



OXITEC

Follow-up to FKMCD-Oxitec July 14, 2020 Public Educational Webinar

Event Summary, List of Questions Asked and Answered, and Additional Resources

July 15, 2020

FKMCD and Oxitec held a public educational webinar on July 14, 2020 at 5pm ET. The following is a summary of the event, a catalogue of attendance, questions asked and answered, answers to questions submitted in the last 10 minutes of the event or afterwards, and additional helpful resources for topics discussed.

Event Summary:

- **A complete recording of the entire three-hour event can be viewed [here](#)**
- All participants received a range of useful informational resources in advance of the call
- 199 people registered for the event; 135 people attended
- Approximately 30% of registrants were local Florida Keys residents; the other attendees represented a diverse range of stakeholders from outside the region, including other mosquito control districts, regulators, academics, companies, media, anti-GMO activist organizations, and international participants
- Questions from local Keys residents were prioritized
- Approximately 30 questions were asked and answered, and similar questions were batched together
- IT issues at the start of the call required that certain panelists made their remarks after the Q&A started, but all panelists spoke as planned

Panelists: The event featured the following panelists:



Dr Oscar Alleyne
Chief of Programs and Services
National Association of County and City Health Officials (NACCHO)



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



Dr Douglas Mader
Veterinary Specialist
Marathon Veterinary Hospital
Fellow, Royal Society of Medicine
Member, Project Independent Advisory Board



Dr Jorge Rey
Director and Professor
University of Florida – IFAS
Florida Medical Entomology Laboratory
Member, Project Independent Advisory Board



Andrea Leal
Executive Director
FKMCD



Dr Lawrence Hribar
Director of Research
FKMCD



Grey Frandsen
CEO
Oxitec



Dr Kevin Gorman
Head of Field Operations
Oxitec



Dr Nathan Rose
Head of Regulatory Affairs
Oxitec

The event was moderated by Meredith Fensom, Oxitec’s Head of Public Affairs, and livestreamed on FKMCD’s website by FKMCD staff.

Resources Sent to All Registrants Before Event: To provide attendees with helpful information for during and after the webinar, the following resources were sent to all registrants (whether or not they attended the event):

- Oxitec’s [resource hub](#) for all things Oxitec and the Florida Keys;
- The U.S. EPA’s [approval](#) of and complete [risk assessment](#) for Oxitec’s proposed pilot project;
- The U.S. EPA’s [responses to public comments](#) relating to Oxitec’s application;
- The U.S. EPA/U.S. CDC [memorandum](#) on vectoral capacity of Oxitec’s technology;
- The U.S. CDC’s [letter](#) confirming their role as independent evaluator of the project;
- The State of Florida’s [approval](#) of the proposed pilot project;
- 100+ independent peer-reviewed [scientific publications](#) on Oxitec technology;
- Monroe County’s [2016 referendum results](#) (31 of 33 precincts in favor of an Oxitec project);
- [FKMCD’s approval](#) of the 2016 project (which was postponed by [regulatory jurisdiction changes](#));
- The U.S. FDA’s [complete risk assessment](#) of Oxitec’s previous technology before regulatory jurisdiction was shifted to EPA;
- Oxitec’s [announcement](#) relating to its OX5034 mini-capsule technology pilot results in Brazil.

Attendance Report

- Of the 199 registrants, almost 70% (135) attended the live event
- Attendees stayed for an average of almost 2 hours
- Approximately 50 attendees were still engaged with event approaching closure

Attendance Summary

Started at 10:00 pm, Ended 12:58 am

199 REGISTERED
 135 ATTENDED
 67.8% SHOW UP RATE
 178 min SESSION LENGTH
 110.6 min AVG. TIME IN ROOM



Question and Answer Catalogue: the following represents the questions asked and answered. A few participants asked the same question multiple times, so we have included the core question and answer here. Where participants submitted comments that we felt were important, we turned them into questions for the benefit of addressing the particular topic/concern.

