



FKMCD-Oxitec Public Educational Webinar #5

Review: 20 Years of Independent Assessment, Oversight and Validation

17 August 2020



OXITEC

Introductions – Panelists With You Today



OXITEC



Andrea Leal
Executive Director
FKMCD



Meredith Fensom
Head of Public Affairs
Oxitec



Kevin Gorman
Head of Field Operations
Oxitec



Nathan Rose
Head of Regulatory Affairs
Oxitec

FKMCD and Oxitec are hosting a series of public educational webinars to provide information to Florida Keys residents and to provide forums to answer their 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
- Questions and answers will be published in writing after the event with external or related online resources/references

Upcoming Events:

FKMCD Board Meeting

Tuesday, August 18th, 5:00 p.m. ET



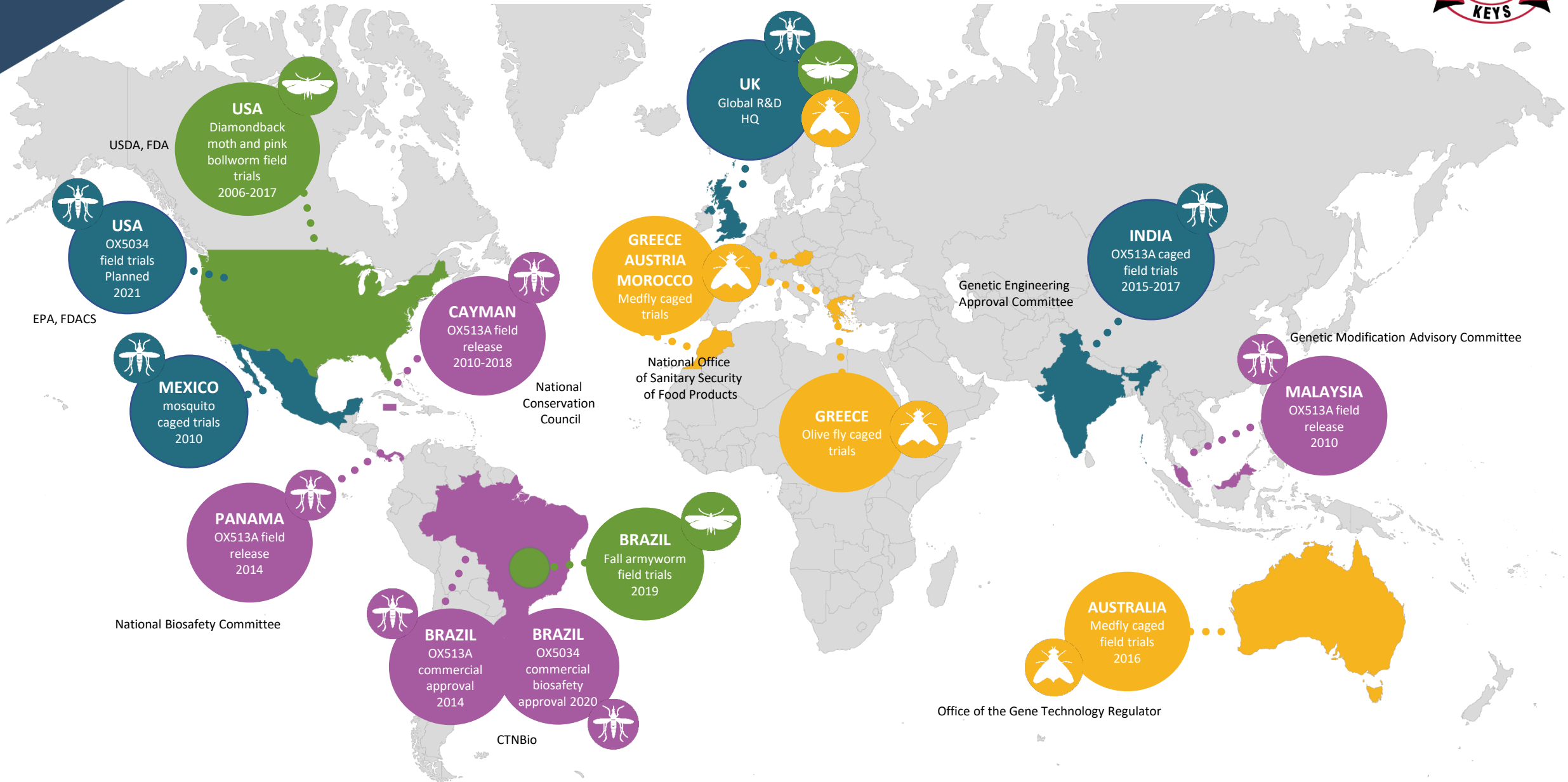
Welcome to Webinar #5 in this 5-part series!

