



OXITEC

## Follow-up to FKMCD-Oxitec August 17, 2020 Public Educational Webinar

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

September 8<sup>th</sup>, 2020

FKMCD and Oxitec held a public educational webinar on Aug 17, 2020 at 5pm ET. The following is a summary of the event, questions asked and answered, answers to questions submitted after the event, and additional helpful resources for topics discussed.

#### Event Summary:

- A complete recording of the event can be viewed [here](#).
- The event was entitled '*Review: 20 Years of Independent Assessment, Oversight and Validation*'.
- The event was moderated by Meredith Fensom (Oxitec, Head of Public Affairs), and presenters were Andrea Leal (Executive Director, FKMCD), Dr Kevin Gorman (Oxitec, Head of Field Operations) and Dr Nathan Rose (Oxitec, Head of Regulatory Affairs).
- The event lasted a little over 60 minutes, devoting half of that time to Q&A.
- 19 questions were individually answered during the event.
- Questions were answered anonymously to ensure attendees were not inhibited by disclosure of their names.

**Title: Review: 20 Years of Independent Assessment, Oversight and Validation.**

**Date:** Aug 17<sup>th</sup>, 2020

**Panelists:** The event featured the following panelists:



**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

**Question and Answer Catalogue:** the following provides details of the 19 questions asked and answered, and additional information resources.

Topic for Easy Reference	Questions Asked	Answers	References
<b>Questions About Regulation, Oversight</b>			
EPA Data Availability	<p><i>Can you summarize again where Oxitec's data is? Has the EPA or Oxitec made this data available?</i></p> <p><i>Where are the tests on humans showing "no risk"? Please share?</i></p>	<p>When the EUP was approved, the EPA published its risk assessment documents, the response to public comments, and the analysis of the proposed field protocols. These are all available on the regulations.gov website by searching for OX5034, or by following the links in this table.</p> <p>The human health risk assessment summarizes all of the data on the OX5034 non-biting male mosquito which relates to human health, and is available by following the links in this table.</p>	<p><a href="#">EPA's full regulatory package.</a></p> <p><a href="#">Human Health and Environmental Risk Assessment.</a></p>
Public Comment Period	<p><i>What is Oxitec's response to the EPA receiving 31,179 comments opposed to this technology and merely 56 comments in favor of this technology?</i></p>	<p>Public comment on an application under FIFRA, like Oxitec's EUP application, is not a vote on the technology. It is an opportunity to submit substantive scientific input to the regulatory agency for their consideration and inclusion in the risk assessment process.</p> <p>The EPA responded in full to all of the substantive scientific issues raised by public comments on the OX5034 EUP application, and their <a href="#">Response to Comments</a> is publicly available.</p> <p>The vast majority of the 31,179 comments received were 'form letters' or electronic petitions which repeated the same content. The EPA responded to the substantive scientific content included in these repetitive comments.</p>	<p><a href="#">Response to Comments.</a></p>
Level of regulation / under-regulation of Oxitec's	<p><i>Why did Oxitec post a two-page document to represent the EUP</i></p>	<p>When providing information about an EUP for public comment, the EPA is required by 40 CFR 172 to provide certain information to the public. EPA complied with the</p>	<p><a href="#">EPA's full regulatory package.</a></p> <p><a href="#">State of Florida findings.</a></p>

