Submitted via email to mosquito.ra@cdpr.ca.gov

April 19, 2022

Dear Director Henderson and Department of Pesticide Regulation staff,

As a follow-up to our April 5, 2022 meeting about the process for a potential Research Authorization (RA) or Environmental Use Permit (EUP) from the Department of Pesticide Regulation (DPR) for the release of Oxitec's OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein,[1] we are sending this letter as part of the public comment process and with the following specific goals:

1) To respond DPR's request for us to share relevant research on genetically engineered (GE) insects and Oxitec's GE mosquitoes. We are also sending the enclosed materials via U.S. mail on a flash drive so that you have at your disposal a comprehensive set of the available scientific information on this proposed project.
2) In response to DPR's invitation to share the names of experts in this field; we include below a list of experts and their affiliations/particular areas of focus.
3) As a follow-up on the topic of process for evaluating an application from Oxitec, we want to lay out in more detail our thoughts regarding how we understand the California Environmental Quality Act applies in this unusual case.

1) ENCLOSED DOCUMENTS

The enclosed materials include: the only independent peer-reviewed study, by Evans et al., of Oxitec's mosquito releases in Brazil;[2] other relevant research; comments from Dr. Helen Wallace, who is an expert in this area and provides important context and understanding of the data; and comments we submitted to United States Environmental Protection Agency (US EPA), among other files.

We are aware there has been critique of the Evans et al. study on GE mosquitoes in Brazil. However, this is the only non-Oxitec review of what happens when GE mosquitoes are released into the environment. The study found that the DNA from the GE mosquitoes spread to wild type mosquitoes, creating a kind of hybrid mosquito. Similar studies carried out over a longer time period should be performed to assess whether the GE OX5034 mosquitoes that would be released in California trials result in introgression of GE DNA into the wild type mosquitoes. Oxitec objected to the Evans et al. study and criticized the suggestion that this genetic mixing could have made the mosquito population "more robust"—more resistant to insecticides, for example, or more likely to transmit disease. Whether or not the release of the GE mosquitoes might make the hybrid mosquitoes more robust is unclear; this lack of clarity is the reason that additional research is needed. The company's resistance to having independent review of its research runs counter to responsible science and a precautionary approach.

We hope these resources will be helpful to you.

2) LIST OF EXPERTS

a. Dr. Michael Turelli, UC Davis, Distinguished Professor of Genetics, Joel Keizer Endowed Chair in Theoretical and Computational Biology, Department of Evolution and Ecology. Dr. Turelli researches theoretical population and quantitative genetics, speciation, and population biology of Drosophila and Mosquitoes, especially cytoplasmic incompatibility.
b. Dr. Helen Wallace, Director of GeneWatch UK, a not-for-profit organization that aims to ensure genetic science and technology is used in the public interest. Dr. Wallace has published widely on the social, environmental, and human rights issues associated with the use of genetic technologies. Since 2010, her research has included issues associated with open releases of genetically modified insects into the environment.

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[1] https://www.oxitec.com/en/news/oxitec-announces-2022-us-pilot-plans-for-mosquito-technology

[2] Evans, B.R., Kotsakiozi, P., Costa-da-Silva, A.L., Ioshino, R.S., Garziera, L., Pedrosa, M.C., Malavasi, A., Virginio, J.F., Capurro, M.L. and Powell, J.R. (2019). Transgenic *Aedes aegypti* mosquitoes transfer genes into a natural population. *Scientific Reports*, *9*(1), pp.1-6. *Available at:* https://www.nature.com/articles/s41598-019-49660-6

c. Dr. Jeffrey Powell, Yale University Professor of Ecology and Evolutionary Biology and Professor of Environmental Health Sciences. Dr. Powell's expertise is in mosquitoes, Zika, Dengue, and transgenic mosquitoes.
d. Dr. Jennifer Kuzma, NC State University, co-founder and co-director of the Genetic Engineering and Society (GES) Center (research.ncsu.edu/ges), at North Carolina State University. Dr. Kuzma specializes in the regulation and risk analysis of genetically engineered animals and insects released into the wild.

