



September 30, 2021

**Californians for Pesticide Reform Opposes Application 93167-EUP-2 from Oxitec (Docket No. EPA-HQ-OPP-2019-0274)**

On behalf of the statewide coalition Californians for Pesticide Reform (CPR), we thank you for the opportunity to comment on Oxitec's 93167-EUP-2 application (Docket No. EPA-HQ-OPP-2019-0274).

CPR is a statewide coalition of 200+ organizations working together to protect public health, improve environmental quality and support a sustainable and just agricultural system by building a diverse movement across California to change statewide and local pesticide policies and practices. Our member organizations include public health, children's health, educational and environmental advocates, clean air and water organizations, health practitioners, environmental justice groups, labor organizations, farmers and sustainable agriculture advocates. We work directly with local coalitions of community members on the frontlines of agricultural pesticide exposure in California's most productive agricultural counties, primarily in the San Joaquin Valley and the Central and South Coast of the state.

**Our position:**

We oppose approval of Oxitec Ltd.'s application, which requests an amendment and extension to the experimental use permit (EUP) for release of its genetically engineered (GE) OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein and a fluorescent marker. We are particularly concerned about the proposed expansion of the company's experimental releases of GE mosquitoes to the state of California without adequate peer-reviewed analysis of potential health and environmental impacts.

EPA and Oxitec did not provide sufficient data, peer-reviewed or otherwise, on which to base any substantial public comment. The docket did not list the 12 California counties in which Oxitec is proposing a release, giving no opportunity for residents in these counties to consider their comfort with proposed release and express their concerns or support. California is a global biodiversity hotspot and is home to more species of plants and animals than any other state in the nation yet there is no discussion on the potential impacts on the unique ecosystems and endangered species habitat in California. Nor does the docket discuss the significant agricultural lands in California and the associated chemicals used in these settings, such as tetracycline, that would impact any field trial. Safer alternatives already exist, such as through use of the benign bacteria *Wolbachia*. Without sufficient and publicly available science, data, analysis, or identification of need, we oppose the experimental field trial proposal for California.

## **Inadequate information assessing the health and safety to people and the environment**

- Importantly, no information regarding populations of *Aedes aegypti* in California has been provided, nor any evidence regarding competitor species or predators/prey. This makes it impossible to assess environmental risks.
- It's also impossible to understand the full risks when some sections of the risk assessment (EPA-HQ-OPP-2019-0274-0359) remain blacked out as Confidential Business Information (CBI), most concerningly 15 lines on p. 28 about the allergic potential of the fluorescent protein DsRed2-OX5034. The section on tetracycline in the environment (p.32) does not say what levels are required for female OX5034 mosquitoes to survive to adulthood. The risk assessment also refers to numerous Oxitec studies which are not public.
- The EPA's 'Response to Comments' (p.132) also refers to CDC advice: however, the full advice has not been provided.
- There is no published information regarding Oxitec's earlier releases of OX5034 GE mosquitoes in Brazil.
- The EPA assessment fails to adequately address interactions in the food chain, including the impact on animals that consume GE mosquitoes or larvae; horizontal gene transfer to other insects, predators, and microbes; the impact of changes in the microbiome; California's endangered species and unique ecosystems; and the possible shift in insect populations due to displacement of the targeted *Aedes aegypti* mosquito population.
- While limiting mosquito populations and the spread of mosquito borne disease is important, this experiment has still not undergone any transparent independent scientific review, which should be a requirement.
- Currently, the data shared by Oxitec remains fraught with many unanswered and critical questions.

Sound science cannot be based on corporate confidential business protections but must be reviewed objectively by independent scientists and made available to the public ahead of any releases into the environment. This is basic to the scientific method and common sense and necessary to ensure the health of the public and the environment are protected.

### **Our health concerns**

Oxitec exposed populations in at least five countries to millions of biting GE females *without ever conducting a study* to see if the GE mosquito saliva—which enters the human bloodstream after a bite—contains new or elevated levels of toxins or allergens.

*No* human clinical trials and *no* public health surveillance related to GE mosquito bites exist. The cause of any associated health problems could therefore go unnoticed. It would require a large-scale outbreak of a serious reaction for health authorities to even mount an investigation, let alone consider the mosquito as a potential source.

