BEN BARTLETT
CITY COUNCILMEMBER, DISTRICT 3

CONSENT CALENDAR
November 9, 2021

To: Honorable Mayor and Members of the City Council
From: Councilmember Ben Bartlett (Author), Councilmember Hahn (Co-Sponsor) and Councilmember Harrison (Co-Sponsor)
Subject: Letter of Opposition to the Environmental Protection Agency and Oxitec Ltd.'s Proposal to Release Genetically Engineered Mosquitoes in California Counties

RECOMMENDATION

That the Mayor and Members of the Berkeley City Council oppose the United States Environmental Protection Agency ("US EPA") and Oxitec Ltd.'s proposal to conduct the world's largest release of genetically engineered ("GE") Aedes Aegypti mosquitoes. The mosquitos are proposed to be released across 12 California counties, which may include: Shasta, Yolo, Sacramento, Alameda, Stanislaus, Fresno, Tulare, Los Angeles, Orange, San Bernardino, and Riverside. The company intends to release several billion of the mosquitoes on 85,000 acres over a 2-year period. The Council should ask the US EPA Administrator Michael Regan, California Environmental Protection Agency ("CalEPA") Secretary Jared Blumenfeld, and Governor Gavin Newsom to deny the experimental use permit ("EUP") application to release genetically engineered mosquitoes across the state. The Council should send letters to State Senator Nancy Skinner, Rep. Barbara Lee, Rep. Mark DeSaulnier, Sen. Dianne Feinstein, Sen. Alex Padilla, Assemblymember Buffy Wicks, and County Supervisor Keith Carson.

CURRENT SITUATION

Oxitec Ltd. has developed a proprietary, genetically engineered, species of Aedes Aegypti mosquitoes. The stated goal is to reduce the number of mosquitoes in the United States carrying dengue, chikungunya, Zika, and yellow fever.

In May 2020, the US EPA approved Oxitec Ltd.'s first release of its GE mosquitoes in Monroe County, Florida. On August 30, 2021, Oxitec Ltd. requested an amendment and extension to their EUP to expand its experimental release of GE mosquitoes to California[1].

Due to the potential regional, and national significance of the EUP, the US EPA sought public comment on Oxitec Ltd.'s application by September 30, 2021.

More than 12,000 comments were submitted on the official government website regulations.gov[2] including many by Scientists. These Scientists are raising significant concerns, which should give regulators pause. Many questioned the necessity of a mosquito release in California when this state has no reported cases of Dengue fever, Chikungunya, or Yellow Fever. Zika virus is

[1]Environmental Protection Agency: "Application: Pesticide Experimental Use Permit," August, 30, 2021.
[2]Environmental Protection Agency: "Application: Pesticide Experimental Use Permit," August, 30, 2021

carried by the Culex mosquito, an entirely different breed than the mosquito being prepped for release in California. Other comments focused on potential threats to the ecological food chain, which is alarming given our status as a bread basket to the country. And still, others noted that endangered species could face the risk of extinction if the food chain was corrupted by the experimental mosquitoes.

Troublingly, Oxitec and the US EPA have failed to release crucial data from previous GE mosquito releases in Florida, Brazil, Malaysia, and the Cayman Islands. This missing data is highly relevant because GE mosquitoes have the potential to create hybrid wild mosquitoes. Were this to happen, the spread of mosquito-borne diseases in the United States could actually increase, and the new mosquitos have an even greater resistance to insecticides than the wild mosquito population.

In 2019, Yale University conducted a field study in Brazil, found that GE mosquitoes' genetic alterations had spread into the wild population[3].

It is imperative that California regulators, affected jurisdictions, parties, and the public have the opportunity to review and analyze data from previous GE mosquito releases. Without this information, it is impossible to make an informed decision on whether to allow the release. Accordingly, CalEPA must deny this application to release billions of genetically engineered mosquitoes into our environment.

BACKGROUND

According to Oxitec, the open release experiments are intended to evaluate the efficiency of GE mosquitoes in suppressing the wild Aedes Aegypti mosquito populations in Florida and California. Oxitec's application also states that the biting female offspring of the GE mosquitoes will die before maturing into adults, which leads Oxitec to claim that there is no risk of humans being bit by female GE mosquitoes. However, these claims are not backed by publicly available scientific data. There are also significant levels of tetracycline in California, an antibiotic used in agriculture that can trigger the survival of female GE mosquitoes. The data on this environmental phenomenon has been redacted by Oxitec, so it is not possible for the public to properly assess this risk in California.

Furthermore, Oxitec is arguing that with the introduction of these GE mosquitoes, the reduction in the overall mosquito population will reduce or eradicate diseases, such as dengue and Zika. However, this could result in more negative impacts on public health. With a smaller number of Aedes Aegypti Mosquitoes, granted that the GE mosquitoes are successful, there would be more room for invasive and harmful mosquito species in the environment to increase their population. For example, the Asian Tiger Mosquito is a widespread mosquito species in the United States.

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[3]Science: "Study on DNA spread by genetically modified mosquitoes prompts backlash," September 17, 2019.

Recent studies have shown that these species are a possible vector for dengue and other diseases, and there is a high risk that this invasive species would take advantage of reduced competition in the ecosystem[4]. Another concern with diseases is the possibility that the dengue virus will evolve, rather than be eradicated when introduced to GE mosquitoes. The Aedes Aegypti could become more virulent, and exacerbate the presence of the dengue virus in the United States[5]. The issue of diseases being spread would still be present.