Today's Agenda:

- Regulatory Evaluation: International
- Regulatory Evaluation: US Federal and State Regulators
- Independent Validation: Scientific Peer Review
- Independent Project Evaluation
- Your Questions



10+ Years of Successful Global Regulatory Decisions and Trials





OXITEC

Exhaustive External Validation and Independent Oversight



Australian Government

Department of Health

Office of the Gene Technology Regulator



Ministério da Agricultura Pecuária e Abastecimento



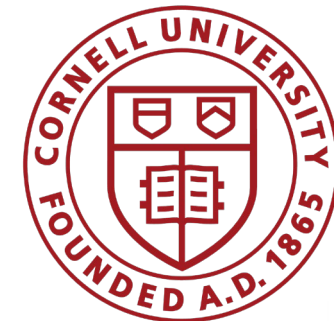


Partner Validation: Mosquitoes and Agriculture

RESEARCH FUNDING BODIES



EXAMPLES OF IN-COUNTRY INSECT DEPLOYMENT PARTNERS



Department of Primary Industries and Regional Development



UNIVERSITY OF CRETE



OX5034 Receives National Biosafety Approval in Brazil



2014 – 1st Generation (OX513A) receives full biosafety approval

- Free to release anywhere without license or restriction
- ~ 1 billion released over 10 years protecting over 100,000 people without any adverse effect

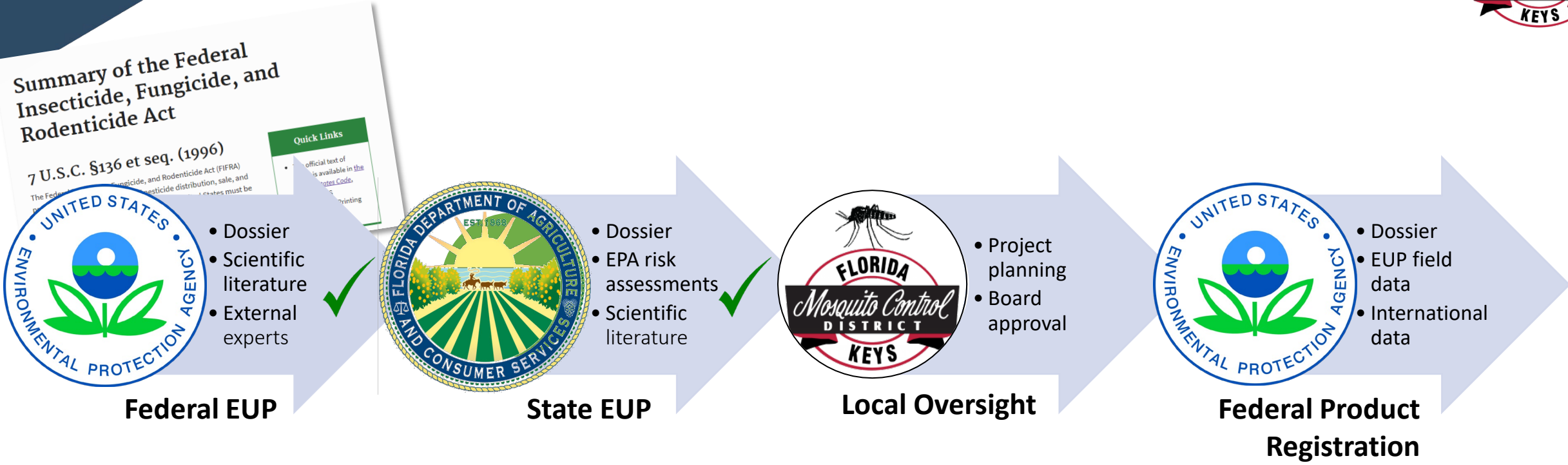
2020 – 2nd Generation (OX5034) receives full biosafety approval

- Free to release anywhere without license or restriction
- ~20 million released over 2 years protecting thousands of people without any adverse effect





Regulating Oxitec Mosquitoes in the US



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

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



HAVE CONFIRMED:

- **Non-biting males only**
- **No female release**
- **No increased vector competence**
- **No risk of spreading antibiotic resistance**
- **Not an experiment on humans**

'OX5034 male mosquitoes cannot bite people or wildlife'

EPA Conclusion: Background Genetic Introgression Presents No Risk

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

Independently validated: no effects on endangered species or critical habitat, whether direct (e.g. in diet) or indirect (if *Aedes aegypti* population reduced).

SAFE FOR

- Fish
- Birds
- Mammals
- Plants
- Invertebrates
- Other aquatic animals



'Aedes aegypti is a negligible part of bird, amphibian or bat diets'

'OX5034 male mosquitoes cannot bite people or wildlife'

- For example, experiments by third-party independent labs showed that **freshwater fish** and **invertebrates** consuming a diet of 70% OX5034 mosquito larvae fared no differently to fish and invertebrates fed 70% non-GM mosquito larvae.





State of Florida Departments/Bureaus Unanimously Approved 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)



State of Florida EUP Assessments:

- Oxitec Dossier (including human and environmental safety data)
- Oxitec Field Project Protocol
- EPA and CDC's independent risk assessments of OX5034 male mosquitoes

State of Florida EUP Conclusions:

- Oxitec mosquitoes are safe for humans
- Oxitec mosquitoes are safe for wildlife and the environment
- Background genetic introgression presents no risks





Who Are Peer Reviewers?

