Follow-up to FKMCD-Oxitec August 4, 2020

Public Educational Webinar

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

August 7th, 2020

FKMCD and Oxitec held a public educational webinar on Aug 4, 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 '*Developing Partnerships with Communities*'.**
- **The event was moderated by Meredith Fensom (Oxitec, Head of Public Affairs), and presenters were Andrea Leal (Executive Director, FKMCD), Chad Huff (Public Education and Information Officer, FKMCD) and Dr Kevin Gorman (Oxitec, Head of Field Operations).**
- **The event lasted a little over 60 minutes, devoting half of that time to Q&A.**
- **19 questions were individually answered, questions were not batched together.**
- **Questions were answered anonymously to ensure attendees were not inhibited by disclosure of their names.**

Title: Developing Partnerships with Communities.

Date: Aug 4th, 2020

Panelists: The event featured the following panelists:

Andrea Leal
Executive Director
FKMCD

Chad Huff
Public Education & Information Officer
FKMCD

Kevin Gorman
Head of Field Operations
Oxitec

Meredith Fensom
Head of Public 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
Questions About Regulation, Oversight			
Level of regulation / under-regulation of Oxitec's mosquito technology	*"Why do you feel that a 2-page marketing memo and only an Environmental Assessment is sufficient level of evaluation?"*	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 relevant regulation when opening public comment on the Oxitec OX5034 EUP, and described the information as follows (p92 of EPA's Response to Comments): "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. Further, the EUP regulations regarding "Publication" at 40 CFR 172.11(a) state, in part: (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: (1) The active ingredients, (2) Use pattern(s),	EPA's full regulatory package. State of Florida findings.

		(3) Quantity of pesticide, (4) Total acreage, (5) Location of area of application, (6) A statement soliciting comments from any interested persons regarding the application. 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 EUP may be of regional or national significance. 84 Fed. Reg. 47,947 (Sept. 11, 2019). The NOR and public comment period provided fulfill the requirements of the "publication" regulations." EPA followed the same procedures when opening public comment periods on the Wolbachia-infected mosquito technology, providing the same information required by 40 CFR 172. Regarding the risk assessment of the EUP, EPA followed the relevant FIFRA requirements when assessing the EUP application for the OX5034 mosquito.	
Misinformation About the Project	*"Can you characterize the types of misinformation about this project out there now?"* *Why don't you have an open public discussion with your experts and those who have challenged your claims and expressed concerns?*	False claims and inflammatory statements are not helpful and very varied in terms of content and context. To avoid this, we strongly recommend reverting to source for data/information as this will avoid misinformation being perpetuated by third parties. We conduct discussion with all stakeholders and pride ourselves on doing so. We speak with those who challenge us in forums such as this, but also on a one-to one basis at every opportunity.	
	Why do you not have anyone who	The Independent Advisory Panel contains representatives who have independent	

	disagrees with you on your board? Like the scientists and local Doctors who have asked and petitioned for you to test the mosquitoes after release to check for bacteria, even if you do not have to?	expertise and a desire to see this project carried out professionally in the interest of finding novel solutions for vector control in the US. Oxitec responds readily to any data requests issued by regulators but does not respond to *ad hoc* requests for data made by private individuals.	
Oxitec Peer-Reviewed Papers	*"Can you please explain exactly what a peer review paper is and how it is created."* *"What should we do if we are having trouble finding the documents?"*	The peer review process works as follows: 1. Scientists carry out experiments and write a journal article describing the results, listing themselves as authors. 2. The journal editors send the article and its supporting data to several carefully selected peer reviewers (usually 3-5 reviewers) who are independent scientists and experts in the field, i.e. not connected to the article authors in any way. Peer reviewers are usually anonymous, and their identities are not typically revealed to the article's authors. 3. Peer reviewers give feedback on the article, focusing on whether the experiments are novel, relevant to the journal, have been correctly carried out, whether the data analysis is appropriate for the type of data, and whether the conclusions are correct based on the data. 4. The editor gives the feedback to the article authors, with instructions to amend or correct the article if required. 5. If the amendments are satisfactory (and this may require the reviewers to re-review the article after amendment), then the journal may accept the article for publication.	https://www.oxitec.com/en/our-technology

