florida keys environmental coalition

January 9, 2021

The Honorable Carlos Gimenez
House of Representatives
419 Cannon House Office Building
Washington, DC 20515

Re: Congressional Letter of Inquiry

As Executive Director of the Florida Keys Environmental Coalition (FKEC.org), its many thousands of active supporters in the Keys, Florida and beyond, the 250,000 people who have sign our petition objecting against any release of Genetically Modified Mosquitoes (GMMs) in our community, our state and our nation, a multitude of recognized scholars, medical doctors, leaders in associated scientific disciplines and the many hundreds of thousands represented by a broader coalition of respected scientific environmental organizations including:

- The Center for Food Safety
- Friends of Earth
- GMO Free USA
- GMO Free Florida
- Institute for Responsible Technology
- Global Justice Ecology Project
- Food and Water Watch
- Never Again Foundation
- Gene Watch UK

we thank you, for your strong commitment to submit a Congressional Letter of Inquiry to the Environmental Protection Agency (EPA) regarding the following summary of our critical concerns regarding the approval process for an experimental release of GMM in Monroe County.

FKEC.org was formed in 2010 as a spontaneous citizen response to the Deep Water Horizon oil spill in the Gulf of Mexico, that threatened the ecosystems and community of the Keys. During this period, FKEC.org was, by unanimous resolution of every elected official, for each of the five municipalities and the Monroe County Board of County Commissioners, appointed to represent the ecosystems of the Keys and work to protect them in behalf of our community.

FKEC.org continues to fulfill this charge with many successful achievements, including recently your work as Mayor of Miami-Dade County in concert with Edward Russo, FKEC.org President,

to achieve the most recent the offshore oil drilling moratorium now expanded to include all of FL and our neighboring states of GA and SC. This achievement in itself also resulted in oil drilling interests discontinuing all seismic testing off the eastern seaboard of the US.

I am writing to you today with a description of key issues we believe have not been addressed by the Environmental Protection Agency regarding the approval of an experiment of GMMs in the Florida Keys as early as this spring.

Our nine plus year initiative of diligent demands to protect the health and safety of the citizen and sensitive ecosystems of the Keys that include several dozen listed endangered species, is based on a precautionary standard that assures any product must be proven safe prior to its release into the wild. Our objections within this summary will demonstrate that the current process has not met this standard, nor has it met any standard of proof, or verification, but is based solely on the EPA trusting a vendor's input and the review of those documents and claims. Many notable experts within relevant fields of science have called this inadequate and insufficient as referenced in the body of the discussion below. In our view, with a vendor that has been attempting for over nine years, to achieve the gold standard of US regulatory agency approval and the marketing credentials to say, their product has been tested in the US, this process has been inexcusably negligent.

The result of the vendor's campaign now lies in contempt by all scientific principles, being successfully politically influenced by vendor lobbying initiatives. The regulatory processes have been purposely obscured, devoid of transparency, clarity and is littered with a history of corrections to failed claims, excuses of performance exceptions and misrepresentative vendor marketing messaging to our public, versus accurate scientific characterization. This campaign of messaging serves to effectively confuse our public about the experimentation that our community will be subjected to. "Informed Consent" remains a core principle human right, but it has not been assured by this process.

Ironically, it would have been a much shorter and beneficial path for all, to employ proper objective and independent scientific investigation methods, versus the political influence campaign by the vendor, to achieve a complicitous regulatory process. which now facilitates a poorly understood experiment on our ecosystems, community and citizens.

We ask your inquiry be addressed to the current, or succeeding, EPA Administrator, to assure there is complete accountability for proper contextual responses being provided, presently this would be:

Michael Regan
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Mail Code 1101A

Please investigate, to your satisfaction, the May 1st, 2020 approval of the Oxitec application for an Experimental Use Permit (EUP), Federal Register Number 2019-19665, with consideration to the following points of concern:

The epa.gov website clearly lists the "Five Principles" that guide their decision-making policy copied from the EPA website. Any responses should justify EPA actions with respect to Sound Science, Transparency, Fairness and Public Trust:

