Message

From: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Sent: 12/9/2019 6:53:08 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: FW: FKEC.org - GM Mosquito Safety

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Monday, December 09, 2019 1:02 PM
To: Overstreet, Anne <overstreet.anne@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: Fwd: FKEC.org - GM Mosquito Safety

Sent from my iPhone

Begin forwarded message:

> **From:** Barry Wray <support@fkec.org>
> **Date:** December 9, 2019 at 9:33:11 AM MST
> **To:** "Dunn, Alexandra" <dunn.alexandra@epa.gov>
> **Cc:** "McNally, Robert" <Mcnally.Robert@epa.gov>, Jack Norris <keywestdoctor@gmail.com>
> **Subject: FKEC.org - GM Mosquito Safety**
>
> HI Alexandra,
>
> For some reason the online staff directory is not providing your email, but I was able to confirm my guess with the help of your staff. I have also copied Robert McNally, whom we have had the pleasure of meeting with in the past, together with a larger EPA team reviewing the Genetically Modified Mosquitoes (GMMs) that Oxitec has proposed for an Experimental Use Permit (EUP) in the FL Key and in Harris County, TX.
>
> I am the Executive Director of the Florida Keys Environmental Coalition (fkec.org). It is largely because of our work, together with a broad coalition of other groups, that objection to Oxitec's flawed prior technology, the OX513A, has been prevented from release in the US. As citizens with standing, in regard to being subjected to any proposed testing, we have been a consistent and informed source of comments and discovery regarding Oxitec series of GMM products and a pattern of obfuscated, undisclosed and poorly investigated the risk factors to human and environmental health and safety.
>
> Our positions on this series of products is clear, it must be proven safe for humans and our environment, and all EUPs considered should assure that certain standards are met, risks are characterized and quantified, and that proper practical mitigation plans need to assure termination of experimentation in the event of performance concerns. We feel these products are sufficiently complex and that the repeated examples of misrepresentations by Oxitec, require a much greater level of investigation to assure proper safety and usage.

Oxitec, has a long history of using marketing instead of science to try to achieve public acceptance and political influence of the evaluation process. Oxitec has exhibited a willingness to obfuscate facts; for example, their current application as shown to the public on Regulations.gov, consists of a 2 page marketing memo and the public is expected to trust the claims made without verifiable scientific measurement, or other supporting data to substantiate such claims. In light of the history of failure and misrepresentation by Oxitec, given they lied on the prior OX513A application for EUP with the EPA in January of 2018, our concerns have increased with this most recent Oxitec EUP application for the OX5034 to be released in the FL Keys and Harris County.

Our goal is to identify a time when we can meet with the team evaluating the EUP application for the OX5034 release. Our concerns include antibiotic resistant bacteria promotion, as a result of tetracycline being used as lethal gene antidote in the rearing process. Oxitec has been shown in laboratory practices absent of any typical quality assurance controls, or handling safeguards resulting in mold growth in the lab and growing evidence of the likelihood of the antibiotic issue. While our concern go far beyond this one issue and are supported by examples of numerous failures by Oxitec and its product in field applications, more concerning is a pattern of behavior by Oxitec to impede investigation and misrepresent actual performance. The claims in the past for the OX513A were that the GMMs did not survive, but data provided from Oxitec lab results showed this was not the case and that "females live long enough to take 2 blood meals and lay 2 clutches of eggs". In fact the claims made by our organization that hybridization would occur, but that Oxitec's field investigation processes would lose traceability of the OX513A in the wild, has occurred. This exact scenario has been shown in recent objective scientific reports from Brazil. The repercussions of off target mutations remain uncharacterized, although technology to assay these errors is not cost prohibitive and relatively rapid.

We feel that after over 8 years of this behavior, an Environmental Impact Statement (EIS) would be the proper level of investigation, and it should be incumbent upon the applicant to participate in and cooperate with these important safety investigations including providing product samples for proper objective scientific analysis and that all claims that affect product safety must be objectively verified by an EPA overseen process and task force.

Please excuse the lengthy discussion, but it is done in hopes of outlining the breadth of discussion we hope to engage in and why we feel Oxitec has reached a point absent of credibility, which must be considered together with any proper review of this technology prior to any EUP approval. Dr Jack Norris is the Chief of Staff for our Lower Key Medical Center and I hold an MSEE degree with over 35 years of experience, with over 8 years focused on this subject and am the Executive Director of FKEC.org since inception in 2010. We can provide additional discussion of our backgrounds as needed. We look forward to a meeting time in as near term as possible, where we can discuss in depth, our concerns and a pathway forward that provide sufficient safety review of this product under consideration.

Thank you, respectfully,

Barry Wray
Executive Director
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florida keys environmental coalition