- Scientific experts in the field
- Proven scientific record
- Selected by journals following a rigorous process
- Independent – No competing interests
- Anonymous
- No remuneration

What Do They Judge?

- Novelty and originality
- Topicality and relevance
- Scientific integrity (study design, data collection and analysis)
- Consistency (results vs conclusions)
- Language, style and use of references
- Ethical standards



OPEN ACCESS Freely available online



The Orthologue of the Fruitfly Sex Behaviour Gene *Fruitless* in the Mosquito *Aedes aegypti*: Evolution of Genomic Organisation and Alternative Splicing

Marco Salvemini^{1*}, Rocco D'Amato¹, Valeria Petrella¹, Serena Aceto¹, Derric Nimmo², Marco Neira², Luke Alphey^{2,3}, Lino C. Polito¹, Giuseppe Saccone¹

¹Department of Biological Sciences – Section of Genetics and Molecular Biology, University of Naples “Federico II”, Naples, Italy, ²Oxitec Limited, Oxford, United Kingdom, ³Department of Zoology, University of Oxford, Oxford, United Kingdom

Abstract

BMC Biology



Research article

Open Access

Late-acting dominant lethal genetic systems and mosquito control
Hoang Kim Phuc¹, Morten H Andreasen¹, Rosemary S Burton¹, Céline Vass¹, Matthew J Epton¹, Gavin Pape¹, Guoliang Fu², Kirsty C Condon^{1,2}, Sarah Scaife², Christl A Donnelly³, Paul G Coleman^{3,4}, Helen White-Cooper¹ and Luke Alphey^{*1,2}

Mem Inst Oswaldo Cruz, Rio de Janeiro, Vol. 108(4): 529-531, June 2013 529

DsRed2 transient expression in *Culex quinquefasciatus* mosquitoes

André Barretto Bruno Wilke^{1/+}, Sarah Scaife², Luke Alphey^{2,3}, Mauro Toledo Marrelli¹

¹Departamento de Epidemiologia, Faculdade de Saúde Pública, Universidade de São Paulo, São Paulo, SP, Brasil

²Oxitec Ltd, Oxford, United Kingdom ³Department of Zoology, University of Oxford, Oxford, United Kingdom

Culex quinquefasciatus mosquitoes have been successfully genetically modified only once, despite the efforts

Marinotti et al. *Malaria Journal* 2013, **12**:142
<http://www.malariajournal.com/content/12/1/142>



RESEARCH

Open Access

Development of a population suppression strain of the human malaria vector mosquito, *Anopheles stephensi*

Oswaldo Marinotti¹, Nijole Jasinskiene¹, Aniko Fazekas¹, Sarah Scaife², Guoliang Fu², Stefanie T Mattingly¹, Karissa Chow¹, David M Brown³, Luke Alphey^{2,4} and Anthony A James^{1,3*}

OPEN ACCESS Freely available online



Female-Specific Flightless (fsRIDL) Phenotype for Control of *Aedes albopictus*

Geneviève M. C. Labbé^{1,2}, Sarah Scaife¹, Siân A. Morgan¹, Zoë H. Curtis¹, Luke Alphey^{1,3*}

¹Oxitec Limited, Oxford, United Kingdom, ²Division of Biology, Imperial College London Silwood Park, Ascot, United Kingdom, ³Department of Zoology, University of Oxford, Oxford, United Kingdom

Abstract

Peer-Reviewed: Technical Development In Multiple Mosquito Species

Full independent evaluation and assessments demonstrate potential of the technology for control of:

- ✓ *Aedes aegypti*
- ✓ *Aedes albopictus*
- ✓ *Culex quinquefasciatus*
- ✓ *Anopheles stephensi*

Application
to a range
of disease
vectors

2nd
Generation
offers
advantages

Minimal
effect on
fitness

Peer Reviewed: Full Biosafety of Oxitec Insects



OXITEC

BMC Biology



Research article

Open Access

Late-acting dominant lethal genetic systems and mosquito control

Hoang Kim Phuc¹, Morten H Andreassen¹, Rosemary S Burton¹, Céline Vass¹, Matthew J Epton¹, Gavin Pape¹, Guoliang Fu², Kirsty C Condon^{1,2}, Sarah Scaife², Christl A Donnelly³, Paul G Coleman^{3,4}, Helen White-Cooper¹ and Luke Alphey^{*1,2}



RESEARCH ARTICLE

Assessment of the Impact of Potential Tetracycline Exposure on the Phenotype of *Aedes aegypti* OX513A: Implications for Field Use

Zoe Curtis^{1,2*}, Kelly Matzen¹, Marco Neira Oviedo^{1,3a}, Derric Nimmo¹, Pamela Gray¹, Peter Winskill^{1,2}, Marco A. F. Locatelli^{3,4}, Wilson F. Jardim^{3,4}, Simon Warner¹, Luke Alphey^{1,5a,b}, Camilla Beech¹