Since first applying for the Pesticide Experimental Use Permit, the Environmental Protection Agency and Oxitec have failed to address public transparency. Critical data and information have been blacked out and withdrawn as Confidential Business Information (CBI). This public health information includes the "allergic potential of the fluorescent protein found in the mosquito's saliva, and details about what levels of tetracycline would allow female GE mosquitoes to survive to adulthood"[6]. There is a significant amount of missing information in Oxitec's application that addresses public health and environmental concerns. This data should be made available to the public to allow for proper assessment, and it allows for the community members in affected counties to leave the field trial areas or express their concerns to halt the release altogether.

TIMELINE:

The United States Environmental Protection Agency ("US EPA") is currently reviewing biotech firm Oxitec Ltd's Experimental Use Permit ("EUP") application to release billions of genetically engineered mosquitoes across California, specifically in Alameda County. There is a short window of time to provide public input before the US EPA's decision is made. It is imperative that Gov. Newsome be given the full scope of information to consider on what is proposed to be the largest release of genetically modified mosquitoes in history.

Although it was not widely publicized, the US EPA held public comment on Oxitec's application. This public comment period ended on **September 30, 2021.** Typically, the EPA takes **2-3 months** to review a EUP application. Federal agencies sometimes release controversial decisions right before major holidays, and typically on Fridays. **This decision can come as early as mid-November.**

Under this potential timeline, the opportunity to educate our communities, elected officials, and regulatory decision-makers are very short, possibly less than one month. If the EPA approves Oxitec's EUP application to release genetically modified mosquitoes, California's Department of Pesticide Regulation ("DPR") under the California EPA ("CalEPA") will then approve or deny the application. DPR typically approves applications within **1 week to 4 weeks.**

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[4] CDC, https://www.cdc.gov/mosquitoes/mosquito-control/professionals/range.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fzika%2Fvector%2Frange.html

[5] Medlock, J., Luz, Paula M., Struchiner, Claudio J., and Galvani, Alison P. (2009) The Impact of Transgenic Mosquitoes on Dengue Virulence to Humans and Mosquitoes. The American Naturalist 174, 565-577.

[6] Friends of the Earth Public Comments: https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/Friends-of-the-Earth-EPA-public-comments-GE-mosquito-EUP-FL_CA.pdf

Although the US EPA hasn't yet released a decision on this Experimental Use Permit, there is already sufficient information to warrant more careful and transparent consideration of the potential impacts on public and environmental health posed by the scale and nature of this experiment.

There is a deficit of science-based regulations of genetically engineered insects. Experts have raised a series of concerns regarding previous field trial data; questioned the experiment's justification; and urge that critical environmental, and health assessments be performed prior to any release of mosquitoes into California and Alameda County.
It is critical that before the US EPA makes its decision, California regulators, elected officials, and the public at large be made aware of the risks, and be given the opportunity to communicate their concerns and address the lack of regulatory process to Governor Newsome and the California EPA. Absent these sensible considerations, CalEPA must deny this application to release billions of genetically engineered mosquitoes into our environment.

RATIONALE FOR RECOMMENDATION

The experimental release of Genetically Engineered mosquitoes in 12 California counties as proposed by the Environmental Protection Agency and Oxitec could result in unintended consequences on human, animal, public, ecological, and environmental health. The publically available data and information is inadequate and does not completely address safety concerns. To address these important and reasonable safety concerns, the City of Berkeley should stand together in opposing Oxitec Ltd.'s proposal to release Genetically Engineered mosquitoes in Alameda County.

ENVIRONMENTAL SUSTAINABILITY

The GE mosquito could have environmental risks, including negative impacts on endangered species, the introduction of more invasive mosquito species, and the potential creation of wild-hybrid mosquitoes.
The EPA has not done an environmental impact assessment nor study/analysis to determine how effective GE mosquitoes would be in reducing disease.

FISCAL IMPACTS

No fiscal impacts besides staff time.

CONTACT PERSON

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ATTACHMENTS AND MATERIALS

1. Sample Letter to Elected and Appointed Officials, Opposition to the Environmental Protection Agency and Oxitec Ltd.'s Proposal to Release Genetically Engineered Mosquitoes in California Counties

2. September 30, 2021 Friends of the Earth's public comments to U.S. EPA "Comments for the EPA's consultation on application 93167-EUP-2 from Oxitec"
3. Issue Brief: Genetically Engineered Mosquitoes Proposed for Release in California: Risks and Concerns

Attachment 1: Sample Letter

RE: OPPOSITION TO RELEASE GENETICALLY ENGINEERED MOSQUITOES IN CALIFORNIA COUNTIES

Dear [Name of Official],

On behalf of the City of Berkeley, California, we are writing to voice our opposition to the Environmental Protection Agency and Oxitec Ltd.'s proposal to release genetically engineered mosquitoes in California Counties. This proposal could have huge environmental risks, including negative impacts on endangered species, the introduction of more invasive mosquito species, and the potential creation of wild-hybrid mosquitoes.