Topic for Easy Reference	Questions Asked	Answers	References
Questions About Regulation, Oversight			
Independent review of project	<i>“Does this project have independent review?”</i>	Oxitec’s technology has been reviewed, analyzed, tested and studied exhaustively by independent reviewers for more than 15 years. Pertinent to this project, the FDA, EPA and CDC conducted exhaustive independent reviews of Oxitec’s technology in advance of this project.	<u>EPA Human Health and Environmental Risk Assessment of OX5034</u>
Independent review of Oxitec technology	<i>“Has Oxitec’s technology been independently reviewed?”</i>	This project, if approved, will be independently monitored by the FKMCD,	<u>FDACS Approval of OX5034 EUP</u> <u>FDA Approval of OX513A</u> <u>CDC Review of OX5034 EUP</u>

	<p><i>“Would Oxitec be willing to debate the scientists who are concerned about this technology?”</i></p>	<p>U.S. Centers for Disease Control and the University of Florida, each serving as independent reviewers. The Monroe County Department of Health and Marathon Veterinary Hospital are part of an Independent Advisory Board that we have established for the project. The EPA and FDACS also require routine reports throughout the project.</p> <p>FKMCD’s Board of Commissioners is also an independent review body, as the project itself is arranged in such a manner to allow FKMCD to evaluate the technology. FKMCD has no interest but to evaluate the technology.</p> <p>Finally, Oxitec’s technology has been independently reviewed by hundreds of scientists around the world and has been the subject of more than 100 peer-reviewed studies, which are by definition independent scientific reviews.</p>	<p><u>CDC Letter of Collaboration</u></p> <p><u>List of 100+ independent peer-reviewed publications on Oxitec technology</u></p>
<p>Level of regulation / under-regulation of Oxitec’s mosquito technology</p>	<p><i>“Has the impact of Oxitec’s technology on ecosystems and on human health under-studied and under-regulated?”</i></p>	<p>Oxitec’s technology has been studied exhaustively by dozens of national regulatory authorities, including the EPA, CDC, and FDA, and remains the only vector control tool ever placed on an electoral ballot.</p> <p>Oxitec’s technology is among the most-studied vector control technologies with more than 100 scientific peer-reviewed publications describing our work and technology in exhaustive detail. Many of these publications are available <u>here</u>.</p>	<p><u>EPA’s full regulatory package</u>.</p> <p><u>FDA’s regulatory findings</u>.</p> <p><u>State of Florida findings</u>.</p> <p><u>Referendum results</u>.</p>
<p>Making data available</p>	<p><i>“Will Oxitec share the 4,000+ pages of data it submitted to the EPA?”</i></p> <p><i>“Will Oxitec make available data</i></p>	<p>Data submitted to the EPA consisted of three main categories: field protocols, strain characterization in support of health and environmental risk assessments, and production and deployment methods.</p>	<p><u>EPA Human Health and Environmental Risk Assessment of OX5034</u></p>

	<p><i>relating to this project?"</i></p>	<p>The field protocols are available to the public here, together with EPA’s reviews of the proposed protocols.</p> <p>Strain characterization data has been summarized in EPA’s human health and environmental risk assessments, and is available here.</p> <p>Production and deployment methods, reviewed in detail by EPA, contain confidential business information and thus are not made available to the public, in keeping with standard practice for any commercial entity.</p> <p>With regard to data from this project, Oxitec will endeavor to publish full peer-reviewed results of the study and its findings after the trial, in collaboration with FKMCD.</p>	
<p>Consent</p>	<p><i>“Is this project going to be testing on humans?”</i></p> <p><i>“Can people opt-out?”</i></p>	<p>Oxitec is not testing on humans and this project is not introducing risk to humans, animals, or the environment, as stated by the EPA and FDA.</p> <p>This project will only be releasing non-biting males that do not interact with humans.</p> <p>Oxitec is demonstrating the efficacy of its mosquito technology to control <i>Aedes aegypti</i> mosquitoes. This is analogous to other control products evaluated for use against mosquitoes like pesticides.</p> <p>Monroe County Department of Health Administrator Mr. Bob Eadie stated that this project is not an activity that would be covered as research on human beings and would not be subject to having to file a request for it to be reviewed by the Institutional Review Board (IRB).</p>	<p>EPA: “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...therefore the requirements of EPA’s human studies rule do not apply to this research proposed by Oxitec.” (p134, Response to Comments.)</p>

