# **Introductions – Panelists With You Today**









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### **Delta MVCD-Oxitec Public Educational Webinar Series**

#### **Introduction to our Webinar Series**

Delta MVCD and Oxitec are hosting a series of public educational webinars to share information with residents of Tulare County and provide forums to answer questions.

- Webinars are open to everyone.
- Webinars are recorded and made available for everyone after the event.
- All questions relating to the webinar topic(s) will be answered (some in batches if questions are similar).
- If time runs out, we will accept questions in writing via <u>info@oxitec.com</u>.



### **Delta MVCD-Oxitec Public Educational Webinar Series**

Today's Agenda

### Today's Agenda:

- About Oxitec (Briefly)
- Oxitec's Friendly<sup>TM</sup> Technology History and Overview
- Partnerships and a Decade of Results Around the World
- Your Questions, Answered









# History: Oxford Roots with Expansive Validation and **Preparation for Scale**



#### PLATFORM VALIDATION

#### PREPARING TO SCALE

#### **PRODUCT LAUNCHES**

#### 2002-2010

- Early platform development
- First GM insect trial: Oxitec pink bollworm pilots on US cotton
- First field demonstration of Friendly™ Aedes, Cayman Islands

#### 2011-2017

- 1st Gen efficacy trials, Panama and Brazil
- Bayer collaboration initiated, fall armyworm
- Friendly™ diamondback moth field trials, USA

#### 2018-2019

- Transition to 2nd Gen Friendly™ Aedes
- Oxitec malaria program initiated
- Bayer collaboration extended to soybean looper

#### 2020

- Friendly™ Aedes deregulation, Brazil
- Friendly™ Aedes device validated, Brazil
- EPA approves Friendly™ Aedes pilot, USA
- First Friendly™ fall armyworm trial, Brazil

#### 2021-22

- Friendly™ Aedes launch, Brazil
- First Friendly™ Aedes pilot, USA
- Friendly™ fall armyworm deregulation, Brazil
- Friendly<sup>™</sup> cattle ticks program initiated

#### **KEY PARTNERSHIP AND REGULATORY MILESTONES**

2002



**SPIN-OUT** & SUPPORT 2006



PINK **BOLLWORM TRIALS** 

2010



1<sup>st</sup> FRIENDLY™ **PILOT** 

2014



FRIENDLY™ **AEDES PILOT**  2015



**PARTNERSHIP** 

2017



1st FRIENDLY™ **AG PILOT** 

2018



**PARTNERSHIP** 

2020



**AEGYPTI DEREGULATION** 

2021



**NEW PARTNERSHIP** 



**COLLABORATION** 



**FAW DEREGULATION** 

**AEDES** 

**EPA PILOT APPROVAL** 

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# Friendly™ Technology Applied to Diverse Pests and Markets



### Applicable to a diverse range of important pests with a set of key traits













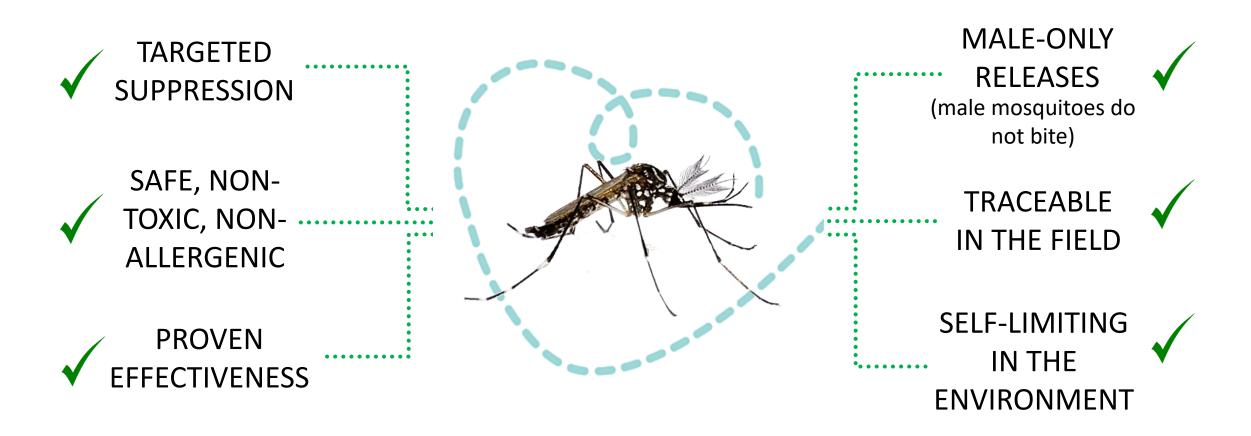
- Reproduces by mating
- Amenable to artificial production
- Life cycle a few months or less