1. During the open public comment period the EPA provided only a 2-page marketing style memorandum as the complete scientific product description for the public to consider on the regulations.gov website for insightful and scientific responses. The EPA received 31,235 comments and posted to the Regulations.gov website, 31,179 of these comments are "strongly opposed" to this experiment; 56 comments represent "in favor of". This action was in the wake of public records requests that revealed in 2017, the EPA hosted meetings with the vendor's registered lobbyist, Roy Bailey CEO of Giuliani Deason Capital Interests, who's introductory emails imply they were entering into these conversations with the power of a beneficial presidential relationship to subjugate those within the EPA who would diverge from the expressed desires of the vendor Oxitec.
    a. Current EPA emails, provided via Freedom Of Information Act (FOIA) requests, included a subset of communications between May and July of 2017. Please provide all communications from January 2017 to present, including, but not limited to, emails, meeting notes and minutes referencing and including the following participants: Registered Lobbyist Roy Baily (gdcillc.com, baileystrategicadvisors.com), his principal client Intrexon (intrexon.com) now named Precigen (precigen.com), the subject subsidiary Oxitec (oxitec.com), Randall J Kirk, Intrexon CEO, Lt Gen (Ret.) Tom Bostick, COO of Intrexon, Jack Bobo (Intrexon), and Robert "Bob" Walsh (Intrexon), Gay Ludwick (gdcillc.com). This is a comprehensive request for any and all communications related to the EPA and the named entities. Those that do not require redactions protected by non-disclosure agreement are requested in 30 days, or less. Any and all redactions should be expected to be challenged with requests for rational supporting any such redaction.
    b. In light of clear evidence of the vendor's, Oxitec's, pattern of and specific incidents of, mistakes, purposeful misrepresentations, including on their prior application to the EPA for the OX513A, divergence from recognized scientific methods, clear questions of field performance in the Cayman, versus Oxitec reported performance for mosquito suppression, and clear requests from both scientific groups with standing and independent recognized experts, within the scope of Oxitec's field of science, requesting independent objective scientific review of the technology, why has this complex germ-line edited technology only received a routine internal evaluation from the EPA and not the beneficial use of a Scientific Advisory Panel (SAP)?

114 W PIPPIN DR
ISLAMORADA, FL 33036
WWW.FKEC.ORG

c. With respect to initiatives pursued by the lobbying team, please explain why critical approvals of the Mosquito Mate Wolbachia trial data and the use of the technology itself have been unusually delayed by the EPA post the Roy Baily and Randall Kirk discussions, causing harm to the health and public safety of the FL Keys, given that versions of the Wolbachia technology are approved for use and data from subsequent trials in Miami were completed and released? The EPA authorized Wolbachia trial in the Keys was characterized as "very successful" by the Director of the Florida Keys Mosquito Control District (FKMCD), Andrea Leal. The dubious delay in approval of the Wolbachia technology restricted accessibility that could have assisted mosquito control efforts to address growing chemically resistant Aedes Aegypti populations in the Keys, prior to the most recent Dengue outbreak during the COVID-19 pandemic.

d. Please explain why the EPA chose an exclusionary policy for recognized groups with standing on this issue, specifically FKEC.org, that historically has provided substantive input in focused meetings with the EPA, FDA and the Office of Science and Technology Policy on this issue.

2. FOIA requests, as follows, have been submitted to the EPA on the subject of the Oxitec EUP for the experimental release of the OX5034 Genetically Modified Mosquito (GMM) these FOIA request have greatly exceeded EPA committed timelines for delivery to the applicant. Please provide explanation of why these requests have been so greatly delayed and fulfill all requested information to the applicant and to this office within 30 days of this request: (Note: The specific wording of these requests is provided in a separate attachment communicated with this letter)

   a. Request No. EPA-HQ-2018-005322 (a partial response has been provided), Submission Date: 3/9/2018

   b. Request No. EPA-HQ-2019-009051, Submission Date: 9/19/2019

   c. Request No. EPA-HQ-2020-002398, Submission Date: 1/21/2020

   d. Request No. EPA-HQ-2020-004953, Submission Date: 5/29/2020

3. This germ-line edited version of genetically engineer technology appears in effect to be a square peg in the proverbial round hole of existing EPA regulatory guidelines and internal expertise. Many recognized leaders in the field of genetic engineering were among the voices asking for EIS, or SAP as more applicable for FIFRA, levels of investigation of the Oxitec technology prior to any release. This Boston Globe article by Jennifer Kuzma Ph.D. NC State and Natalie Kofler, Ph.D. Harvard, are an example of the numerous voices calling for what seems to be a responsible step in the evaluation process. (https://www.bostonglobe.com/2020/06/22/opinion/before-genetically-modified-mosquitoes-are-released-we-need-better-epa/; jkuzma@ncsu.edu; Natalie_Kofler@hms.harvard.edu)

   Additionally, over the past two years independent scientific data obtained and independent research work, has repeatedly exposed contradictions to Oxitec's

performance claims, including the creation of hybrid mosquito species shown in the Brazilian trials. Please this link to the nature.com article from Jeffrey Powell, Ph.D, Yale. (https://www.nature.com/articles/s41598-019-49660-6; Jeffrey.powell@yale.edu)

There currently exists no sufficient regulatory framework in the United States to manage oversight of genetically engineered biotechnology that is designed to be inherited by subsequent generations, commonly referred to as "germ-line editing", or "Gene-Drive". These are patented life forms, living and evolving and effectively a manmade invasive species serving as a propagating weapon. It cannot be contained if there is a "spill." It cannot be rescinded nor remediated once released.

a. Given the discussion outlining that complexity of this technology appeals from vetted recognized experts and the question of the vendor's understanding, or proper disclosure of, the present and evolutionary performance of their product, why would the EPA proceed with such a low level review of this technology where only the vendors submissions and claims serve as the reported actual scientific verification of performance, versus a SAP investigation and subsequent specific scientific investigative process to investigate and assess the performance of this technology comprehensively?