<p>New referendum</p>	<p><i>“Will another referendum be held?”</i></p>	<p>Andrea Leal reported that there is no discussion being had at FKMCD to hold another referendum.</p> <p>Oxitec’s technology received support in 31 of 33 Monroe County precincts in 2016 in a first-ever referendum for a GM technology, highlighting a broad base of support. The original referendum question was not specific to OX513A, but rather asked <i>“Are you in favor of the Florida Keys Mosquito Control District conducting an effectiveness trial in Monroe County, Florida, using genetically modified mosquitoes to suppress an invasive mosquito that carries mosquito-borne diseases?”</i></p>	<p>https://www.keys-elections.org/Election-Data/Past-County-Results-2009-Current</p>
<p>Public engagement</p>	<p><i>[One individual submitted a number of comments on this topic; we tried to turn them into questions here]</i></p> <p><i>“A friend of mine in the northern Keys hadn’t heard of this issue and it’s clear Oxitec hasn’t done any communications or community engagement. Why?”</i></p> <p><i>“What outreach has Oxitec done to date?”</i></p> <p><i>“Have a broad range of key stakeholders been engaged/consulted?”</i></p>	<p>Oxitec and FKMCD have spent 10 years engaging communities in the Keys via multiple methods, forums, formats across a broad range of stakeholders.</p> <p>For this event specifically, Oxitec and FKMCD made a range of announcements on radio, social media, in the newspapers, in public forums, via websites, via paid advertising, and other means.</p> <p>While we cannot reach everyone, the event was communicated broadly across multiple channels in the weeks leading up to the event.</p> <p>Oxitec and FKMCD will continue to carry out extensive public engagement efforts for this project, should it be approved, and will continue their commitment to open dialogue, transparency, information sharing, education, and accessibility.</p>	

Questions About the Technology			
<p>Tetracycline usage and antibiotic-resistant bacteria</p>	<p><i>“Will Oxitec mosquitoes carry antibiotic resistant bacteria?”</i></p> <p><i>“Will a male mosquito land on our skin even though they do not bite us? Is there a chance they could transmit bacteria from their egg casings that they hatched from to us?”</i></p> <p><i>“Why won’t Oxitec just test?”</i></p>	<p>Oxitec will not be using tetracycline in Florida, and the eggs shipped to Florida will have never been in contact with tetracycline. There is no risk and thus no scientific basis for testing.</p> <p>The EPA, FDA and Florida regulators looked at this exhaustively and found no risk. No exposure of Oxitec male mosquitoes to tetracycline, either as eggs in the UK or as adults in the US, means no potential for selection of resistant bacteria. The entire production process was reviewed and validated by the EPA and state regulators.</p> <p>Dr. Nathan Rose provided a detailed overview of Oxitec’s production process and how tetracycline is used in the UK, and how Oxitec’s mosquitoes being used in Florida will not be in contact with tetracycline. He highlighted that a small amount (less than a sugar packet, or approximately 5 g) of tetracycline will be used to manage the OX5034 colony in the UK, but all eggs from that process are surface-sterilized with a sanitizing agent 4x the strength of hospital-grade disinfectant before being shipped.</p> <p>He also noted that Oxitec responds readily to any data requests issued by regulators but does not respond to ad hoc requests for data made by private individuals.</p>	<p>EPA: “negligible risk that testing of OX5034 mosquitoes would spread antibiotic resistant bacteria in the US environment”</p> <p><i>(p75-76, <u>Response to Comments</u>).</i></p>
<p>Male mosquitoes biting</p>	<p><i>“If I get bitten by a male mosquito treated by tetracycline, and scratch it resulting in an infection, specifically a staph infection - will tetracycline/ doxycycline work to eradicate my infection?”</i></p>	<p>Male mosquitoes cannot bite. They lack the mouthparts to do so. No female Oxitec mosquitoes will be released during this project.</p> <p>Therefore, there is no possibility of this type of infection being caused by Oxitec’s (or any other) male mosquitoes.</p>	