<p>mosquito technology</p>	<p><i>application to the EPA.GOV website during the public comments period? Later after the approval was announced, twelve documents were posted to the EPA.GOV website, and I wonder where were these documents during the public comment period? Certainly this speaks to a lack of transparency in the regulatory process. What is your response to this?</i></p>	<p>relevant regulation when opening public comment on the Oxitec OX5034 EUP, and described the information as follows (p92 of EPA’s <u>Response to Comments</u>):</p> <p>“For an EUP notice of receipt (NOR) EPA customarily provides the following information: the name of the pesticide, the name of the submitter, purpose of the EUP, the maximum application rate and use site, maximum number of treated acres requested, duration of EUP, and location of test site(s). In addition to that information, EPA provided the public a summary of the key differences between the first generation OX513A mosquitoes and this second-generation product (0002) as described in Unit I of this Response to Comment document.</p> <p>Further, the EUP regulations regarding “Publication” at 40 CFR 172.11(a) state, in part:</p> <p>(a) Notice of receipt of an experimental use permit application. The Administrator shall publish notice in the FEDERAL REGISTER of receipt of an application for an experimental use permit upon finding that issuance of the experimental use permit may be of regional or national significance. This notice shall include:</p> <ol style="list-style-type: none"> <li>(1) The active ingredients,</li> <li>(2) Use pattern(s),</li> <li>(3) Quantity of pesticide,</li> <li>(4) Total acreage,</li> <li>(5) Location of area of application,</li> <li>(6) A statement soliciting comments from any interested persons regarding the application.</li> </ol> <p>Here, EPA published a Notice of Receipt (NOR) of the EUP application in the Federal Register, in compliance with 40 CFR 172.11, soliciting public comment for 30 days, upon a finding that issuance of the</p>	
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	<p><i>Why is a living genetically modified insect considered a "biopesticide"? It doesn't really fit the definition of "biopesticide" on the EPA.GOV website. Can you please explain?</i></p>	<p>EPA regulates most pesticides which are not conventional chemicals, as biopesticides – these include biochemical pesticides like proteins, microbial pesticides like <i>Bacillus thuringiensis israelensis (Bti)</i> used for mosquito control, and plant-incorporated protectants (PIPs) like Bt corn. However, these categories are not exhaustive and EPA also has jurisdiction under FIFRA for regulating any kind of biopesticide.</p> <p>In the case of OX5034 male mosquitoes, the biopesticide is actually not the mosquito, but the protein called tTAV, and the genetic material required to produce it in the mosquito. Hence it is regulated as a biopesticide.</p> <p>EPA stated in its <u>Response to Comments</u>:</p> <p><i>“EPA is primarily regulating tTAV-OX5034 and DsRed2-OX5034, much like EPA regulates “plant-incorporated protectants” (PIPs), defined</i></p>	<p><a href="https://www.epa.gov/pesticides/biopesticides">https://www.epa.gov/pesticides/biopesticides</a></p> <p><a href="#">Response to Comments.</a></p>

		<p><i>in part as “a pesticidal substance that is intended to be produced and used in a living plant, ... and the genetic material necessary for production of such a pesticidal substance” (40 CFR 174.3). EPA has jurisdiction to regulate these substances under FIFRA because tTAV-OX5034 is intended for preventing, destroying or mitigating a pest, and therefore meets the definition of “pesticide” under Section 2(u) of the FIFRA.” (p 133, Response to Comments).</i></p> <p>Similarly, the <i>Wolbachia</i>-infected mosquito is not considered a biopesticide by EPA, but rather the <i>Wolbachia</i> bacteria themselves are regulated as a microbial pesticide.</p>	
	<p><i>Why did you not apply for an EIS?</i></p>	<p>An EIS (Environmental Impact Statement) is not something that can be applied for; it is an analysis tool used in some contexts to assess potential impacts on the environment. However, an EIS is not required under FIFRA, the law that governs EPA’s regulation of pesticides and biopesticides. Under FIFRA, EPA carries out an extensive Environmental Assessment which takes into account all of the relevant potential risks to the environment.</p> <p>For OX5034 male mosquitoes, EPA concluded that there was no risk of unreasonable adverse effects to the environment or to human health as a result of releases of OX5034 male mosquitoes.</p> <p>A full discussion of the questions relating to the use of an EIS can be found on p137-139 of the EPA’s <u><a href="#">Response to Comments</a></u>.</p>	<p><a href="https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program">https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program</a></p> <p><u><a href="#">Response to Comments</a></u>.</p>
<p>Purpose of EUP</p>	<p><i>Why do you still need trials if everything is already proven safe?</i></p>	<p>The EUP approved by the EPA and FDACS is not intended to demonstrate safety; that has already been done as part of the application and risk assessment process. The EUP is aimed at assessing efficacy and performance of the OX5034 male mosquito in the US environment, as part of the process towards registration of the new biopesticide under FIFRA.</p>	<p><u><a href="#">Human Health and Environmental Risk Assessment</a></u>.</p>