Research Article

Received: 11 August 2015 Revised: 9 September 2015 Accepted article published: 16 September 2015 Published online in Wiley Online Library: 16 October 2015
(wileyonlinelibrary.com) DOI 10.1002/ps.4151



Short-term suppression of *Aedes aegypti* using genetic control does not facilitate *Aedes albopictus*

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

Hindawi
Psyche
Volume 2018, Article ID 7814643, 7 pages
<https://doi.org/10.1155/2018/7814643>



Research Article

Self-Limiting OX513A *Aedes aegypti* Demonstrate Full Susceptibility to Currently Used Insecticidal Chemistries as Compared to Indian Wild-Type *Aedes aegypti*

Prabhakargouda B. Patil¹, Kevin J. Gorman,² Shaibal K. Dasgupta,¹ K. V. Seshu Reddy,¹ Shirish R. Barwale,¹ and Usha B. Zehr¹

¹Gangabishan Bhikhal Investment and Trading Limited (GBIT), P.O. Box 76, Jalna-Auramohad Road, Dawalwadi, Badnashir, Jalna, Maharashtra, India 431 305, India

SCIENTIFIC REPORTS

OPEN

Exposure to genetically engineered olive fly (*Bactrocera oleae*) has no negative impact on three non-target organisms

Received: 16 May 2017
Accepted: 30 August 2017
Published online: 13 September 2017

Thea Marubbi¹, Clare Cassidy^{1,3}, Esther Miller¹, Martha Koukidou¹, Enca Martin-Rendon¹, Simon Warner¹, Augusto Loni² & Camilla Beech^{1,4}

Available online



Oral Ingestion of Transgenic RIDL *Ae. aegypti* Larvae Has No Negative Effect on Two Predator *Toxorhynchites* Species

Oreanaiza Nordin¹, Wesley Donald¹, Wong Hong Ming¹, Teoh Guat Ney¹, Khairul Asuad Mohamed¹, Nor Azlina Abdul Halim¹, Peter Winskill^{3,4}, Azahari Abdul Hadi¹, Zulkamal Safi'in Muhammad¹, Renaud Lacroix³, Sarah Scaife³, Andrew Robert McKemey³, Camilla Beech³, Murad Shahnaz¹, Luke Alphey^{2,3}, Derric David Nimmo^{3,5}, Wasi Ahmed Nazni¹, Han Lim Lee¹

¹Medical Entomology Unit, Institute for Medical Research, Jalan Pahang, Kuala Lumpur, Malaysia, ²Department of Zoology, University of Oxford, Oxford, United Kingdom, ³Oxitec Limited, Abingdon, Oxford, United Kingdom, ⁴Medical Research Council Centre for Outbreak Analysis and Modelling, Department of Infectious Disease Epidemiology, Imperial College, London, United Kingdom

Peer-Reviewed: Full Biosafety of Oxitec Insects

Full independent evaluation and assessments demonstrate:

- ✓ No impact on non-target organisms
- ✓ No evidence of niche replacement
- ✓ No long-term persistence of the self-limiting gene
- ✓ Biology comparable to wild-type counterparts

Non-toxic
and non-
allergenic

Rapidly
disappears
from the
environment

Insecticide
susceptible

Peer-Reviewed: Field Performance of Oxitec Mosquitoes



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RESEARCH ARTICLE

Suppression of a Field Population of *Aedes aegypti* in Brazil by Sustained Release of Transgenic Male Mosquitoes

Danilo O. Carvalho^{1,2*}, Andrew R. McKemey^{1*}, Luiza Garziera³, Renaud Lacroix¹, Chris A. Donnelly⁴, Luke Alphey^{1,5,6}, Aldo Malavasi³, Margareth L. Capurro^{2,7}



RESEARCH ARTICLE

Assessment of the Impact of Potential Tetracycline Exposure on the Phenotype of *Aedes aegypti* OX513A: Implications for Field Use

Zoe Curtis^{1,2*}, Kelly Matzen¹, Marco Neira Oviedo^{1,3}, Derric Nimmo¹, Pam Peter Winkill^{1,2}, Marco A. F. Locatelli^{3,4}, Wilson F. Jardim^{3,4}, Simon Warn Luke Alphey^{1,5,6}, Camilla Beech¹

Research Article

Received: 11 August 2015 | Revised: 9 September 2015 | Accepted article published: 16 September 2015 | Published online in Wiley Online Library: 16 October 2015
(wileyonlinelibrary.com) DOI 10.1002/ps.4151

Short-term suppression of *Aedes aegypti* using genetic control does not facilitate *Aedes albopictus*

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 Phillips,^a Cecilia Kosmann^a and Lorenzo Cáceres^b



RESEARCH ARTICLE

Dispersal of Engineered Male *Aedes aegypti* Mosquitoes

Peter Winkill^{1,2*}, Danilo O. Carvalho^{3*}, Margareth L. Capurro^{4,5}, Luke Alphey^{2,6,7}, Christi A. Donnelly^{1*}, Andrew R. McKemey^{2*}