Genetic modification	<p><i>“Is there any herpes simplex or E. coli in the second-generation mosquitos?”</i></p>	<p>No. The 2nd Generation OX5034 mosquitoes are not made with <i>E. coli</i> bacteria or Herpes simplex viruses (HSV).</p> <p>The mosquitoes do contain synthetic DNA sequences not found in nature, but which are based on naturally occurring DNA sequences found in a number of organisms. The gene products are safe, non-toxic and non-allergenic.</p>	
Powell paper	<p><i>[2 participants submitted multiple comments about this but did not form questions. We have tried to capture their concerns in these questions.]</i></p> <p><i>“Do Oxitec mosquitoes create unintended consequences?”</i></p> <p><i>“Can GM mosquitoes, or their genetic material, integrate into the wild?”</i></p> <p><i>“Are GM-wild hybrid mosquitoes more difficult to control or be better at spreading disease?”</i></p> <p><i>“What type of test or data has been collected to ensure that this new version and strain of mosquitoes does</i></p>	<p>As confirmed by the publication itself, the article making these claims contains multiple misleading statements and speculations. The publishers, Nature and Scientific Reports, <u>issued an Editorial Expression of Concern</u>, after the peer-review process which validated the misgivings of the scientific community regarding the authors’ claims and interpretations of the data.</p> <p>The EPA found no scientific grounds for concern on this matter, nor did the CDC.</p> <p>Yes. In EPA’s review of the data, they noted that “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 risk resulting from such introgression is negligible” (p134, EPA <u>Response to Comments</u>).</p> <p>No. Hybrids would have increased susceptibility to insecticides, making them easier to control, and no enhanced ability to spread disease is expected. “In conclusion, given the data on insecticide resistance, longevity, and fecundity, the large impact of the environment on all traits evaluated, and the complexity of vector competence, EPA believes it is unlikely that the introgression of OX5034 strain genetics would result in increased vectoral capacity of the local mosquito populations under the applied for EUP.”</p>	<p>Scientific Reports <u>article is here</u>.</p> <p>Scientific Reports <u>Expression of Concern is here</u>.</p>

	<p><i>not spread disease even more than the current local Florida strains.”</i></p>	<p>(p40, <u>Human Health and Environmental Risk Assessment</u>).</p> <p>Independent panellist Dr. Jorge Rey concurred with EPA’s assessment of the complexity of vector competence assessments, the impact of the environment on traits evaluated, etc.</p>	
Genetic monitoring	<p><i>“Any type of genetic monitoring program to help detect any unanticipated outcomes or consequences? Especially since this new version is supposed to be female killing only.”</i></p> <p><i>“Is there an accepted ‘tolerance level’ of introgression stipulated by the regulating agencies?”</i></p>	<p>This version of the mosquito is female-lethal only, meaning that males survive and are intentionally able to introgress background genetics into the local wild population.</p> <p>In EPA and CDC’s review of the data, they noted that “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 risk resulting from such introgression is negligible” (p134, EPA <u>Response to Comments</u>).</p> <p>A genetic monitoring program to measure the extent and duration of introgression is not relevant to risk assessment and has therefore not been included by regulatory agencies in the monitoring requirements for this project. There is also no tolerance level or threshold for introgression established by the regulatory agencies, for the same reasons. Nevertheless, such a study may have additional merit and is being explored with University groups.</p>	<p>U.S. EPA and U.S. CDC issued a joint <u>memorandum</u> assessing the likelihood and risks of introgression.</p>
Female release	<p><i>“Did Oxitec unintentionally release OX513A females in past projects?”</i></p> <p><i>“Will Oxitec be releasing female mosquitoes in this project?”</i></p>	<p>Zero females will be released with OX5034, as the new strain is male-selecting, female-lethal.</p> <p>Oxitec’s 1st generation OX513A, as reported in all regulatory filings around the world, caused >95% death of larvae. This, together with manual sex separation methods that were required for production of male OX513A (similar to the same production methods still used by Wolbachia and SIT technologies) has</p>	<p>Harris et al (2011) <i>Nature Biotech.</i>, 29:1034-1037.</p> <p>Carvalho et al (2015) <i>PLoS Negl Trop Dis</i> 9(7): e0003864.</p> <p>Gorman et al (2016) <i>Pest Man. Sci.</i> 72(3):618-28. doi: 10.1002/ps.4151.</p>