### Set to deliver value to multiple markets

PUBLIC HEALTH	AGRICULTURE		LIVESTOCK
	BROADACRE	HORTICULTURE	
Malaria	Corn	Fruits	Cattle
Dengue, Zika, Yellow Fever,	Soybeans	Vegetables Vegetables	Poultry
Chikungunya	Cotton		<b>74</b>
Nuisance Biters	Sugarcane	Tree nuts	Pigs

# Overview of Oxitec's Aedes aegypti Mosquito





Unique combination of characteristics is a key differentiator of Oxitec's technology

# World-Class Partners, Collaborators and Regulatory Record





Select Partners and Underwriters



BILL & MELINDA GATES foundation



Horticulture Innovation Australia



UK Research and Innovation













































Positive Regulatory Approvals and Opinions























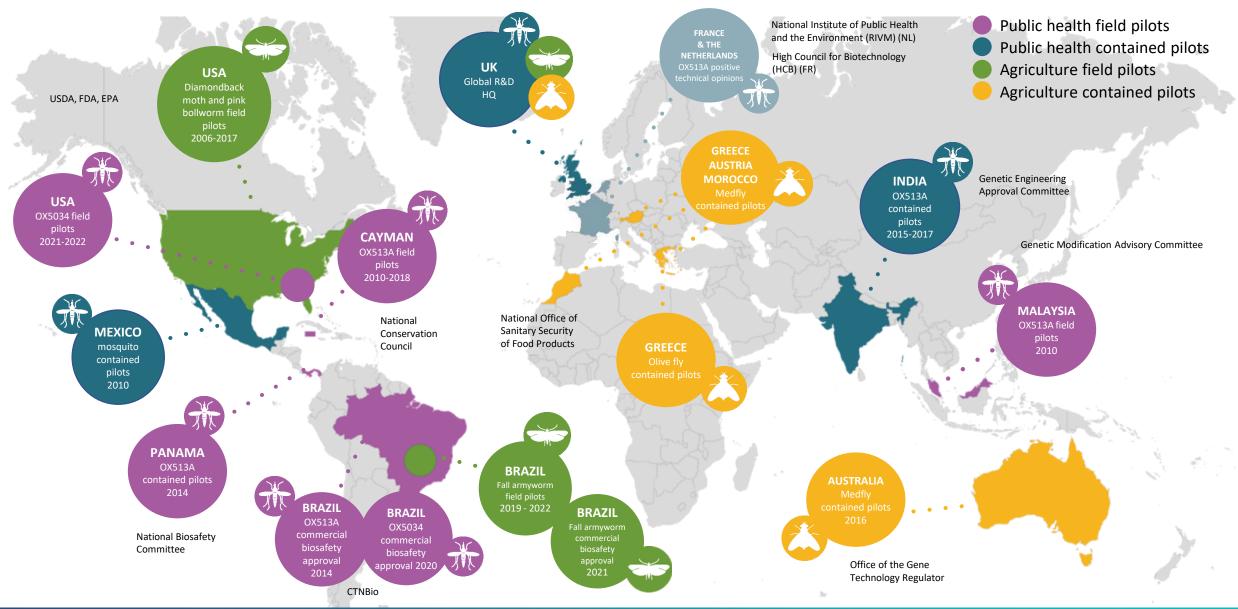


Department of Health
Office of the Gene Technology Regulator



### 10+ Years of Successful Regulatory Decisions





# 10 Years of Community Support Every Place We've Worked



### WE DELIVER IMPACT WORKING IN CLOSE PARTNERSHIP WITH COMMUNITIES

Example: a public survey of 2,000 people carried out in March 2021 in the city of Indaiatuba highlights that:

97%

Would like the Friendly™ project to continue

97%

Would like to see the project expanded

















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

#### OXITEC'S PROVEN VECTOR CONTROL RESULTS, SELECTED DEPLOYMENT PROGRAMS, 2010-2020

- 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

2021-22 **INITIAL BR** LAUNCH

OX5034 **Market Launch** In BR

2021-22





Platform in 2018

96% 1st OX5034 **Product Trial** Indaiatuba, Brazil

2019-2020 2018-2019

**US OX5034 Product Trial** Florida 2021

2020-21

**Product Trial** 

Indaiatuba, Brazil 2020-2021

Scaled-up OX5034



**DECADE OF DEVELOPMENT AND PROOF-POINTS** 

PREPARING FOR COMMERCIAL LAUNCH

# Oxitec in Cayman





OX513A Demonstration Trial – East End (2010)



Extremely high pest populations tackled
Published in respected international scientific journal

Photo by RH43 (unmodified)
https://web.archive.org/web/20161021023351
/http://www.panoramio.com/photo/65908716

**Purpose: Proof of Concept** 

**Duration: 23 weeks** 

**Partner: MRCU** 

**Independent Validation: Yes** 

World's first GM mosquito performance trial

Proof of concept completed

80-96% Suppression

### **Oxitec in India**

OX513A Regulatory Trials – Dawalwadi (2011 – present)



Facility opened by current Chief Scientist at WHO

Population elimination in all field cages after 10-15 weeks of releases



**Purpose: Caged Suppression** 

**Duration: 34 weeks** 

**Partner: GBIT** 

**Independent Validation: Yes** 

Proven
Aedes
aegypti
eliminations

Confirmed insecticide susceptibility

Confirmed strong mating capability

Three peerreviewed publications

### Oxitec in Panama



OX513A Demonstration Trial - Nuevo Chorrillo (2014)

Panama residents named Oxitec male mosquitoes "Mosquitos Amigables"