Oxitec has applied to the U.S. EPA for an experimental use permit to release hundreds of billions of GE Aedes Aegypti across 12 undisclosed counties in California. The project claims to reduce the Aedes Aegypti population. While addressing mosquito borne diseases is important, California does not have any cases of dengue, and there is no publicly available data from previous field trials proving the efficacy of this approach. Recent data from a Yale study in Brazil highlighted that, instead, Oxitec's GE mosquitoes could pose irreversible risks to the environment, public health and animals.

We are opposed to this proposal for the following reasons:

- **No endangered species assessments have been done.** The EPA has not done an environmental impact nor an endangered species assessment, study, and analysis to determine how effective GE mosquitoes would be in reducing disease.

- **No studies on human health impacts have been done.** GE mosquitoes may inject novel genetically engineered proteins into humans and other animals. Oxitec has yet to show that these novel proteins would not harm humans or other animals
- **The public cannot assess the effects of the trial.** Oxitec's risk assessment provided to the EPA is redacted, so the public has no information on the effects of their test trials.
- **Lack of existing science-based regulations.** There are limited regulations specific to genetically engineered insects, the concerns raised from field trial data, and the critical environmental and health assessments needed ahead of any release.
- **Potential creation of new harmful species**. The GE mosquitoes' novel protein could create hybrid mosquitos that may be more aggressive, more difficult to eradicate, and may increase the spread of mosquito-borne disease

It is critical that before the US EPA makes its decision, California regulators, elected officials, and the public at large be made aware of the risks, and be given the opportunity to communicate their concerns and address the lack of regulatory process to Governor Newsome and the California EPA. Absent these sensible considerations, CalEPA must deny this application to release billions of genetically engineered mosquitoes into our environment.

Sincerely,
[Mayor of Berkeley and Members of the City Council]

Friends of the Earth

September 30, 2021

Docket No. EPA-HQ-OPP-2019-0274
OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Comments for the EPA's consultation on application 93167-EUP-2 from Oxitec

To Mr. Smith and United States Environmental Protection Agency (EPA):

Friends of the Earth (FOE) respectfully submits the following comments on behalf of its over 4 million members and advocates in response to EPA's proposed Experimental Use Permit amendment and extension allowing the release for investigational use of Oxitec, Ltd. (Oxitec)'s genetically engineered (GE) *Aedes aegypti* mosquitoes (OX5034) in California and Florida.

Friends of the Earth is the U.S. voice of the world's largest network of grassroots environmental organizations, with groups in 74 countries. For more than 50 years, Friends of the Earth has worked at the nexus of environmental protection, economic policy and social justice to fundamentally transform the way our country and the world value people and the environment. It is in this light that Friends of the Earth has been following the development of genetic engineering, raising awareness about the environmental and health risks, and the need for more robust government oversight and assessment related to genetically engineered organisms including genetically engineered mosquitoes.

We request that the EPA reject Oxitec's request for an amendment to release OX5034 mosquitoes across 12 undisclosed counties in California and its request for an extension to its Experimental Use Permit (EUP) for the release of genetically engineered mosquitoes in Monroe County, Florida. There should be a full Environmental Impact Statement (EIS) under the National Environmental Policy Act (NEPA) for each of the proposed counties, and this should be reviewed by a committee of independent ecologists and entomologists, public health experts, and other key experts and public stakeholders. There should be long term caged trials in each California county, an endangered species review, and a publicly accessible full CDC review of potential public health impacts. The EPA should release the full data from the current field trials in Monroe County, FL, and Oxitec's full application to the EPA should be publicly available for review. EPA should also convene public meetings in Monroe County, FL and in each of the 12 California counties, advertised in the Federal Register, for the review of the company's proposal and EIS. The EPA should develop new regulations for genetically engineered insects designed to be bio-pesticides -- only after these regulations are in place should EPA consider an application for GE insects.

This docket contains insufficient data and information for a thorough and responsible assessment. While we support the EPA's intentions to limit mosquito populations and the spread of mosquito borne disease, Friends of the Earth believes this experiment with Oxitec's mosquitoes is too risky for Florida and California's ecosystems and public health and is fraught with many unanswered and critical questions.

Background on issue

Oxitec has applied for an amendment to its permit to do field releases of genetically engineered Aedes aegypti mosquitoes. Oxitec proposes to extend its permit to release GE mosquitoes in Florida for 2 more years, and to expand its experimental releases to 12counties across California.

Oxitec's application proposes that the open release experiments are to evaluate the efficacy of OX5034 mosquitoes as a tool for suppression of wild Aedes aegypti mosquito populations in Florida and California. The application also states that female offspring of the OX5034 mosquitoes in the environment die before they mature into adults, and therefore exposure to biting female mosquitoes is not anticipated. There is incomplete data and testing to substantiate the claim that no females will survive in the environment, particularly given the vast diversity of ecosystems and agricultural systems across California. Both these claims are questioned in the following response.

According to the application amendment, Oxitec proposes to release its GE mosquitoes in Florida for up to 2 more years, across 6,240 acres, and up to 20,000 male GE mosquitoes per acre, per week. It proposes to expand its EUP to release GE mosquitoes across 12 counties in California, across 84,600 acres, and up to 30,000 male GE mosquitoes per acre, per week.