Tetracycline and related antibiotics are used in rearing the GE mosquitoes, increasing the risk of creating antibiotic-resistant diseases. A petition signed by nearly three dozen physicians in the Florida Keys demanded tests to rule out this danger prior to any release. It was ignored.

### **This application demonstrates a bigger, unacceptable failure in regulation of GE technology to date**

We share concerns similar to those expressed by The Institute for Responsible Technology that approval of Oxitec's application is a result of a larger failure of the EPA, to date, to adopt proper assessment protocols for approving GMOs. When FDA scientists were tasked with proposing assessment protocols for approving GMOs in the early 1990s, the consensus was that genetic engineering introduced a unique set of risks and therefore required safety testing. They stated that GMOs could contain new or higher levels of existing toxins, allergens, and anti-nutrients, and determined the risk was so great that they recommended human toxicological studies.

Instead, the FDA created the new position of Deputy Commissioner of Policy and hired Michael Taylor, the outside attorney for Monsanto, the soon-to-be GMO giant, for the position. Taylor was to oversee the creation of GMO policy, among others. Based on documents made public by a lawsuit, *Taylor's revisions of the GMO policy statement systematically removed concerns by the scientists*. The final published FDA document ultimately declared that the agency knew of no meaningful difference between GMOs and other foods and that no safety testing was required. After establishing this non-scientific policy, Taylor left the FDA to become Monsanto's Vice President of Government and Regulatory Affairs.

In the twenty-nine years since the FDA policy was enacted, substantial evidence has validated the FDA scientists' concerns. **In fact, the most common result of genetic engineering is surprise side effects.** But as FDA microbiologist Louis Pribyl predicted in an internal memo, over time, there was "less concern about safety, because of a false sense of knowing what one is doing and it's been done hundreds of times before without a problem, why check it now."

The U.S. EPA appears to be operating under this myth of predictability and safety. Thus, they don't require GMO companies to conduct a thorough evaluation, even of changes in the genome, let alone those in the RNA, proteins, and metabolites. In the case of GE mosquitos, these unassessed changes could translate into unpredicted outcomes in all the areas addressed above: environment, health, economy, etc.

### **Recommendations for improving the regulation of GE technology**

We urge the EPA not to approve this application, nor any future releases of GE mosquitos, until and unless:

- An independent expert committee has been established to produce a publicly-available, peer-reviewed analysis of environmental, health and social impacts of any genetically engineered insect release proposal;
- The committee of independent ecologists and entomologists, public health experts (including dengue fever and zika virus specialists), and other key experts and public stakeholders have reviewed the proposal;

- The EPA has convened public meetings, in all relevant languages, at various times of the day and evening, across all potentially-affected communities for public comment and discussion of the proposal with the above committee present;
- The EPA has developed new, robust regulations for genetically engineered insects that are designed to be bio-pesticides; and
- A referendum has been conducted, so potentially-affected residents can vote on whether there should be a release of genetically engineered mosquitoes in their area.

Our elected officials and government agencies must not rely solely on data from the companies that would profit from genetically engineered organisms to decide what information the public and regulators should know or what is considered safe. Until the above requests are met, any application for the field release of genetically engineered mosquitoes should not be allowed to move forward.

### **Safer alternatives exist**

In parallel with the development of GE mosquitoes, other companies developed and verified effective methods for reducing mosquito populations or rendering mosquitoes incapable of transmitting diseases using a bacteria called Wolbachia. The bacteria are already found throughout the insect world and are an example of a tool that does not introduce the unpredictable side effects from genetic engineering, as well as the threat from export markets, the risks of horizontal gene transfer, the potential dangers from a GE mosquito bite, and more.

### **Conclusion**

When EPA began to regulate GMOs in the early 1990s, their assessments were already inadequate. Now the technology has far outpaced those insufficient safeguards. **We urge you to protect nature, protect the gene pool, and protect our population by rejecting Oxitec's proposed trials and by overhauling your GMO regulations in favor of rigorous independent assessments.**

Sincerely,



Sarah C. Aird  
Co-Director