OPEN ACCESS Freely available online



Open Field Release of Genetically Engineered Sterile Male *Aedes aegypti* in Malaysia

Renaud Lacroix^{1,2*}, Andrew R. McKemey^{2,3}, Norzahira Raduan^{1,3}, Lim Kwee Wee³, Wong Hong Ming³, Teoh Guat Ney³, Siti Rahidah A.A.³, Sawaluddin Salman³, Selvi Subramaniam³, Oreenaiza Nordin³, Norhaida Hanum A.T.³, Chandru Angamuthu³, Suria Marlina Mansor³, Rosemary S. Lees⁴, Neil Naish², Sarah Scaife², Pam Gray², Geneviève Labbé², Camilla Beech², Derric Nimmo², Luke Alphey^{2,5*}, Seshadri S. Vasan^{1,4}, Lee Han Lim^{3*}, Nazni Wasi A.³, Shahnaz Murad³

1 Oxitec Sendirian Berhad, Kuala Lumpur, Wilayah Persekutuan, Malaysia, 2 Oxitec Limited, Oxford, Oxfordshire, United Kingdom, 3 Medical Entomology Unit, Institute for Medical Research, Kuala Lumpur, Wilayah Persekutuan, Malaysia, 4 Centre for Research in Biotechnology for Agriculture, University of Malaya, Kuala Lumpur, Wilayah Persekutuan, Malaysia, 5 Department of Zoology, University of Oxford, Oxford, Oxfordshire, United Kingdom

Abstract



nature
biotechnology

Correspondence | Published: 10 September 2012

Successful suppression of a field mosquito population by sustained release of engineered male mosquitoes

Angela F Harris, Andrew R McKemey, Derric Nimmo, Zoe Curtis, Isaac Black, Siân A Morgan, Marco Neira Oviedo, Renaud Lacroix, Neil Naish, Neil I Morrison, Amandine Collado, Jessica Stevenson, Sarah Scaife, Tarig Dafa'alla, Guoliang Fu, Caroline Phillips, Andrea Miles, Norzahira Raduan, Nick Kelly, Camilla Beech, Christi A Donnelly, William D Petrie & Luke Alphey

Research Article

Received: 17 February 2014 | Revised: 10 July 2014 | Accepted article published: 31 July 2014 | Published online in Wiley Online Library: 1 September 2014
(wileyonlinelibrary.com) DOI 10.1002/ps.3873

Mating competitiveness and life-table comparisons between transgenic and Indian wild-type *Aedes aegypti* L.

Prabhakargouda B Patil,^{a*} BP Niranjan Reddy,^{a*} Kevin Gorman,^b KV Seshu Reddy,^{a*} Shirish R Barwale,^a Usha B Zehr,^a Derric Nimmo,^b Neil Naish^b and Luke Alphey^b

Entomologia
Experimentalis et Applicata



DOI: 10.1111/eea.12618

SPECIAL ISSUE - STERILE INSECT TECHNIQUE

Effect of interruption of over-flooding releases of transgenic mosquitoes over wild population of *Aedes aegypti*: two case studies in Brazil

Luiza Garziera¹, Michelle Cristine Pedrosa^{1,2}, Fabrício Almeida de Souza¹, Maylen Gómez², Márcia Bento Moreira³, Jair Fernandes Virginio¹, Margareth Lara Capurro² & Danilo Oliveira Carvalho^{2*}

Peer-Reviewed: Field Performance of Oxitec Mosquitoes



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7
OX513A field studies published

Strong mating and dispersal

Operational viability

STRAIN	COUNTRY	LOCATION	YEAR	INDEPENDENT SCIENTIFIC REVIEW
1st Gen (OX513A)	Grand Cayman	East End	2009	Harris et al (2011) <i>Nature Biotech.</i> , 29:1034-1037
	Grand Cayman	East End	2010	Harris et al (2012) <i>Nature Biotech.</i> 30:828-830
	Malaysia	Pahang	2011	Lacroix et al (2012) <i>PLoS One</i> , 7(8): e42771
	Brazil	Itaberaba	2012	Carvalho et al (2015) <i>PLoS Negl Trop Dis</i> 9(7): e0003864.
		Mandacaru	2012-2013	Garziera et al (2017) <i>Entomol. Experiment. Appl.</i> 164, 327–339 (2017).
		Pedra Branca	2013-2015	
Panama	Nuevo Chorrillo	2014	Gorman et al (2016) <i>Pest Man. Sci.</i> 72(3):618-28. doi: 10.1002/ps.4151.	
2nd Gen (OX5034)	Brazil	Indaiatuba – adult release	2018-2019	Publication expected later in 2020
		Indaiatuba – egg release	2019-2020	Project ongoing (post-release monitoring)

Peer-Reviewed: Technical Development In Agricultural Pest Insects



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ACS Publications
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My Activity Publications