Although Oxitec claims that the GE mosquito could reduce Aedes aegypti mosquito populations, it is uncertain that, even if Aedes aegypti mosquito populations were reduced, there would be a reduction in rates of disease as other mosquitoes also carry dengue, zika, and related viruses. Oxitec has also not provided data to assess whether population reductions of Aedes aegypti, if they did occur, would lead to disease eradication or reduction.

Environmental impacts

Oxitec's application and the publicly accessible information as provided by EPA leaves critical environmental questions to assess. The GE mosquitoes could pose unique risks to the environment in California and Florida, including to endangered species.

It is unclear what the impacts of the GE mosquitoes on wild animals, including endangered or threatened species, and farm animals are. There is no publicly available data about any feeding trials for mammals or birds, which given the prevalence of endangered species in California, is critical. There is also missing information about mosquito predators or prey, which could be impacted by GE mosquito releases and fluctuating mosquito populations. More feeding trials are needed to assess the risk of ingestion to wild species that eat mosquitoes. Ingestion may also be a potential exposure route, as females are expected to die at the larval stage in the water where they breed. There should also be caged trials in each of CA's 12 counties, and in Monroe County, FL, ahead of any open release.

EPA should not assume that all female GE mosquitoes will die, particularly given the prominence of chemicals like tetracycline in the environment in California's vast agricultural areas, which could impact the survival rate of female GE mosquitoes. As noted further below, Oxitec's data about levels of tetracycline in the environment which could trigger survival is redacted, and thus not possible to assess the full risk.

We also need adequate assessment of the potential impacts of increased mosquito populations when the trial GE mosquitoes are initially released in ecosystems, particularly in the12 California counties and the surrounding areas where the mosquitoes could spread. GeneWatch UK's public comments[1] note

that increases in non-target mosquito species as a result of the proposed releases could pose risks to human and animal health, as could increases in the target species in areas neighboring the releases.

The concerns about introgression of the Aedes aegypti into wild type mosquitoes and the potential vectoral capacity have not been addressed, despite evidence from Brazil[2] highlighting that the genetic material from Oxitec's GE mosquitoes were found in wild mosquitoes. The vectoral capacity of Oxitec's GE mosquitoes should be fully assessed, as well as the potential vectoral capacity of hybrid mosquitoes that could carry the genetic material from Oxitec's GE mosquito. This information should be made publicly available ahead of a public comment period.

Oxitec's application does not consider the complexity of ecosystems carefully enough, nor the vast diversity of California's ecosystems across the state. A complete EIS in each county should not only look at the risks from one release, but the potential impacts of releasing millions of mosquitoes on a continual basis and whether the proposed experimental use will cause unreasonable adverse effects on the environment.

Response to tetracycline

Oxitec's GE mosquitoes are engineered to be dependent on the presence of tetracycline and to die in its absence. In theory, the males will mate and then die off while their tetracycline-dependent gene passes onto their offspring. The offspring should die in the late larvae or pupae stage, and *the Aedes aegypti* population in a given area, such as Monroe County and the 12 undisclosed California counties, will theoretically be suppressed.

However, three key factors point to the limits of this hypothesis. First, 3 to 4 percent of Oxitec's mosquitoes survived into adulthood in the lab in the absence of tetracycline despite carrying the lethal gene.[3,4]

Even more concerning, tetracycline is a common antibiotic used in agricultural production. Florida citrus growers use significant amounts of tetracyclines (oxytetracycline) on agricultural lands as a pesticide in efforts to control the bacteria responsible for the Citrus Greening disease. California has massive agricultural regions, and it is necessary to look at levels of tetracycline use in each of the counties targeted for release and to compare this with the levels of tetracycline in the environment that could impact the survival of female GE mosquitoes. EPA has redacted information about tetracycline levels from Oxitec's proposal, however, so it is not possible to assess this potential risk. The significant presence of tetracycline in the environment may obviate the lethal trait in the GE mosquitoes, and their offspring could survive and continue to breed.

Third, tetracycline is also a prevalent compound found in sewage due to contamination from agricultural run-off and consumer disposal. Aedes aegypti may be found to breed in sewage treatment plants, septic tanks, and cesspits in the Florida Keys and in California. [5]

The possible widespread application and presence of tetracycline in the environment could significantly undermine the efficacy of GE mosquitoes to reduce overall mosquito populations. This further accentuates the EPA's need for a complete EIS and more thorough examination of unintended consequences before allowing Oxitec's application to be considered.

Friends of the Earth

Public health concerns

Oxitec's rationale is based on an assumption that mosquito population reduction will reduce or eradicate diseases such dengue and zika. However, Oxitec has not provided the EPA data to support this claim. Even in its trials in Grand Cayman, the company did not demonstrate that reducing overall populations of mosquitoes will reduce or eradicate disease, as dengue is not endemic in the Cayman Islands.[6] Oxitec should provide a specific mechanism through which its proposed releases might reduce the risk of diseases spread through mosquitoes. Without this information, Oxitec's proposed "pesticide" experiment will not address disease reduction.