	<p><i>“Why didn’t Oxitec share that its 1st generation mosquito included female release?”</i></p> <p><i>“Please provide independent scientific data on the number of females to be released.”</i></p>	<p>always been documented to allow for a limited level of female release. The level of any female release is something all technology providers take seriously, and this was always monitored, reported to regulators, and published in peer-reviewed literature.</p> <p>Oxitec and highly-cited scientific publications have always disclosed >95% death of larvae in its first-generation mosquito.</p> <p>OX5034 does not allow for female survival, and thus no females will be released. These data have been reviewed by EPA and Florida state regulators: “exposure to female mosquitoes ... was determined to be negligible given that the penetrance of the tTAV-OX5034 lethal trait was shown to be 100% in female mosquitoes” (p50, <u>Human Health and Environmental Risk Assessment</u>).</p>	<p><u>List of independent peer-reviewed Oxitec technology publications.</u></p>
<p>Use of Oxitec mosquitoes during dengue epidemic</p>	<p><i>“Can Oxitec mosquitoes be released during a dengue outbreak?”</i></p>	<p>Oxitec mosquitoes are intended to be deployed as a part of Integrated Pest Management carried out by organizations like FKMCD; they can and have been safely deployed effectively during dengue and other outbreaks.</p> <p>Although Oxitec does not make health claims relating to its technologies, the city of Piracicaba independently reported a dramatic drop in dengue cases in the areas treated by Oxitec in the 2015/2016 season. In the neighborhoods where Oxitec's mosquitoes were released, the city reported a significant reduction in disease compared to the rest of the city. The city’s Epidemiological Service (Vigilância Epidemiológica) registered only 12 cases of dengue in these neighborhoods in a period of one year in the 2015-2016 season, compared to 133 in the previous year.</p>	<p><u>http://saude.piracicaba.sp.gov.br/oxitec-inicia-soltura-de-mosquitos-aedes-do-bem-no-sao-judas/</u> for details.</p>

Technology effectiveness	<i>“Is there any data or evidence that this process works to lessen the populations of disease carrying mosquitoes?”</i>	Yes. Oxitec has completed two seasons of field trials in Brazil with the 2 nd Generation male mosquito. It successfully suppressed wild mosquito populations by 95% in both field seasons. e	Oxitec’s press statements here .
Impact on disease reduction	<i>“Will Oxitec mosquitoes reduce pathogen prevalence without causing extinctions?”</i>	Reductions in vector populations are expected to result in reductions in pathogen prevalence. This is the premise of all mosquito control activities, whether using chemicals, biological control tools like Oxitec mosquitoes or Wolbachia, or habitat reduction. Oxitec mosquito releases are designed to result in reduced mosquito populations when deployed appropriately but will not cause extinction of the targeted mosquito species.	
Malaria, other vectors	<i>“Can Oxitec technology be used to combat mosquitoes that transmit diseases like malaria?”</i>	Yes. Oxitec has development programs underway, funded by the Bill and Melinda Gates Foundation, to develop the same technology in malaria vectors.	https://www.oxitec.com/en/our-technology
Climate change and mosquito biology	<i>“New research by Tang and Davis published in Communications Biology indicates that climate change could enable mosquitoes to mutate more rapidly. This could have a profound effect on any release of experimental mosquitoes. Have you considered the impact of this research?”</i>	<p>The article referred to in this question reported mathematical modelling demonstrating that climate change over hundreds of millions of years may have contributed to the evolution of different mosquito species over extremely long periods of time.</p> <p>This project is planned for less than two years, and so the extent of genetic change reported in this paper is not relevant for the releases of Oxitec mosquitoes.</p> <p>Further, as highlighted by panelist Prof Jorge Rey, the impacts of climate change are heterogeneous, with some areas warming and some cooling, and the impact of climate change on mosquito population movement and genetics is extremely difficult to predict. However, on the</p>	https://www.nature.com/articles/s42003-018-0191-7

