to humans, they cannot bite people or spread disease.*
  - *More than one billion Oxitec mosquitoes produced for release worldwide, with no negative impacts.*
- OX5034 could reverse increasing resistance to insecticides.







# Question and Answers



**Any and all questions on this evening's topics are welcome!**

*(If we run out of time tonight, email [florida@oxitec.com](mailto:florida@oxitec.com) and we will attempt to answer your question if it isn't included in the growing FAQ or post-event summary we publish online at [oxitec.com/florida](http://oxitec.com/florida) and [keysmosquitoproject.com](http://keysmosquitoproject.com))*



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# Conclusion



## THANK YOU!

A summary of this event, as well as more Q&As, resources, facts, and background materials are available at [oxitec.com/florida](https://oxitec.com/florida) and [keysmosquitoproject.com](https://keysmosquitoproject.com).