4. After years of claiming only sterile males would be released and repeatedly denying their first version of GMM, OX513A, would put the public at risk with biting females being released, Oxitec publicly admitted that indeed females are released and others were born and survived in the wild.

   The corporate marketing continues to purport, "only males will be released" for the new version of GMM, the OX5034; however, in light of a clear and repeated history of misrepresentation, or mistakes, by Oxitec on this issue and a recent peer reviewed study identifying performance issues with the "Tet-On, Tet-Off" technology that Oxitec employs in the OX5034 mosquito, there has been no verification of this critical issue by any qualified independent scientific body.

   The following article appeared in June 2020 shortly after the EPA approval of the Oxitec EUP for the OX5034 and identifies flaws in the technology and statistical evidence of substantial probabilities of female production. Also, shown is the genetic modification that makes the insects florescent for tracking purposes, weakens and can disappear after a several generations, permitting erroneous claims of the species disappearing from the environment. (Genetic breakdown of a Tet-off conditional lethality system for insect population control: (https://www.nature.com/articles/s41467-020-16807-3)

   Regarding the Zhao research, in response to an inquiry to the EPA by FKEC.org, Assistant Administrator Alexandra Dunn, in a January 19, 2021 letter to FKEC.org states that:

   "Based on the product-specific data evaluated by EPA, the Agency finds that instances of female survival into adulthood due to genetic resistance are expected to be negligible

within the parameters of this EUP. EPA has posted a detailed review of the Zhao et al. publication in in docket EPA-HQ-OPP-2019-0274 at www.regulations.gov. The review is entitled "Review of the Zhao *et al*., 2020 study on 'Genetic breakdown of a Tet-off conditional lethal system for insect population control' and its relevance to the OX5034 *Ae. aegypti* Experimental Use Permit; EPA File Symbol 93167-EUP-1"."

All searches for any publication within the docket folder, or outside of it, are unsuccessful in identifying any such response from the EPA.

Administrator Dunn's response to the inquiry neglects to acknowledge that faults noted in the fluorescent marker provide a pathway for obscuring the production of OX5034 females, while agreeing that there is a likelihood that females will be produced. Concerns are subjectively dismissed based on Oxitec being required to monitor for females, setting up a clear conflict of interest. Any science, or mathematical formulas with assumed constants and variables that support the assertion that female production is an insignificant quantity is not provided.

a. Respectful of the preceding discussion, please provide support that proves 1,000,000,000 eggs per year, or more, as permitted under the EUP, would not result in female production.

Any female production clearly conflicts with the EPA termination clause, that is absolute.

b. Please explain the rationale behind the EPA continuing to leave the EUP active, when science is in clearly predicts it will breach the termination clause.

There is total reliance on Oxitec to provide honest and accurate scientific data, where their history is one of errors, and dubious reporting both with the EPA and documented in other major experimentation venues, as shown in this link to emails released from, Dr Alan Wheeler, the Chief Scientist for the Mosquito Research and Control Unit (MRCU) who oversaw the Oxitec's Cayman OX513A trials. **Dr A Wheeler MRCU staff communications.pdf**

c. Please explain how the EPA can permit the EUP to proceed without independent oversight for the vendor in light of the Oxitec authored contract signed with the Florida Keys Mosquito Control District (FKMCD), similar to past contract requirements, where all information and data released from the experiment require approval of Oxitec alone.

d. Please explain in light of potential female production how the EPA can justify "informed consent" is not required, especially when considering collaterally affected vulnerable classes who have no means of opting out.

e. Please clarify why a simple very low cost, independent assessment to prove, or disprove any antibiotic resistance promotion characteristics is not performed given the request of nearly 3 dozen local physicians in the targeted community?

Novel as it may be, no consideration has been given to the many negative affects a trail with an open release of a GM Species with clear areas of minimal investigation, may have on the FL Keys community during an ongoing pandemic that has yet to quelled in any signficant regard. We would believe the EPA would wish to be mindful and sensitive to this fluid condition and withhold the permission to proceed until a time when a level of normalcy can be resumed.

An EIS level of evaluation process, or more applicable to FIFRA, a SAP and independent scientific evaluation of the vendor claims, would address many of the concerns expressed by experts and the community, further serving to provide the applicant vendor with scientific feedback on the strengths and weaknesses of their product. We strongly request the re-consideration of this decision and that the EUP be immediately suspended until a transparent, objective, independent scientific investigation has been prescribed, performed and results analyzed to assure genetically engineered species are proven safe prior to any use, or testing in the wild and on our citizens.

Thank you for your consideration.

Barry Wray
Executive Director