		The list of Oxitec's peer-reviewed publications is available on the company's website: https://www.oxitec.com/en/our-technology by scrolling to the bottom of that page to the section headed 'Scientific Publications.' Many, but not all, of the papers are 'open access' and can be freely accessed by clicking on the links provided. Some papers are behind journal paywalls which require subscriptions to access the publications. If you would like to access a specific publication, please email florida@oxitec.com and Oxitec will endeavor to provide a copy of the publication (may be subject to copyright restrictions).	
FKMCD Board Oversight	*"Has there been a signed agreement or contract between Oxitec and FKMCD?"* *"Will the contract be available to the public prior to the Aug 18 meeting?"*	An agreement was signed in 2016, but that was for the previous project with OX513A. FKMCD is currently deliberating over the current project, with a vote planned for Aug 18, 2020. The current proposed agreement is available from the FKMCD website.	FKMCD website
	"What is the connection of Oxitec to DARPA in this experimentation in our community?"	There is no connection whatsoever to DARPA for the project proposed by Oxitec and FKMCD in the Florida Keys.	
Questions About the Technology			
Genes used in the OX5034 mosquito	*"Could you explain again how you make sure it is a female only effect?"* *Can you dispel the misinformation surrounding the use of E. coli and*	The tTAV protein is produced in large quantities inside cells in the developing female mosquito. It blocks the cells from carrying out normal cellular processes and from producing many of the other proteins required for normal mosquito development. This stops the female larvae from developing to pupae and adults, and they die as early-stage larvae. The action of the tTAV protein can be blocked by	

	herpes to develop OX5034?	tetracycline-class antibiotics if used at the right concentrations. The 2nd Generation OX5034 mosquitoes do not contain E. coli bacteria or Herpes simplex viruses (HSV). 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 Human Health and Environmental Risk Assessment).	
Female release	*"What percentage of females are you allowed to release according to your agreement? You mentioned it in a previous meeting."*	**Zero females will be released with OX5034, as the new strain is male-selecting, female-lethal.** 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, Human Health and Environmental Risk Assessment). If female OX5034 mosquitoes were to be detected during the project, EPA has prescribed specific steps to be followed: *"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*	The U.S. EPA's approval of Oxitec's proposed pilot project. EPA's Human Health and Environmental Risk Assessment.

		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).	
Previous Trial Data	*"How can we learn about the results in Panama? Were those results confirmed?"* *"How do you explain the cherry picking of data to falsify the suppression levels expressed in both the Cayman and Brazil?"*	The results of the trial of Oxitec's 1st generation mosquito OX513A in Panama were published in a peer-reviewed scientific article the journal *Pest Management Science* in 2016. In that trial, the wild *Aedes aegypti* population was suppressed by up to 93% through repeated releases of OX513A. Importantly, that trial also demonstrated that *Aedes albopictus* abundance was unaffected by reductions in *Aedes aegypti*, i.e. there was no niche replacement by *Aedes albopictus*. 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.	https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.4151
Questions About the Project Location, Environment and COVID			
	"Will Oxitec's mosquitoes impact human health or properties negatively? What happens if there is negative impact?"	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. EPA stated "*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*." Approximately 1 billion Oxitec mosquitoes have been released over 10 years in 4 countries representing 3 continents. Not one single adverse effect	EPA statement approving Oxitec's EUP.

		on environmental or human health has ever been documented. 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, there is no risk posed by them. Oxitec must routinely report to FKMCD, EPA and FDACS on the progress of the project.	
Community Engagement	*What is FKMCD doing now to educate the community?*	The FKMCD referenced the ongoing series of five webinars and frequent utilization of the radio for information sharing, including interviews and ads.	
	Will Oxitec and FKMCD share the results of the trial?	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), CDC specialists, regulators at the state and federal level, and FKMCD themselves. 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.	
Informed Consent	*How can you answer to those who do not consent to being part of your experiment?*	**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. This project will only be releasing non-biting males that do not bite humans. Oxitec is demonstrating the efficacy of its mosquito technology to control *Aedes aegypti* mosquitoes. This is analogous to	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

		other control products evaluated for use against mosquitoes like pesticides.	apply to this research proposed by Oxitec." (p134, Response to Comments.)
	"Will I get a chance to talk one to one with someone before I have a device in my community?" *"How can I sign up to get one in my yard?"*	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. The locations would be subject to FKMCD board approval of the project are not yet defined. They would 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.	
	Will I have to do anything if a device is in my yard, e.g. do I need to fill it with water each day?	No. All devices would be deployed, maintained, and removed by project staff. There would be no requirement for resident to interact with the devices at all.	
	"Can you please explain the relationship of the project and COVID?"	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.	
Cost-Benefit Analysis	*"Has Oxitec completed a cost benefit analysis?"*	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.	