Oxitec's GE mosquitos could also increase other vectors for diseases like dengue fever. If Oxitec's mosquitoes were to successfully reduce the Aedes aegypti population and reduce competition for breeding sites, there could be a new ecological niche for other pests to fill, such as the Aedes albopictus (Asian Tiger Mosquito). The Asian Tiger Mosquito is one of the most invasive mosquito species, and research has shown it is a possible vector for dengue fever and other tropical diseases, possibly leading to more harm to human health.[7] The Asian Tiger Mosquito is widespread in the USA, including in Florida.[8]

Oxitec's intention of elimination targets one vector, whereas other vector control methods target breeding grounds for many vectors, either through removing breeding sites in an area or by using repellents for many species.

The experimental release of *Aedes aegypti* raises serious concerns about possible negative impacts on public health. Given the high number of mosquitoes that are proposed for release, and based on experience in the Brazil, there is a high likelihood that humans or animals could swallow the GE mosquitoes upon release. As reported in Brazil, because of the high number of GE mosquitoes released, "it's impossible to talk during the liberation sessions without accidentally swallowing a few."[9] The risks of ingestion, whether intentional or unintentional, of GE mosquitoes by mammals, reptiles, birds, or other organisms, have not been adequately assessed.

There are also concerns about the impacts of biting. Oxitec's initial Draft Environmental Assessment (EA) to the Food and Drug Administration (FDA) acknowledges that it is inevitable that some biting female GE mosquitoes will be released. The sorting is conducted by hand and could result in up to 0.5 percent of the released insects being female.[10] If 100 million mosquitoes were released, 0.5 percent could mean that an additional 500,000 biting mosquitoes could be present in the environment.[11] However, checks by the Mosquito Research and Control Unit (MRCU) in the Cayman Islands on one production batch on May 12, 2017 revealed 9 females in one release pot of 500 (1.8%), nine times the agreed level. If the sorting of GE mosquitoes for the field trials were to have similar results as the Cayman Islands, millions of GE female mosquitoes, which can bite and transmit disease, could be released into the environment during the experiments.

Also of concern is that biting female GE mosquitoes may inject a novel engineered protein (*tTAVOX5034 and DsRed2-OX5034)* into humans; Oxitec has yet to conduct or publish any study showing that this novel protein is not expressed in the mosquito's salivary gland, nor has it determined the protein's allergic or toxic potential. Oxitec claims the exposure will be negligible.

However, Oxitec's claim about the potential toxicity or allergenicity from biting GE mosquitos and the lack of exposure to biting females depends on the assumption that females do not survive to adulthood.

In reality, survival may occur if resistance develops or because of environmental exposure to tetracycline (see more detail in the section above and our previous submission[13]).

Lastly, there is concern around the possibility of the dengue virus to evolve and become more potent and virulent in response to the introduction of the GE mosquitoes, and this could put human health at greater risk.[12]

Lack of regulations

No federal agency has formal regulations specific to GE insects and animals. The current U.S. regulatory system is outdated and lacks clear oversight of the use of biotechnology to address insect vectors of animal and human diseases. The EPA should issue new regulations that cover GE mosquitoes before it allows any experimental use of this novel technology.

Regulatory action under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) predominantly focuses on the component which would serve as a pesticide, in this case, the tetracycline Trans-Activator Variant (tTAV) protein that Oxitec's GE mosquitoes have been genetically engineered to express. However, it is critical that the EPA examine the whole mosquito, the method of delivery in this case, and its direct and indirect impacts on the environment, human and animal health.

Also, because the Aedes aegypti mosquito is considered a disease vector, the EPA should clarify the legal basis for a proposal which would allow Oxitec to be released from the contained use requirements of its import permit, as delineated by the Center for Disease Control, in order to allow its GE mosquitoes to be deliberately released into the environment.

Under the National Environmental Policy Act (NEPA), the EPA should consider all environmental effects of the environmental release of Oxitec's GE mosquitoes, analyze potential risks, and analyze alternatives to these actions. As part of these requirements, the EPA should undertake a full EIS so that it may thoroughly examine the potentially substantial impacts that the proposed action may have.

Although, in some cases, proposed actions under FIFRA have been exempt from NEPA, Oxitec's proposed actions for a deliberate release of disease vectors into the environment raise complex environmental issues which may not be adequately captured under FIFRA, therefore an assessment under NEPA should be required.

In addition to preparing a full EIS for public consideration, the EPA should ensure that it is complying with the Endangered Species Act.

Ethical concerns

The release of GE mosquitoes as an attempt to curb the spread of disease should be considered a medical trial and must follow the laws and guidelines in place to protect human subjects in medical trials. Central to ethics on human subject trials is the idea of free and informed consent. However, Oxitec has a track record of releasing GE mosquitoes without public consent, including in their field releases in the Cayman Islands in 2009[13] and in Malaysia in 2010.[14] Throughout the 2021 field trials in Florida, residents consistently asked for the trials to stop, for there to be a process of consent and transparency, and for a process of redress.

EPA notes that consent is not necessary and that this is not a human trial because Oxitec's research "does not meet the regulatory definition of research involving human subjects." This is based on Oxitec's claims that female GE mosquitoes won't survive into adulthood. However, there is not publicly available data to support this company claim. There have not been caged trials in the proposed counties in California that show that females wouldn't survive, particularly in the presence of tetracycline. There is a risk that female GE mosquitoes will survive and could bite people living in the release areas. It is also possible that people in surrounding areas will be affected. Aedes aegypti mosquitoes could move to nearby areas, there could be a hybrid GE-wild type mosquito as was found in Brazil, or other types of mosquitos, like the Aedes albopictus, could move into the open ecological niche and introduce new diseases.