		timescales of this project, these considerations are not relevant.	
Questions About the Project Location, Environment and COVID			
Impact on ecosystem and endangered species	<p><i>“Will Oxitec’s mosquitoes impact our local ecosystem and endangered species?”</i></p> <p><i>“What if animals ingest Oxitec mosquitoes?”</i></p> <p><i>“Will there be any side effects on the natural predators that feed on these Mosquitoes, e.g. birds, amphibians.”</i></p> <p><i>“Can you elaborate on why there is little to no impact on other animal species?”</i></p>	<p>Oxitec mosquitoes will NOT have a negative impact on the Keys’ ecosystem, or any effect on endangered species. Oxitec’s non-chemical approach is targeted to the invasive <i>Aedes aegypti</i> mosquito only and will have no effect on beneficial insects, animals, plants, soil, water, or other parts of the ecosystem.</p> <p>Oxitec commissioned third-party scientists to study the effects on mosquito predators (freshwater fish and invertebrates) of ingesting OX5034 mosquito larvae and pupae, compared with a diet of non-GM mosquito larvae and pupae. No adverse effects on predators were observed as a result of consumption of OX5034 mosquitoes. EPA and FDACS reviewed these data as part of their environmental risk assessment (p43-49, Human Health and Environmental Risk Assessment).</p> <p><i>Aedes aegypti</i> invasive mosquitoes also do not form a major part of the diet of any species in the Florida Keys ecosystem, whether birds, bats, fish, amphibians and reptiles, invertebrates, etc.</p>	<p>EPA: “no adverse effects are anticipated for nontarget organisms as a result of the experimental permit to release OX5034 mosquitoes” (p 49, Human Health and Environmental Risk Assessment).</p> <p>With regard to endangered species, EPA made a ‘No Effect’ determination for direct and indirect effects to federally listed endangered and threatened species, and for their designated critical habitats (p 49, Human Health and Environmental Risk Assessment).</p>
Number of mosquitoes	<i>“Why are so many mosquitoes needed?”</i>	<p>The purpose of releasing male Oxitec mosquitoes is to release enough male mosquitoes to find and mate with as many wild females as possible. So the number of males released may vary depending on the wild population.</p> <p>EPA has determined a maximum release rate which may not be exceeded, which is up to 20,000 non-biting males per acre per week. Oxitec does not expect to release at the maximum rate, having achieved successful population suppression in Brazil with far lower mosquito release rates.</p>	EPA Human Health and Environmental Risk Assessment of OX5034

Dengue in the Keys	<p><i>“Please provide a reference to support your data on dengue cases in the Keys.”</i></p>	Data on dengue is held by FKMCD and local health authorities in Monroe County, not by Oxitec.	http://keysmosquito.org/2020/06/26/fkmcd-details-dengue-response-plan-in-key-largo/
<p><i>Aedes albopictus</i> and other mosquito species</p>	<p><i>“Will Aedes aegypti control allow other species to take its place?”</i></p> <p><i>“Will Aedes albopictus replace Aedes aegypti?”</i></p> <p><i>“Will Oxitec mosquitoes have an impact on mosquitoes blown in from other areas?”</i></p> <p><i>“In the upper keys, when the wind is out of the everglades, mosquitoes blow in and get really bad. These would be non gmo mosquitoes replacing those here. How would this be mitigated.”</i></p>	<p><i>Aedes aegypti</i> occupies a unique ecological niche, and it is unlikely that other species will take its place when <i>Aedes aegypti</i> populations are suppressed.</p> <p>Oxitec has monitored populations of <i>Aedes albopictus</i> (the Asian Tiger Mosquito), a secondary vector of dengue, Chikungunya and Zika, throughout its trials in Panama in 2014 and Brazil in 2015 to 2019, and shown that <i>Aedes albopictus</i> does not replace <i>Aedes aegypti</i> when the <i>Aedes aegypti</i> populations were suppressed by releases of Oxitec mosquitoes.</p> <p>The monitoring strategy for the Florida project will enable Oxitec and FKMCD scientists to monitor <i>Aedes albopictus</i> presence in the field sites and measure any changes in the <i>Aedes albopictus</i> population that may occur, although these are unlikely.</p> <p>As highlighted by Dr Lawrence Hribar during the discussion, other mosquito species, for example the salt marsh mosquito <i>Aedes taeniorhynchus</i>, which is often blown into the Florida Keys from the Everglades, occupy very different ecological contexts and are also unlikely to be affected by changes in <i>Aedes aegypti</i> populations.</p>	Gorman et al (2016) <i>Pest Man. Sci.</i> 72(3):618-28. doi: 10.1002/ps.4151.
Traditional control measures	<p><i>“Will FKMCD continue traditional control measures during this project?”</i></p> <p><i>“How will effectiveness be measured if traditional control</i></p>	Where needed, traditional control measures will be continued during this project. This project will compare sites treated with Oxitec male mosquitoes with untreated sites. Both treated and untreated sites will have the same traditional control measures in place, to ensure valid comparisons between them.	