Engineered Female-Specific Lethality for Control of Pest Lepidoptera

Li Jin^{1,2}, Adam S. Walker¹, Guoliang Fu^{1,2}, Timothy Harvey-Samuel^{1,2}, Tarig Dafa'alla¹, Andrea Miles¹, Thea Marubbi¹, Deborah Granville¹, Nerys Humphrey-Jones¹, Sinead O'Connell¹, Neil I. Morrison¹, and Luke Alphey^{1,2*}

View Author Information

Cite this: *ACS Synth. Biol.* 2013, 2, 3, 160–166
Publication Date: January 8, 2013
https://doi.org/10.1021/sb300123m
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Article Views: 1008 | Altmetric: 39 | Citations: 37

PDF (2 MB) | Access Through Your Institution | More Access Options | Supporting Info (1)

SUBJECTS: Plants, Genetics, Circuits, Synthetic biology, Pest control

First Field Release of a Genetically Engineered, Self-Limiting Agricultural Pest Insect: Evaluating Its Potential for Future Crop Protection

Anthony M. Shelton¹, Stefan J. Long¹, Adam S. Walker², Michael Bolton^{2,3}, Hilda L. Collins¹, Loïc Revuetta², Lynn M. Johnson⁴ and Neil I. Morrison²

¹Department of Entomology, AgriTech, New York State Agricultural Experiment Station, Cornell University, Geneva, NY, United States
²Oxitec Ltd, Milton Park, Abingdon, United Kingdom
³School of Biological Sciences, Norwich Research Park, University of East Anglia, Norwich, United Kingdom
⁴Cornell Statistical Consulting Unit, Cornell University, Ithaca, NY, United States

PROCEEDINGS OF THE ROYAL SOCIETY B

BIOLOGICAL SCIENCES

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Genetic elimination of field-cage populations of Mediterranean fruit flies

Philip T. Leftwich, Martha Koukidou, Polychronis Rempoulakis, Hong-Fei Gong, Antigoni Zacharopoulou, Guoliang Fu, Tracey Chapman, Aris Economopoulos, John Vontas and Luke Alphey

Published: 07 October 2014 | <https://doi.org/10.1098/rspb.2014.1372>

Abstract

The sterile insect technique (SIT) is a pest control strategy involving the mass release of radiation-sterilized insects, which reduce the target population through nonviable matings. In Lepidoptera, SIT could be more broadly applicable if the deleterious effects of sterilization by irradiation could be avoided. Moreover, male-only release can improve the efficacy of SIT. Adequate methods of male-only production in Lepidoptera are currently lacking, in contrast to some Diptera. We describe a synthetic genetic system that allows male-only moth production for SIT and also replaces radiation sterilization with inherited female-specific lethality. We sequenced and characterized the *doublesex* (*dsex*) gene from the pink bollworm (*Pectinophora gossypiella*). Sex-alternate splicing from *dsex* was used to develop a conditional lethal genetic sexing system in two pest moths: the diamondback moth (*Plutella xylostella*) and pink bollworm. This system shows promise for enhancing existing pink bollworm SIT, as well as broadening SIT-type control to diamondback moth and other Lepidoptera.



BMC Biology

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Research article | Open Access | Published: 16 July 2015

Pest control and resistance management through release of insects carrying a male-selecting transgene

Tim Harvey-Samuel, Neil I. Morrison, Adam S. Walker, Thea Marubbi, Ju Yao, Hilda L. Collins, Kevin Gorman, T. G. Emyr Davies, Nina Alphey, Simon Warner, Anthony M. Shelton & Luke Alphey

BMC Biology, 13, Article number: 49 (2015) | Cite this article

14k Accesses | 25 Citations | 704 Altmetric | Metrics

PROCEEDINGS OF THE ROYAL SOCIETY B

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Genetic elimination of field-cage populations of Mediterranean fruit flies

Philip T. Leftwich^{1,2}, Martha Koukidou¹, Polychronis Rempoulakis^{1,3}, Hong-Fei Gong¹, Antigoni Zacharopoulou⁴, Guoliang Fu¹, Tracey Chapman², Aris Economopoulos³, John Vontas³ and Luke Alphey^{1,5,6}

¹Oxitec Limited, 71 Innovation Drive, Milton Park, Oxford OX14 4RQ, UK
²School of Biological Sciences, University of East Anglia, Norwich Research Park, Norwich, Norfolk NR4 7TJ, UK
³Faculty of Biotechnology and Applied Biology, Department of Biology, University of Crete, Heraklion, Crete, Greece
⁴Department of Biology, Division of Genetics, Cell and Developmental Biology, University of Patras, Patras, Greece
⁵Department of Zoology, University of Oxford, South Parks Road, Oxford OX1 3PS, UK
⁶The Pirbright Institute, Ash Road, Woking GU24 0NF, UK

OPEN ACCESS Freely available online

Engineered Repressible Lethality for Controlling the Pink Bollworm, a Lepidopteran Pest of Cotton