Given these risks, it is critical that all potentially affected communities are given the right to free and prior informed consent to being part of this experiment.

Public transparency

The current information available to the public for review is inadequate and blocks critical information necessary for responsible analysis of environmental and public health risks. In addition, the public engagement process as witnessed in Monroe County, Florida has lacked transparency, been riddled with contradictions, and misled the public.

As with Oxitec's 2018 EUP application for releases in Florida, the lack of transparency and missing information makes any meaningful independent assessment nearly impossible. Information critical for health and environmental analysis is blacked out and withdrawn as Confidential Business Information (CBI). Public health information withdrawn or redacted from the application includes: details about the allergic potential of the fluorescent protein found in the mosquito's saliva, and details about what levels of tetratcycline would allow female GE mosquitoes to survive to adulthood. Given the human populations in California and Florida, this public health information should not be allowed to be withdrawn as CBI. The EPA has also not included the CDC's full advice.

There is also missing information critical for environmental assessments. Neither EPA nor Oxitec publicly name the counties proposed for release. There is no information about populations of Aedes aegypti in California or competitor mosquito species that could move into its ecological niche, and it remains unclear how any analysis about population reduction will be conducted. Despite Oxitec's previous completed field trials in Brazil and Florida, there is still no publicly available data.

In addition to missing public health and environmental data, EPA has not provided potentially affected communities with critical notice about the application. Community members across all 12 counties must be informed of this proposal and amendment, be informed about the public comment period, and have the full information to do assessments related to their communities. However, the counties proposed for release sites in California haven't been formally named, so people will not know if they could be impacted by the proposed release. There should be communication in multiple languages throughout the process of assessment through a number of mechanisms, including the establishment of local institutional review boards and ethics committees and hosting of community meetings and public forums. Community members must know the parameters of the trial areas, have a right to leave the field trial areas, or demand the halt of the experiment entirely if they so decide. [15]

Friends of the Earth

Conclusion

Friends of the Earth believes that there is inadequate information on which to base a public analysis; EPA's docket offers only partial science and analyses. The analyses do not have the necessary data or appropriate risk assessments needed to draw safety conclusions, and the assessments do not adequately address potential unintended consequences. In light of the unanswered questions and the gaps in data analysis, FOE urges EPA to reject Oxitec's amendments and extension requests for genetically engineered mosquitoes to be released in California and Florida. EPA should request further studies from Oxitec and require a full EIS be published for public consultation ahead of an application for an EUP.

Recommendations

Questions remain about the GE mosquitoes' environmental and health impacts as well as their effectiveness in reducing disease. At this point, the EPA should reject Oxitec's application for the release of GE mosquitoes.

The EPA must require Oxitec to obtain the free and informed consent of all potentially affected communities in California and Florida before any trial is allowed to move forward, and mechanisms should be made available to halt the experiment if the community demands. We urge the EPA to conduct a full EIS and to:

- Establish an independent committee of independent ecologists and entomologists, public health experts (including dengue fever and zika virus specialists), and other key experts and public stakeholders to review the proposal and consider the potential environmental, health and social impacts of the release of GE insects;
- Convene public meetings, at various times of the day and evening, across all potentially affected communities for public comment and discussion of the proposal with key independent experts present;
- Develop new regulations for genetically engineered insects that are designed to be bio-pesticides — only after these regulations are in place should EPA, the State of Florida, and the State of California consider an application for the release of genetically engineered insects; and
- Conduct a referendum for Florida and California residents to vote on whether there should be a release of Oxitec's genetically engineered mosquitoes.

Friends of the Earth thanks the EPA for the opportunity to comment on this Pesticide Experimental Use amendment and extension. Until the above requests have been met, the missing information has been provided, and the EPA has formal regulations for the oversight of GE insects, we urge the EPA to not allow any permits for environmental release of genetically engineered mosquitoes to move forward.

Sincerely,

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Dana Perls
Food and Technology Program Manager
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[1] Public comments from GeneWatch UK. http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/genewatch-uk-response-to-the-epa.pdf

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[3] Phuc, H.K., Andreasen, M.H., Burton, R.S., Vass, C., Epton, M.J., Pape, G., Fu, G., Condon, K.C., Scaife, S., Donnelly, C.A., Coleman, P.G., White-Cooper, H. and Alphey, L. (2007) Lateacting dominant lethal genetic systems and mosquito control. BMC Biology 5:11. http://www.biomedcentral.com/content/pdf/1741-7007-5-11.pd

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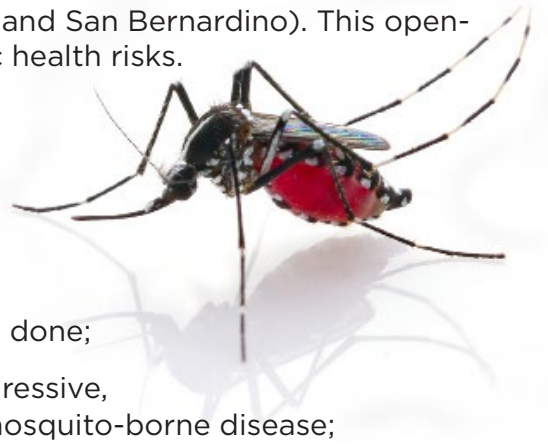
Friends of the Earth

Genetically Engineered Mosquitoes
Proposed for Release in California: Risks and Concerns

California is poised to be the second state where genetically engineered (GE) mosquitoes are released, unless the public and California's government officials demand otherwise. Earlier this year, half a billion GE mosquitoes were released in Florida. Now, 12 California counties are targeted for the largest mass releases of GE mosquitoes (potentially including Alameda, Riverside, Fresno, Tulare, Stanislaus, Los Angeles, Orange, Sacramento, Yolo, Shasta and San Bernardino). This open-air genetic experiment poses significant environmental and public health risks.