**Purpose: Suppression pilot** 

**Duration: 28 weeks** 

**Partner: Gorgas Institute** 

**Independent Validation: Yes** 

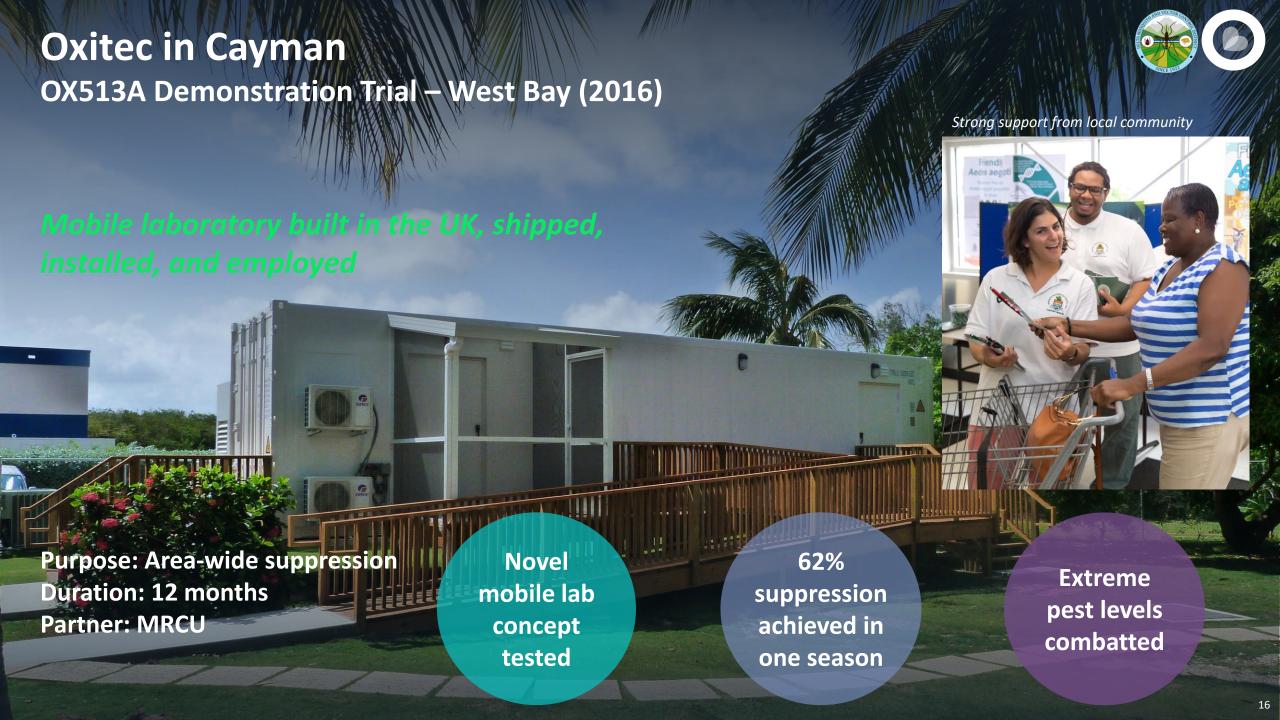
91% & 95% suppression in 1 season

Proven safe & no niche replacement

Two peerreviewed publications

Strong mating performance





# **Oxitec in Cayman**







"The 2018 collaborative project was a professional scientific endeavor. MRCU's relationship with Oxitec senior scientists and management was positive and supportive. This was a successful collaboration that fully adhered to the mutually agreed upon contract and Operational Plan that was steered through an active Stewardship Committee."

MRCU DIRECTOR MINIMALITY (JULY 2020)

**Purpose: Area-wide suppression** 

**Duration: 22 weeks** 

**Partner: MRCU** 

Photo by RH43 (unmodified)
https://web.archive.org/web/20161021023351
/http://www.panoramio.com/photo/65908716

First actively combining OX513A and chemicals

All releases under threshold for females Lessons
learned on
Integrated
Vector
Management



### **Oxitec in Brazil**



OX5034 Capsule Demonstration Trial Indaiatuba (2019-2020)

Just add water technology in use for the first time

**Purpose: Replicated Field Trial** 

**Duration: 18 weeks** 

**Partner: Indaiatuba Municipality** 

**Independent Validation: CTNBio** 

92%
Suppression
in just 15
weeks

6
weeks faster
than
OX513A





### **Brazil Authorizes Oxitec Mosquitos for Commercial Use**

Oxitec's Aedes aegypti mosquitoes evaluated by an independent body of 27 academic experts that comprise Brazil's regulator CTNBio.

### May 2020 – Oxitec mosquitoes received full biosafety approval from CTNBio, Brazil's national regulatory authority

- Approved after demonstrating the technology's full safety to human health and the environment.
- Free to release anywhere without license or restriction
- Over 20 million released protecting thousands of people without any adverse effect.
- Available for sale commercially (<u>aedesdobem.com.br</u>).