Coordination with other US Government Agencies	<i>How did Oxitec coordinate with the U.S. Department of Health, National Institute of Health and the CDC in developing their technologies?</i>	<p>Oxitec has excellent relationships with these departments and institutes. However, they were not involved in the development of the OX5034 male mosquito technology.</p> <p>CDC’s Vector Borne Disease experts will offer independent review and robust evaluation of the data generated by the proposed field projects in the Florida Keys.</p>	
Bill and Melinda Gates Foundation	<i>What is the purpose of your collaboration with the Gates Foundation?</i>	The Bill and Melinda Gates Foundation (BMGF) is funding Oxitec’s work to develop self-limiting strains of two <i>Anopheles</i> species which transmit malaria: <i>Anopheles stephensi</i> (present in the Horn of Africa, Arabia and South Asia) and <i>Anopheles albimanus</i> (found in Meso-America). This project forms part of the BMGF’s global efforts to eradicate malaria worldwide.	
Decisions in other jurisdictions.	<i>Oxitec recently received full biosafety approval in Brazil for this technology after two years and two field trials. Why can't EPA use the full biosafety review that took place in Brazil?</i>	Each country’s regulatory agencies conduct their own independent review of the relevant data when carrying out risk assessments for any new technology. Hence EPA and FDACS were required by US federal law and Florida state law, respectively, to carry out their own comprehensive assessments of OX5034.	
Regulations in other jurisdictions.	<i>Two questions relating to Europe: How does Oxitec answer to the higher standards in the European Union regarding regulation of biotechnology? and what happened to Oxitec's Olive fly in Spain?</i>	<p>Europe’s regulatory frameworks for biotechnology are broadly similar to those in other countries where Oxitec operates, e.g. the USA, Brazil, Australia, etc.</p> <p>Oxitec’s olive fly application to Spanish regulators was formally withdrawn as it was not possible to meet the timelines of additional data requirements.</p>	
FKMCD Board Oversight	<i>“Has there been a signed agreement or contract</i>	An agreement was signed in 2016, but that was for the previous project with OX513A. FKMCD is currently deliberating over the	<a href="#">FKMCD website.</a>

	<p><i>between Oxitec and FKMCD?”</i></p> <p><i>“Will the contract be available to the public prior to the Aug 18 meeting?”</i></p>	<p>current project, with a vote planned for Aug 18, 2020.</p> <p>The current proposed agreement is available from the <a href="#">FKMCD website</a>.</p>	
	<p><i>How do we know that this technology will not be used to pave the path for bioweapons? Or flying vaccines? Why did the US defense department help finance your company? It was not the department of health and human services. The US Military will somehow benefit from this technology.</i></p>	<p>There is no connection whatsoever to the U.S. Department of Defense or DARPA for the development of OX5034 or for the project proposed by Oxitec and FKMCD in the Florida Keys.</p>	
	<p><i>This is also a question that a few individuals continue to ask, so we wanted to answer it again. The question is: Why did Oxitec hire a lobbyist to pressure the EPA instead of taking a hands off approach like most science based companies do?</i></p>	<p>This question is focusing on a set of FOIA’d documents (<a href="#">a selection here</a>) showing that in May 2017 a lobbyist named Roy Bailey helped facilitate a meeting for the then chairman of Intrexon Corporation, the then-parent company of Oxitec. Intrexon no longer exists, and its successor company does not own Oxitec.</p> <p>This meeting related to the FDA’s announcement in January 2017 that it was transferring jurisdiction for our mosquitoes to the EPA after a six-year review, and the fact that after a further five months the transfer was stuck. This was during the Zika crisis.</p> <p>Oxitec’s later applications to the EPA in December 2017 and March 2019 for OX513A and OX5034 respectively, were</p>	



		submitted and governed under the formal <a href="#">FIFRA</a> and <a href="#">PRIA</a> processes.	
Informed Consent	<p><i>Why is this not considered an experiment on humans when the mosquitoes land on humans? Tests on pregnant women? Tests on immunocompromised individuals? Tests on children? Tests on the elderly? Tests on disabled people?</i></p>	<p><b>Oxitec is not testing on humans</b> 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 bite 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>The real risks to human health are the diseases (dengue, Zika, chikungunya, etc.) that are spread by the wild <i>Aedes aegypti</i> mosquito, which this technology is designed to control.</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, <a href="#">Response to Comments.</a> )
	<p><i>Why does it appear that so many doctors, scientists and environmentalists are concerned that your data is incomplete and that you are lying to people about the possible effects?</i></p>	<p>This is not correct. There is not a large group of doctors, scientists or environmentalists concerned. Oxitec’s EUP approvals are based entirely on science, on data and on peer-reviewed publications, all of which form the basis for careful government oversight and risk assessment.</p>	
<b>Questions About the Technology</b>			
Genes used in the OX5034 mosquito	<p><i>What is the risk of people becoming sick with other viruses that are used in creating these eggs?</i></p> <p><i>Can you dispel the misinformation surrounding the use of E. coli and herpes to develop OX5034?</i></p>	<p>The 2nd Generation OX5034 mosquitoes do not contain E. coli 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. (p5, p12, EPA <a href="#">Human Health and Environmental Risk Assessment</a>). There is no risk to human health.</p>	p5, p12, EPA <a href="#">Human Health and Environmental Risk Assessment</a> .