	<i>measures are ongoing?"</i>		
Project metrics	<p><i>"What is the project's threshold for success?"</i></p> <p><i>"What is "success" in this project?"</i></p>	<p>There is no formal threshold for performance success set by the regulatory authorities or internally. The project will be evaluating many different components covering biology, behavior, operations and performance. Some of this data will also likely be submitted to regulators should further regulatory applications follow and those agencies will make their own determination on the potential of the product.</p> <p>Oxitec will also seek to meet performance expectations of end-users, like FKMCD, to ensure the technology is sustainable and effective and efficient to manage operationally.</p>	<u>EPA Human Health and Environmental Risk Assessment of OX5034</u>
Location	<p><i>"Why did Oxitec target the Florida Keys?"</i></p> <p><i>"Where will the trial be held?"</i></p> <p><i>"How will the locations be chosen?"</i></p> <p><i>"How can I get one in my yard?"</i></p> <p><i>"Why does Oxitec want to experiment in populated areas? Why not release the experiment where the area is not populated by humans?"</i></p>	<p>The Florida Keys are an at-risk area for diseases transmitted by <i>Aedes aegypti</i>, as evidenced by the current local dengue transmission in Key Largo. The Keys also have some of the highest <i>Aedes aegypti</i> pest pressures in the United States.</p> <p>Exact project locations within the Keys will be determined by FKMCD and Oxitec, taking into account the local wild mosquito prevalence and the results of the 2016 referendum. Community engagement in planned project areas will be carried out in advance of releases, to find suitable locations for placement of mosquito release boxes.</p> <p><i>Aedes aegypti</i> is a mosquito that has evolved to live near humans and is not found in unpopulated areas. Therefore the releases will take place in populated areas, where <i>Aedes aegypti</i> are found and are able to transmit diseases to humans.</p>	
Wind and mosquito dispersal	<i>"Have you taken into consideration the Tovi Lehmann peer-reviewed</i>	It is possible for male Oxitec mosquitoes to move outside of the release areas, a possibility which was considered by all regulators in granting permits for this	<u>https://www.nature.com/articles/s41586-019-1622-4</u>

	<p><i>paper about windborne mosquitoes published in October, 2019? This is hurricane season. Windy weather is likely which raises containment issues...”</i></p>	<p>project to proceed. Oxitec male mosquitoes pose no risk to humans or the environment, and do not persist in the environment more than a few generations after releases cease. Even if Oxitec mosquitoes were to be transported by wind or human activity, this poses no additional risk to humans or the environment.</p> <p>In the event of severe weather conditions, Oxitec and FKMCD have agreed measures in place with regulators to protect staff, project equipment, and the success of the project.</p>	
COVID	<p><i>“How will this project be managed during COVID?”</i></p> <p><i>“Will this project present risks associated with COVID?”</i></p>	<p>COVID presents risks to all human activity, and this project does not include any additional risks not already present. FKMCD operations have adapted using standard measures to minimize COVID-related risks, and this project will be no different.</p>	
Liability	<p><i>“Does Oxitec have bonds/insurance for this project?”</i></p> <p><i>“Who is held accountable for unintended consequences?”</i></p>	<p>Oxitec’s project and technology is highly-regulated by EPA and Florida state authorities and is following standard U.S. government regulatory pathways for piloting new vector control technologies in the US.</p> <p>The project will be overseen fully by the FKMCD and evaluated by independent bodies – the CDC and University of Florida – from start to finish. It will also be advised by experts on the independent advisory board, including medical professionals and scientists.</p> <p>Oxitec will provide routine reporting to the EPA and Florida state regulators throughout the project.</p> <p>The EPA, CDC and Florida state all approved the project and validated that the technology and this project will pose</p>	