Neil I. Morrison^{1,2}, Gregory S. Simmons^{3,4}, Guoliang Fu^{1,2}, Sinead O'Connell¹, Adam S. Walker¹, Tarig Dafa'alla¹, Michelle Walters³, John Claus³, Guolei Tang³, Li Jin^{1,2}, Thea Marubbi¹, Matthew J. Epton², Claire L. Harris¹, Robert T. Staten³, Ernest Miller³, Thomas A. Miller⁵, Luke Alphey^{1,2*}

¹Oxitec Limited, Oxford, United Kingdom, ²Department of Zoology, University of Oxford, Oxford, United Kingdom, ³Animal Plant Health and Inspection Service, Plant Protection and Quarantine, Centers for Plant Health Science and Technology, United States Department of Agriculture, Phoenix, Arizona, United States of America, ⁴Animal Plant Health and Inspection Service, Plant Protection and Quarantine, Centers for Plant Health Science and Technology, United States Department of Agriculture, Salinas, California, United States of America, ⁵Department of Entomology, University of California Riverside, Riverside, California, United States of America

Abstract

The sterile insect technique (SIT) is an environmentally friendly method of pest control in which insects are mass-produced, irradiated and released to mate with wild counterparts. SIT has been used to control major pest insects including the pink bollworm (*Pectinophora gossypiella* Saunders), a global pest of cotton. Transgenic technology has the potential to overcome

BMC Biology 2012, 10:51 | biomedcentral.com/1741-7007/10/51

RESEARCH ARTICLE | Open Access

Control of the olive fruit fly using genetics-enhanced sterile insect technique

Thomas Ant^{1,2}, Martha Koukidou¹, Polychronis Rempoulakis^{1,3}, Hong-Fei Gong¹, Aris Economopoulos³, John Vontas³ and Luke Alphey^{1,2*}

1,662 Views | 0 CrossRef citations to date | 3 Altmetric

Preventative releases of self-limiting *Ceratitis capitata* provide pest suppression and protect fruit quality in outdoor netted cages

Romisa Asadi, Rachid Elaini, Renaud Lacroix, Thomas Ant, Amandine Collado, Lucy Finnegan, ... show all

Pages 182-193 | Received 12 Mar 2018, Accepted 25 Mar 2019, Published online: 23 Apr 2019

Download citation | <https://doi.org/10.1080/09670874.2019.1601293> | Check for updates

Full Article | Figures & data | References | Citations | Metrics | Licensing | Reprints & Permissions

Peer-Reviewed: Technical Development In Agricultural Pest Insects



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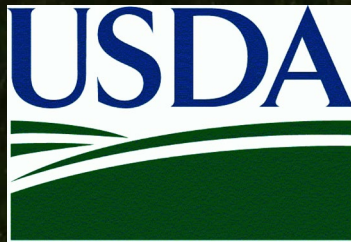
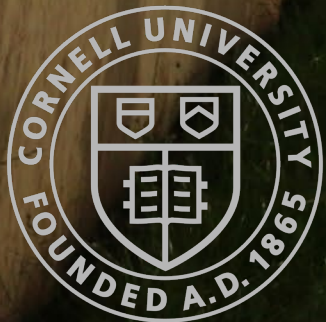
Promising
and
sustainable
crop
protection

Strong field
performance

2nd
Generation
dilution of
insecticide
resistance

Full independent evaluation and assessments demonstrate technical development in agricultural pests:

- ✓ Mediterranean fruit fly (fruit)
- ✓ Pink bollworm (cotton)
- ✓ Diamondback moth (field crops)
- ✓ Olive fly (olives)