<p>Genetic modification process</p>	<p><i>Given that genetic modification is not an exact process, why hasn't Oxitec assayed a full DNA sequencing of the Oxitec mosquitoes to determine what off target mutations do exist? If they have done this has the data been made available to the regulatory agencies and the FKMCD?</i></p>	<p>The genetic modification process used to create OX5034 inserted only a single copy of the OX5034 genes into the genome of the <i>Aedes aegypti</i> mosquito, and the data verifying this have been reviewed by EPA. The insertion site did not disrupt any known protein-coding sequences in the <i>Aedes aegypti</i> mosquito, and had no impact on fitness, fecundity, vector competence, insecticide resistance, or any other relevant factors. It is not clear what whole-genome sequencing of OX5034 would achieve that would be relevant to risk assessment.</p> <p>The gene products themselves are safe, non-toxic and non-allergenic. (p5, p12, EPA <a href="#">Human Health and Environmental Risk Assessment</a>). There is no risk to human health.</p>	<p>p5, p12, EPA <a href="#">Human Health and Environmental Risk Assessment</a>.</p>
<p>Tetracycline</p>	<p><i>Why do you refuse to do a simple inexpensive test on the released mosquitoes to check for germs and antibiotic resistance as the local doctors have asked? What is the risk of people becoming antibiotic resistant from this release?</i></p> <p><i>Oxytetracycline widespread agricultural applications on citrus groves in Florida-- did you test for tetracycline in the environment?</i></p>	<p>Oxitec responds readily to any data requests issued by regulators but does not respond to <i>ad hoc</i> requests for data made by private individuals.</p> <p>Oxitec will not be using tetracycline in Florida, and the eggs shipped to Florida will have never been in contact with tetracycline.</p> <p><b>There is no risk and thus no scientific basis for testing.</b></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</p>	<p>The U.S. EPA's <a href="#">approval</a> of Oxitec's proposed pilot project.</p> <p>EPA's <a href="#">Human Health and Environmental Risk Assessment</a>.</p>

	<p><i>How about doxycycline levels in the environment?</i></p>	<p>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. No tetracycline is used to produce male adult mosquitoes in Florida, which will be deployed in the field.</p> <p>In the unlikely event of a female bred with OX5034 laying eggs in an environment with tetracycline present, then female OX5034 mosquitoes could survive if the growth conditions were appropriate and if the tetracycline concentration were high enough. However, EPA assessed this possibility:</p> <p>“Several lines of evidence including a survey of environmental levels of tetracycline, tetracycline dose-response testing of OX5034 females, and oviposition behavior of <i>Ae. aegypti</i>, indicate that the risk of hemizygous OX5034 female mosquitoes emerging in the environment due to high levels of tetracycline is low. Trial site location restrictions using known <i>Ae. aegypti</i> dispersal distances to limit exposure to locations with higher probabilities of containing tetracycline would further reduce the likelihood of OX5034 females in the environment to the point where the risk would be considered negligible.” This is a summary of a much more extensive discussion of this issue, which is available on p31-34 of the Human Health and Environmental Risk Assessment.</p> <p>EPA has also included restrictions on the project locations: releases will not be carried out within 500 m of citrus groves (where oxytetracycline could potentially be</p>	
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		<p>used for control of citrus greening) or within 500 m of municipal wastewater treatment plants (where pharmaceutical-use doxycycline might be present in effluent) (see EPA’s approval of Oxitec’s proposed pilot project).</p> <p>If female OX5034 mosquitoes were to be detected during the project, EPA has prescribed specific steps to be followed:</p> <p>“If at any time during the course of the EUP Oxitec finds female individuals containing the OX5034 genetic construct surviving to adulthood Oxitec must take the following remediation actions: immediately cease releases of all OX5034 mosquitoes, as soon as practicable apply adulticide and larvicide pesticides to the treated area where the surviving females were detected and continue to monitor for the presence of the OX5034 genetic construct in female <i>Ae. aegypti</i> until OX5034 mosquitoes are no longer found for at least two successive mosquito generations, a minimum of 10 weeks. EPA may require additional applications of adulticides and larvicides if fluorescent mosquitoes continue to be found in the treated area after the initial detection.” (EUP Issuance Letter, EPA).</p>	
	<p><i>Would hospital grade disinfectants not kill the larvae? I mean windex kills bugs!</i></p>	<p>Oxitec’s OX5034 mosquito eggs are treated with disinfectant that is stronger hospital-grade disinfectant, as part of the production process. This does not impact the viability of the eggs. The larvae are not treated with disinfectant.</p>	
	<p><i>Many anti-GMO groups are saying this is a "Jurassic Park" experiment. Can you speak to this? Would negative effects not be seen in the last 10 years of releases? Have any</i></p>	<p>Anti-GMO groups that say this are not basing this assertion on science. Oxitec has carried out a decade of mosquito releases without a single adverse effect, documented by regulators and independent scientists worldwide.</p>	

