June 3, 2020

Andrew Wheeler, Administrator
Environmental Protection Agency
Office of the Administrator, 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Wilbur Ross, Secretary
Department of Commerce
1402 Constitution Ave NW
Washington, DC 20230

Chris Oliver, Assistant Administrator for Fisheries
National Oceanic and Atmospheric Administration
1401 Constitution Avenue NW, Room 5128
Washing, DC 20230

David Bernhardt, Secretary of the Interior
Department of the Interior
1849 C Street, N.W.
Washington, DC 20240

Aurelia Skipwith, Director
Fish and Wildlife Service
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Willam Barr, US Attorney General
U.S. Department of Justice
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Washington, DC 20530-0001

Francis S. Collins, Director
National Institutes of Health
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Bethesda, Maryland 20892

Ron DeSantis, Governor
State of Florida
400 S Monroe St,
Tallahassee, FL 32399

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Nikki Fried, Commissioner
Florida Dept. of Agriculture and Consumer Services
Florida Capital
Tallahassee, FL 32399-0800

Re: Letter of Inquiry

Administrator Wheeler:

I am writing you on behalf of the 75,000 residents and 3,000,000 tourists of the Florida Keys to determine how the EPA could ever approve and Experimental Use Permit (EUP) for the release on millions of manmade Genetically Modified (GM) insects into our environment and in close proximity to homes, schools, churches, hospitals, and senior centers. I believe in and defend the basic rights of the individual, and your agency should reconsider approving this release without strict and fundamental safety standards and proper informed consent of all people directly subjected to this experimentation.

Please submit to my office copies of all data and opinions used to allow this release. The EPA approval document clearly states that only "non-biting" male mosquitos will be released. In addition, send to my attention the technical procedures which will be required to be put in place for the EPA to make this claim.

Please provide all documentation on safety reviews and the criteria weighed with regard to evaluating the elevated risk associated with an aberrant use of Tetracycline, one of the most important antibiotics remaining in the human defense against bacterial infection. It has been clearly shown that these mosquitoes and documented laboratory practices by Oxitec, present a significant risk of promoting antibiotic resistant bacteria, yet it is unclear if the EPA, or any other agency has provided, or reviewed any measured testing, or designed safeguards to assure human safety and prevent the mitigation of tetracycline as an effective antibiotic.

Please send to my attention the statutory authority that would allow the United States to allow private citizens to be used in a public health experiment without written and authorized individual informed consent, in conflict with the Common Rule and ethical standards for human rights forged and reaffirmed starting with the Nuremberg trails that outlawed experimentation on humans without informed consent.

It is our understanding that in Oxitec's previous application to the EPA for an EUP for the OX513A mosquito, that they knowingly misrepresented critical data, specifically regarding the number of females released. Subsequently, in the most recent application by Oxitec for an EUP to release the OX5034, the public disclosure that the EPA provided, was void of scientific data, supporting measured evidence of performance of any kind and only included claims without substantiation, or validation. In effect the application, as presented to the public for comment, was a two-page marketing memorandum, written by Oxitec's

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attorney. Please provide all justification and the source of authorization supporting this limited disclosure to the public of actual data, preventing the public from providing beneficial scientific responses.

It would be dereliction of duties to approve any trial on this level of data. If there is additional evidence, data, test results, genetic assays, or discussion provided to the EPA, we request immediate release and delivery to my office along with dates that disclosure of each was made to the public via the Federal Registry.

Please provide all documentation emails and discussion around the decision to not extend the initial comment period, especially without disclosure of scientific measured data that would afford the public the ability to provide insightful comments that have historically identified safety concerns regarding this product line and the scientific, ethical and corporate practices of Oxitec.

Finally, we intend to review the discussion surrounding the approval of this EUP for the OX5034 mosquito and request delivery to my office of all correspondence, email, written, or notes taken from phone calls, between the EPA and the applicant, Oxitec and all internal EPA emails that relate to this application and the predecessor application for the OX513A.

In summary, over 31,000 comments were submitted to the EPA with the vast majority urging denial of the Experimental Use Permit (EUP) and 56 commenters in support. The body of work performed by organizations from within the Keys community has provided scientific insight into this technology and Oxitec, exposing unacceptable public and environmental safety concerns regarding professional practices, species technology, erroneous claims and questionable ethical practices in field trials. This history along with the irregular disclosure practice surrounding this application further amplifies risk to our community health and the pristine ecosystems of the Florida Keys.

We respectfully ask that the EPA stay the EUP until these serious safety and ethical concerns can be addressed.

Sincerely,

Barry Wray
Executive Director

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