comissã C de bio

comissão técnica nacional

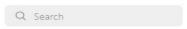
CTNBio de biossegurança



### **Commercial Launch - Engaging Brazilian Consumers at all Levels**



Instagram



































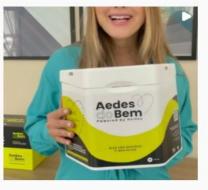


















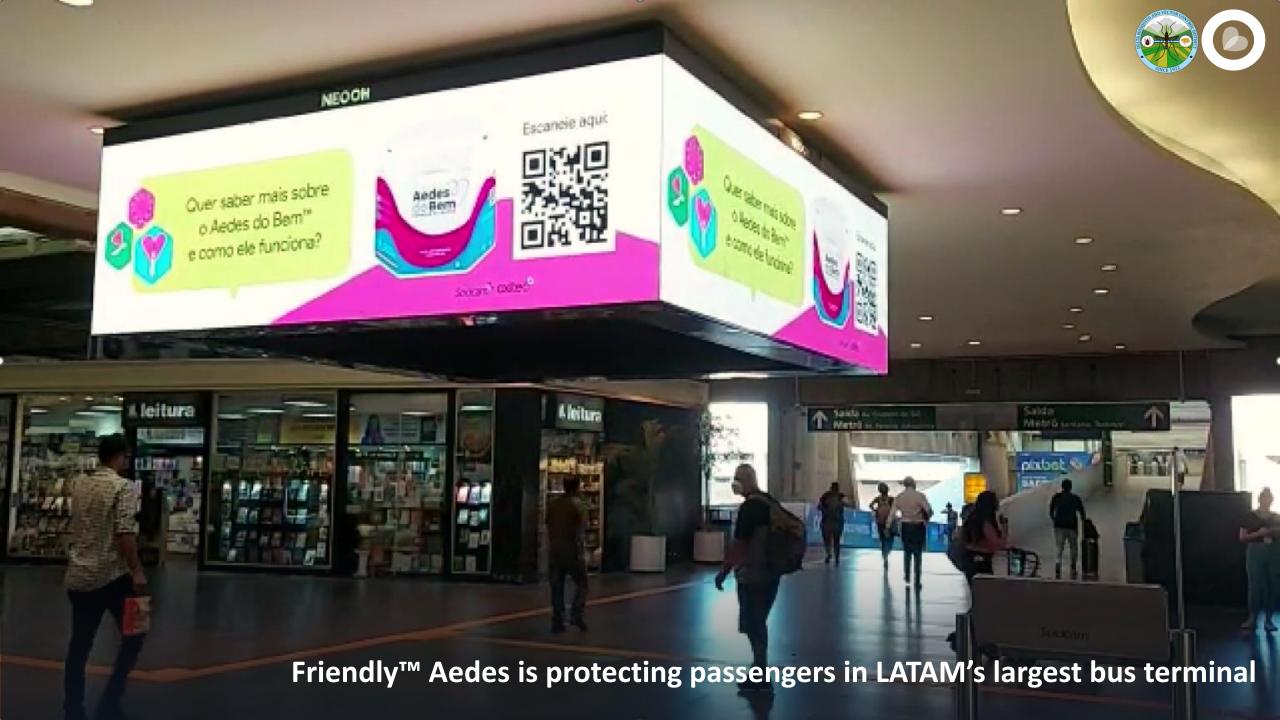








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# Overview of EPA's Scientific Assessment and Approval

#### **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
- Analytical Methodologies

# EPA Conclusion: Oxitec Mosquitoes are Safe for Humans, Wildlife, and the Environment



Independently validated: no effects on endangered species or critical habitat, whether direct or indirect.

Fish

Birds

SAFE FOR

- Mammals
- Plants
- Invertebrates
- Other aquatic animals
- For example, third-party independent labs found that freshwater fish and invertebrates consuming a diet of 70% OX5034 mosquito larvae fared no differently to fish and invertebrates fed 70% non-Oxitec mosquito larvae.



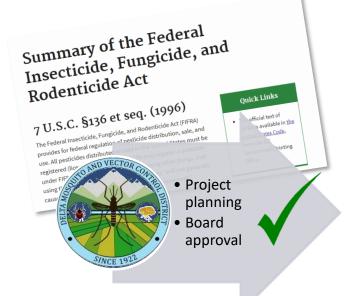
OX5034 male mosquitoes do not bite people or wildlife'





# **Preparing for Oxitec Deployments in California**





• Dossier
• Scientific literature
• External experts







**Local Approval** 

Federal approval

**State Approval** 

**Federal Product Registration** 

#### **Dossiers:**

- Environmental Impact
- Human Health
- Feeding Studies
- Technical Data
- Operating Procedures

Oxitec mosquitoes regulated as a 'biopesticide' by EPA Protocols, metrics, and analysis are predetermined by EPA Wolbachia
mosquitoes
are regulated
under the
same rules

### **Question and Answers**



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

(If we run out of time tonight, email info@oxitec.com and we will attempt to answer your question if it isn't included in the growing FAQ we publish online at californiamosquitoproject.com, oxitec.com/california and deltamvcd.org)