Department of
Primary Industries and
Regional Development

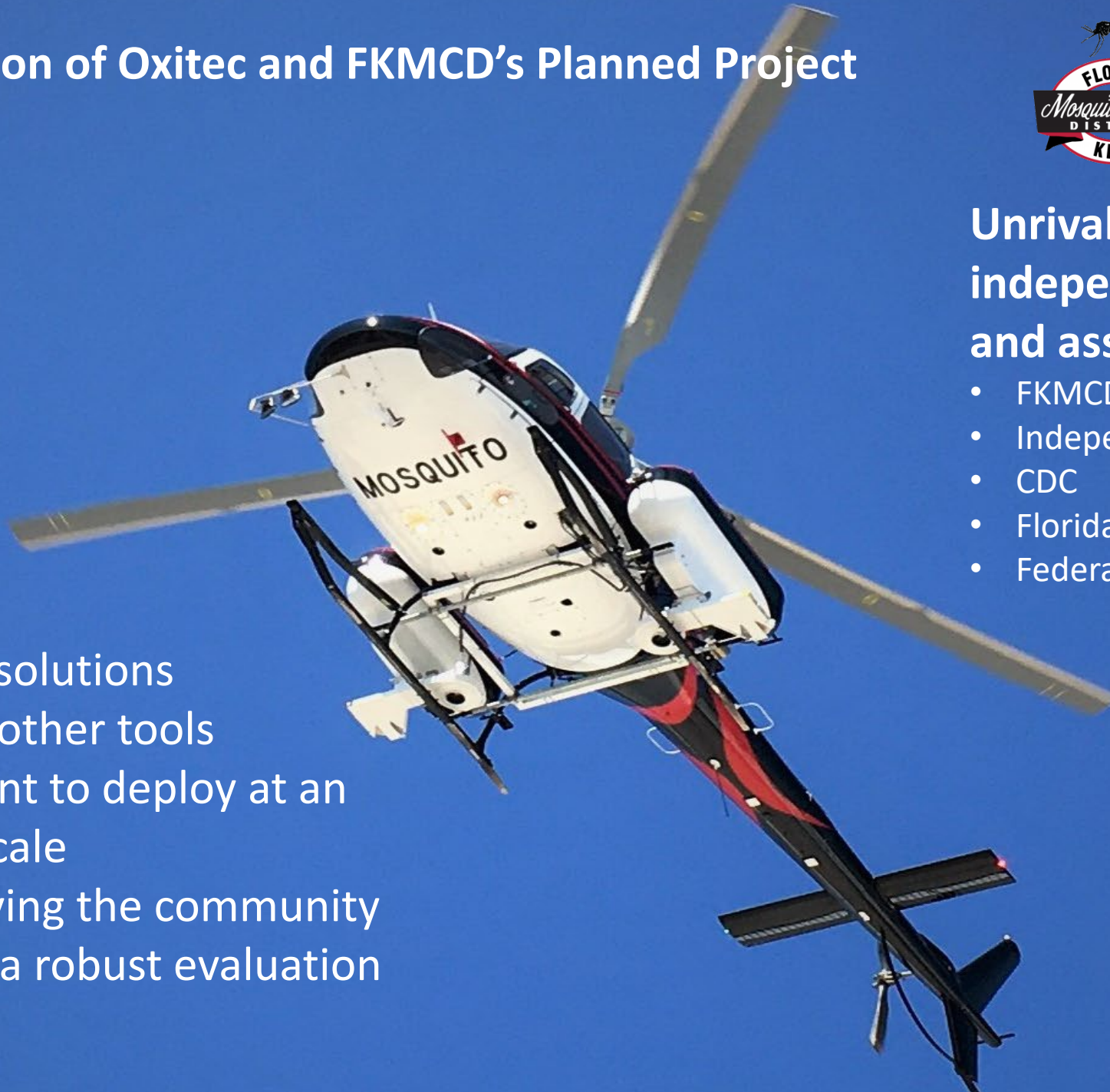


UNIVERSITY
OF CRETE

Independent Validation of Oxitec and FKMCD's Planned Project



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Unrivalled level of independent scrutiny and assessment

- FKMCD
- Independent Advisory Board
- CDC
- Florida State Regulators
- Federal Regulators

- Need for new solutions
- Evaluated like other tools
- No commitment to deploy at an intervention scale
- Priority of serving the community
- Committed to a robust evaluation

Independent Validation of FKMCD and Oxitec's Proposed Project



PROTOCOL DESIGN AND EVALUATION

INDEPENDENT REVIEW ROBUST EVALUATION

INDEPENDENT ADVISORY BOARD TECHNICAL AND OPERATIONAL OVERSIGHT



CENTERS FOR DISEASE CONTROL AND PREVENTION



Protocol design is driven by US regulatory agencies, and they will assess and evaluate program results.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Section G for an Experimental Use Permit 93167-EUP-E to Test OX5034 *Aedes aegypti* Mosquitoes



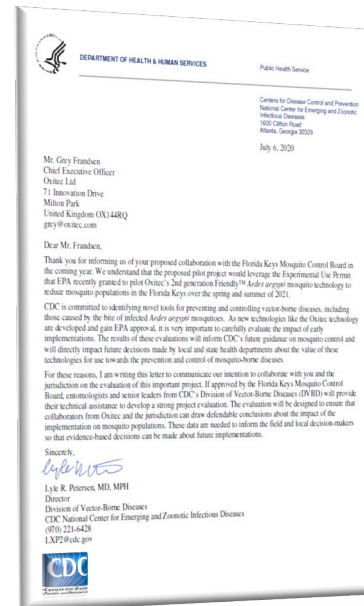
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of the Updated Section G Dated April 30, 2020 for an Experimental Use Permit 93167-EUP-E to Test OX5034 *Aedes aegypti* Mosquitoes
Decision #549249

**Section G:
OX5034
Field Trial
Protocol**



Bob Eadie
Monroe County
Department of Health
Member, Project
Independent Advisory
Board



Dr Douglas Mader
Marathon Veterinary
Hospital
Fellow, Royal Society of
Medicine
Member, Project
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What's Next?

FKMCD Board Meeting

Tuesday, August 18th 2020

Agenda item 5:00 p.m. ET

<https://keysmosquito.org/board-meetings/>



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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 and we will attempt to answer your question if it isn't included in the growing FAQ or post-event summary we publish online.)



OXITEC

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.