		no risk to humans, animals or the environment.	
Questions About Product Cost and Availability			
Cost	<p><i>“Is this project going to be expensive?”</i></p> <p><i>“Who is paying for this trial?”</i></p> <p><i>“Has Oxitec given FKMCD money for this project?”</i></p> <p><i>“Has Oxitec donated to FKMCD?” (question was unclear what this meant, but same answers to related questions applied)</i></p>	<p>Oxitec is fully funding this project.</p> <p>Oxitec has not paid FKMCD or donated any amount to FKMCD.</p> <p>FKMCD will not be funding this trial.</p>	Oxitec’s Florida page
Cost of the product once registered	<p><i>“What is the anticipated cost difference between responding to Aedes aegypti with this novel technology versus the traditional adulticide response? Since Mosquito Control Districts have budgetary concerns, how will this treatment compare to others cost-wise, in other words.”</i></p>	<p>This product, like all others, will be used by vector control authorities only if it offers a valuable cost-benefit ratio and delivers value.</p> <p>Comparing costs to existing adulticides is difficult, as traditional adulticides are losing effectiveness. As mentioned by the FKMCD during the event, new tools are needed urgently.</p> <p>Oxitec is focused on delivering value by way of low cost, superior performance and environmental sustainability.</p> <p>OX5034’s mini-capsule product removes all requirements for intensive local production facilities, complex deployments, hi-tech equipment, adult rearing and releases and a range of other complexities associated with Oxitec’s 1st generation technology and other biological tools available today. It can be shipped, stored, stocked, and deployed like a normal product as well, allowing it to</p>	

		fit within the supply chain of the mosquito control product distribution system, where efficient.	
Product availability	<i>“When will the product be available for wide-scale use?”</i>	Oxitec is following the standard registration process in the US, which requires multiple components as part of a registration application. This trial will be used to generate data for one part of that registration process. We anticipate that the product will be ready for market within just a few years.	
Questions About Cayman Projects			
Cayman projects	<p><i>“What did the Cayman projects entail?”</i></p> <p><i>“Did Oxitec fail in the Caymans?”</i></p> <p><i>“What about the recent project? When is data going to be made available?”</i></p>	<p>Four Cayman Islands projects were conducted with Oxitec’s 1st generation OX513A between 2009 and 2018.</p> <p>One was the world’s first ever GM mosquito release; one was the world’s first ever GM mosquito performance trial; one was the world’s first trial actively combining GM mosquitoes and chemical insecticides; one project designed, built, shipped and validated mobile laboratories.</p> <p>Between them they provided a wealth or learning and experience while attaining agreed and/or published performance figures ranging between 62% and 96%.</p> <p>The MRCU and Oxitec are still evaluating data for the 2018-2019 project using agreed-upon scientific methods, which are rightfully protected by an agreement that neither party will communicate results until the Joint Research Committee (JRC) has provided its final assessment. This ensures that the JRC has an opportunity to fully review, discuss, and determine scientific results prior to any individual or entity sharing her or his singular viewpoint. That project combined, for the first time ever, Oxitec mosquitoes with other <i>Aedes aegypti</i> control methods, and was intended to develop learnings on how best to combine approaches</p>	<p>Harris et al (2011) Nature Biotech., 29:1034-1037.</p> <p>Harris et al (2012) Nature Biotech. 30:828-830.</p> <p><u>List of independent peer-reviewed publications on Oxitec technology.</u></p> <p><u>Link to Oxitec’s press release about the 2018 project.</u></p>

		<p><u>The MRCU Director, Dr. James McNelly, released the following statement on July 11, 2020:</u></p> <p><i>“The 2018 collaborative project between the Mosquito Control and Research Unit-Grand Cayman and Oxitec was a professional scientific endeavor. MRCU's relationship with senior scientists and management was positive and supportive of the integration of different approaches. This was a successful collaboration that fully adhered to the mutually agreed upon contract and Operational Plan that was steered, as the project progressed, through an active Stewardship Committee.”</i></p>	
--	--	--	--