	<i>of Oxitec's projects created undesired effects?</i>		
Female release	<i>When the saliva of accidentally escaped females is drawn into my bloodstream and the altered proteins impact my DNA on a cellular level, such as with sections of DNA from Herpes simplex virus and E. coli bacteria, what is my recourse and how will Oxitec "help" me with that?</i>	<p><b>Zero females will be released with OX5034, as the new strain is male-selecting, female-lethal.</b></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, <a href="#">Human Health and Environmental Risk Assessment</a>).</p> <p>If female OX5034 mosquitoes were to be detected during the project, EPA has prescribed specific steps to be followed:</p> <p><i>“If at any time during the course of the EUP Oxitec finds female individuals containing the OX5034 genetic construct surviving to adulthood Oxitec must take the following remediation actions: immediately cease releases of all OX5034 mosquitoes, as soon as practicable apply adulticide and larvicide pesticides to the treated area where the surviving females were detected and continue to monitor for the presence of the OX5034 genetic construct in female Ae. aegypti until OX5034 mosquitoes are no longer found for at least two successive mosquito generations, a minimum of 10 weeks. EPA may require additional applications of adulticides and larvicides if fluorescent mosquitoes continue to be found in the treated area after the initial detection.”</i> (EUP Issuance Letter, EPA).</p>	<p>The U.S. EPA’s <a href="#">approval</a> of Oxitec’s proposed pilot project.</p> <p>EPA’s <a href="#">Human Health and Environmental Risk Assessment</a>.</p>
Previous Trial Data	<i>“How can we learn about the results in Panama? Were those results confirmed?”</i>	The results of the trial of Oxitec’s 1 <sup>st</sup> generation mosquito OX513A in Panama were published in a peer-reviewed scientific article the journal <i>Pest Management Science</i> in 2016. In that trial,	<a href="https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.4151">https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.4151</a>

	<p><i>“How do you explain the cherry picking of data to falsify the suppression levels expressed in both the Cayman and Brazil?”</i></p>	<p>the wild <i>Aedes aegypti</i> population was suppressed by up to 93% through repeated releases of OX513A. Importantly, that trial also demonstrated that <i>Aedes albopictus</i> abundance was unaffected by reductions in <i>Aedes aegypti</i>, i.e. there was no niche replacement by <i>Aedes albopictus</i>.</p> <p>All field performance data, and the parameters that define published metrics, are reported transparently without cherry-picking. A range of metrics can be and are utilized to appropriately suit their specific context.</p>	
<b>Questions About the Project Location, Environment and COVID</b>			
	<p><i>“Will Oxitec’s mosquitoes impact human health or properties negatively? What happens if there is negative impact?”</i></p>	<p>The approval of this project by EPA and Florida state regulators confirmed that there would be no danger to humans, flora, or fauna in the Florida Keys environment due to the releases of OX5034 male mosquitoes.</p> <p>EPA stated <i>“Since only male mosquitoes will be released into the environment and they do not bite people, they will not pose a risk to people. It is also anticipated that there would be no adverse effects to animals such as bats and fish in the environment.”</i></p> <p>Approximately 1 billion Oxitec mosquitoes have been released over 10 years in 4 countries representing 3 continents. Not one single adverse effect on environmental or human health has ever been documented.</p> <p>There is no risk to humans or to properties, as identified by 9 oversight agencies. Oxitec mosquitoes do not bite, and they will have no impact on homes or properties. As can be seen in the investigational agreement, Oxitec will carry all required permits and insurance. But as our mosquitoes are safe, non-toxic, non-allergenic, non-biting, and self-limiting,</p>	<p>EPA <a href="#">statement</a> approving Oxitec’s EUP.</p>