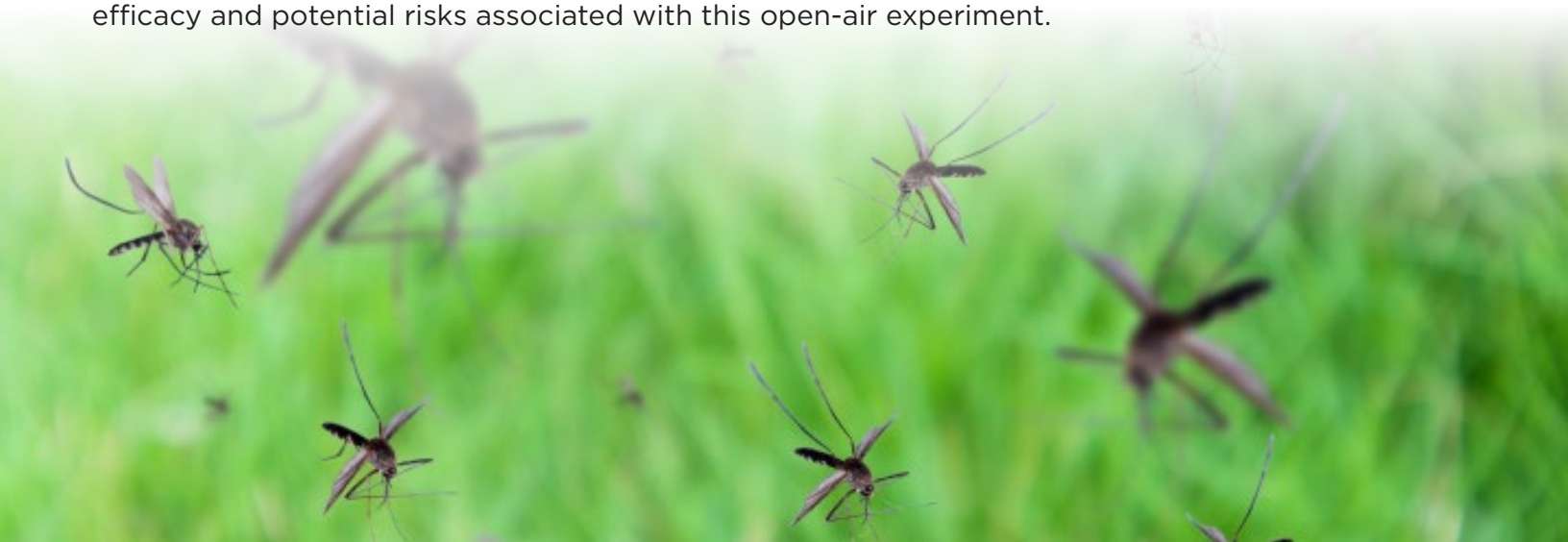
Summary of Concerns

Oxitec, a UK-based corporation, is proposing a mass release in California even though:

- No endangered species assessments have been done;
- No assessment of potential human health impacts have been done;
- This could result in hybrid mosquitoes that may be more aggressive, more difficult to eradicate, and may increase the spread of mosquito-borne disease;
- The communities where the GE mosquitoes would be released have not been consulted and have not consented to being part of this open-air genetic experiment; and
- Oxitec claims the data and results from earlier trials in other countries and in Florida are confidential business information and will not make them available to the public.

What is the GE Mosquito?

Oxitec has genetically engineered *Aedes aegypti* mosquitoes to depend on the presence of tetracycline, an antibiotic, and to die in its absence. In theory, the GE male mosquitoes would mate and their tetracycline-dependent gene would be passed on to their offspring. The offspring are meant to die in the late larval or pupal stage. The proposed experiment is meant to determine whether the mass release of GE mosquitoes can reduce the population of *Aedes aegypti*, one mosquito species that can carry the viruses that cause yellow fever, dengue, chikungunya and Zika.[1] None of these diseases are endemic in California or in the U.S. outside of Puerto Rico.[2] While limiting the spread of mosquito-borne disease is important, once GE mosquitos are released into the wild, there is no calling them back, and scientists have raised important concerns about the efficacy and potential risks associated with this open-air experiment.