		there is no risk posed by them. Oxitec must routinely report to FKMCD, EPA and FDACS on the progress of the project.	
	<i>SIT, Wolbachia, Bti, Gambusia, dragonflies, reduce habitat by dumping standing water, public outreach and education... all great "tools for the toolbox!!" Why are you not using them instead of doing an experiment?</i>	The tools at our disposal are not providing full control of the threat posed by this mosquito. Continuing to investigate and develop new tools is essential to ensure the safety of local communities.	
Community Engagement	<p><i>What is FKMCD doing now to educate the community?</i></p> <p><i>Many local people do not do zoom meetings. What other methods are you using to inform our community about this project?</i></p>	<p>The FKMCD referenced the ongoing series of five webinars and frequent utilization of the radio for information sharing, including interviews and ads.</p> <p>The Oxitec team has actively engaged the Keys community for over a decade. COVID has required us to take additional steps and limit the number of in-person forums. Zoom is not required to communicate with us, anyone with an internet browser can view our live or recorded webinars. We make these and many other materials available on our <a href="http://oxitec.com/florida">oxitec.com/florida</a> page and through our social media channels. The webinars have been advertised on 7 local Keys radio stations for weeks and two weeks' worth of full-page ads were taken out in four local newspapers. Each social media post promoting these webinars reached an average audience of 1,800 in the Monroe County area. We often answer questions and arrange calls with residents when we hear from them on <a href="mailto:florida@oxitec.com">florida@oxitec.com</a>.</p>	
Referendum	<i>Why are you not giving the general public a vote on this now? The last vote was over 4</i>	<b>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.</b> The original referendum question was not specific to OX513A, but rather	<a href="https://www.keys-elections.org/Election-Data/Past-County-Results-2009-Current">https://www.keys-elections.org/Election-Data/Past-County-Results-2009-Current</a>

	<i>years ago on a different product!</i>	asked “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>Is it a conflict of interest for Florida Keys Mosquito Control board commissioners or staff to own or purchase stock in Oxitec/ Intrexon / Precigen?</i>	Oxitec is privately owned and no Oxitec stock is for sale. It is not possible for FKMCD Board members or staff to own stock and no FKMCD Board or staff member has an investment or ownership interest in Oxitec. We are unaware of any conflicts of interest.	
	<i>Who funded the lab in Marathon?</i>	The lab refit required was funded by Oxitec in accordance with the previously approved Investigational Agreement. The lab remains the property of FKMCD.	
	<p><i>Can you explain why independent evaluation is being done on this project? Is this common for new mosquito control tools to have such interest or involvement?</i></p> <p><i>Can you explain how this project will be monitored and reviewed throughout the project? It sounds like EPA, state regulators, the CDC, University of Florida, FKMCD and the independent advisory board...can you walk through the role each will play?</i></p>	<p>If approved by FKMCD, the project has substantial independent review built-in, including by an Independent Advisory Board (Florida Department of Health, University of Florida, local veterinary specialist) providing expert advice, CDC specialists providing technical support and oversight, regulators at the state and federal level, and FKMCD themselves.</p> <p>As a team, we intend to publish all novel scientific findings in peer-reviewed scientific journals, constituting further independent review. We always aim to publish in open access journals, so the data become publicly available for free.</p>	



	<p><i>Will I get a chance to talk one to one with someone before I have a device in my community?</i></p> <p><i>How long before the release will the residents in the trial area be notified?</i></p>	<p>Yes. It is important for FKMCD and Oxitec to have 1:1 interaction with the people in every neighborhood where we could place boxes and would have 1:1 interaction and permission before placement of any release device box.</p> <p>The locations would be subject to steering committee approval and are not yet defined. They will be chosen in due course. However, residents who wish to host a release device should contact FKMCD and we would do our best to accommodate.</p>	
Covid-19	<p><i>This decision was postponed last month due to the board's desire to be mindful of COVID. What has FKMCD and Oxitec done to manage this project in light of COVID? Does the project up for a vote address the board's concerns?</i></p>	<p>The FKMCD Board postponed their vote last month by 30 days to examine in more detail the interaction between the project and COVID. Should approval of the project by FKMCD Board be forthcoming, releases would not begin before 2021 to minimize any impact. Operations would be carried out sensitively with staff and public safety at the forefront of any decisions.</p>	
Cost-Benefit Analysis	<p><i>Can you discuss the costs of your technology to control the mosquitoes?</i></p> <p><i>Do you have cost benefit analyses comparing it to alternative ways of controlling mosquito populations?</i></p>	<p>We anticipate that this technology will cut 90% of costs and complexities associated with rearing and releasing adult mosquitoes. We are studying cost effectiveness closely with our partners, and we would do so with FKMCD if this proposed pilot project progresses.</p>	