Scientific Concerns

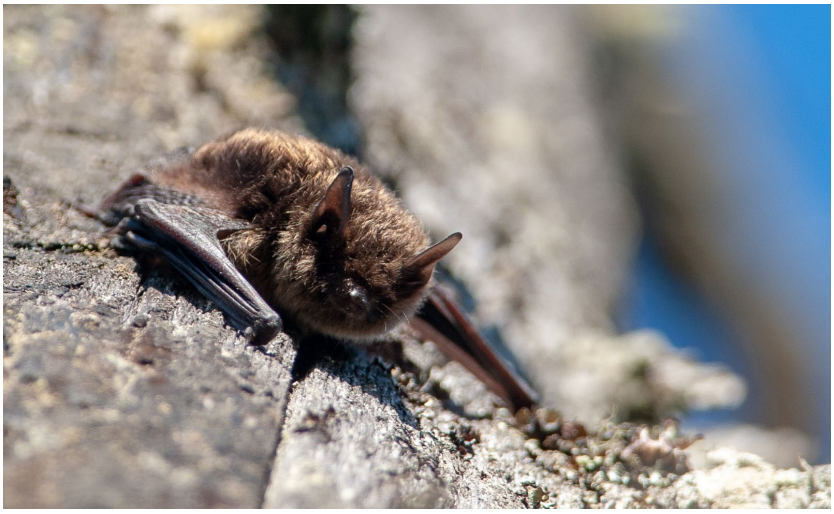
To date, GE mosquito trials have failed to reduce mosquito populations. Oxitec has conducted GE mosquito field trials in the Cayman Islands, Malaysia, Panama and Brazil. To date, none have effectively reduced the *Aedes aegypti* mosquito population.[3] Also to date, there is no publicly available data from the 2021 field trials in Florida, neither from Oxitec nor the Monroe County (Florida Keys) mosquito control district, to support Oxitec's claims that their GE mosquitoes reduced local *Aedes aegypti* populations.

Hybrid GE-wild mosquitoes could be created that may be more resistant to pesticides and more aggressive. Data from a trial in Brazil found genetic material from Oxitec's GE mosquitoes in wild mosquitoes, creating hybrid mosquitoes.[4] The researchers concluded that hybrid wild-GE mosquitoes could result in increased mosquito populations and could potentially contribute to the spread of viral diseases like Zika, West Nile, and Dengue.[5] A study highlighted that these hybrid mosquitoes may be more resistant to insecticides and even more aggressive than their wild counterparts. Wild hybrids may also be able to transmit viruses more easily.[6]

Reduction in populations of one type of mosquito could result in an increase in others. *Aedes aegypti* mosquitoes are only one of several species of mosquitoes that can carry diseases. If the experiment succeeded in reducing populations of *Aedes aegypti*, other varieties, such as the *Aedes albopictus* (Asian tiger), which also transmit dengue and other similar viruses, could increase in number to fill the ecological niche.[7,8]

Female GE mosquitoes could survive and spread disease. Oxitec's trial application states that female offspring — which bite and spread disease — will die before they mature into adults, and therefore exposure to biting female mosquitoes is not anticipated. However, females have been inadvertently released in Oxitec's experiments.[9,10] Data also show that females may survive in the presence of tetracycline — an antibiotic that is widely used in California agriculture and therefore present in the environment. Because of the very large numbers of GE mosquitoes proposed for release (up to 30,000 mosquitoes per acre, per week), even a small percentage of surviving biting female GE mosquitoes may lead to a significant number of females in the environment. This could lead to an increased mosquito population in the nearly 100,000 acres in California where mosquitoes are proposed for release.

GE mosquitoes may inject novel proteins into humans and other animals. Biting female GE mosquitoes may inject a novel engineered protein into humans and other animals.[11] Oxitec has yet to show that these novel proteins would not harm humans or other animals. However, EPA declares that the risk assessment information about allergenic or toxic effects of the genes inserted into the mosquitoes is "confidential." [12,13]



No studies have been completed to assess risks to endangered species. There are 87 federally listed endangered species in the state of California.[14] Yet, the U.S. Environmental Protection Agency (EPA) has not required any endangered species assessments prior to the release of GE mosquitoes. Feeding trials for key mammals and birds could provide important insights about what impacts the GE mosquitoes may have on endangered or threatened species. However, no feeding trials have been done for mammals or birds, only for "aquatic invertebrates" (crayfish and guppies).[15]

Lack of Transparency

Oxitec's proposal has not undergone independent scientific review, and EPA has not convened a Scientific Review Panel as it has done for other new pesticides. Neither the full proposal nor data from the 2021 releases in Florida are publicly available. In addition, Oxitec's community engagement has not been transparent. In 2021, Oxitec released GE mosquitoes as part of an experimental trial in Monroe County, Florida. Neither the mosquito control board nor Oxitec informed community residents about the locations of release until three days beforehand. Residents were not given advance warning about the exact date the release was set to occur and there was no free and prior informed consent by affected community members — a fundamental tenet of any research involving human subjects.

Lack of Regulations Specific to GE Insects

Currently, there are no regulations in the U.S. specific to GE insects. EPA regulates GE mosquitoes as biopesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but because of their potential impacts on the environment and human health,[16] critics have named the need for full environmental and health assessment and oversight.[17] Prior to any further consideration of a release in California, CEQA analysis, as well as regulations specific to GE insects, must be in place. In addition, government agencies must not solely rely upon company self-assessment of risks and must require third-party peer-reviewed public health and environmental assessments.

For More Information: Contact Dana Perls, Food and Technology Program Manager, Friends of the Earth, **Dperls@foe.org** or see **https://foe.org/projects/gmo-animals/**

Endnotes

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