3) ROLE of CALIFORNIA ENVIRONMENTAL QUALITY ACT in EVALUATING A GE MOSQUITO FIELD TEST

Now that US EPA has given approval, if DPR approves Oxitec's GE mosquito release proposal, California would be only the second U.S. state where GE mosquitoes could be experimentally released, with the potential to ultimately be the site of the largest mass release to date.[3] We have not seen the full details of Oxitec's application to DPR and US EPA withheld the specific locations for Oxitec's releases as "confidential business information," but the agency's approval allows Oxitec to apply to DPR to conduct releases in 4 counties in California (Stanislaus, Fresno, Tulare, and San Bernardino[4]). DPR's FAQ, dated April 5, 2022, says Oxitec has applied for research authorization in Tulare County, for up to 48 test release sites, but does not specify where in the county these release sites will be located. The FAQ states that 5,000-30,000 mosquitoes per site/week are proposed for release.

Despite the more limited scope of the current application to DPR, because this mosquito would be the first release of a GE insect in California, this proposed project and decisions about it will nonetheless have significance both in terms of potential health and environmental impacts and in regard to setting precedent for how proposals to release genetically modified animal organisms in California are evaluated. The release of a genetically modified organism into the environment cannot be undone whether the research outcomes point to the technology as promising or not for use in the state. For these reasons, we believe a robust California Environmental Quality Act (CEQA) process that recognizes the potential for significant impacts should be followed in evaluating Oxitec's application, as described below.

A. Potential significant impacts

Based on publicly available data from previous GE mosquito field trials, and the public records from EPA's docket (EPA-HQ-OPP-2019-0274), there are critical outstanding questions about the health and environmental safety of any release of genetically engineered mosquitoes, particularly given that there is no guarantee that females will not be released, and there is uncertainty regarding how GE mosquitoes might interact with chemicals such as tetracycline in the environment. There are also questions about whether DPR can responsibly assess, have oversight, monitor, and track GE mosquitoes.

Releasing a GE species into the environment, even in small numbers, is a clear example of letting a genie out of a bottle. Because of the rate at which insects can multiply, spread, and potentially interbreed with wild populations, and because of the range of known and unknown potential impacts of releasing genetically modified organisms, the release of these mosquitoes has the potential to cause significant health and environmental impacts that it might not be possible to undo. Because a decision about this GE organism could also establish a precedent for other future proposed releases of GE insects or similar organisms in the state, this application merits comprehensive scrutiny and a process commensurate with its potential impact.

The proposed experiment is to investigate whether the GE mosquito can reduce the population of *Aedes aegypti* mosquitoes, which can carry diseases including yellow fever, dengue, chikungunya, and Zika. As noted above, a recently published scientific paper by Evans et al. examining Oxitec's release of GE mosquitos over 27 months in Brazil highlights the potential risk that a

[3] Several of the groups included in this letter have also raised concerns about the GE mosquito releases in Monroe County, FL. In 2021, Friends of the Earth published this press release condemning the release: https://foe.org/news/genetically-engineered-mosquitoes-fl/
[4] US EPA has issued Experimental Use Permit Amended for 93167-EUP-2 to Allow Releases of OX5034 Aedes aegypti in Florida and California Experimental Use Permit No.: 93167-EUP-2 OPP Case No.: 00295569 (Mar. 7, 2022). ("EPA EUP"). The EPA EUP allows Oxitec to release adults and eggs of OX5034 Aedes aegypti mosquitoes against wild Aedes aegypti mosquitoes within Monroe County, Florida and Stanislaus, Fresno, Tulare, and San Bernardino counties, California.

release of Oxitec's GE mosquitoes could pose to the environment and public health in California.[5] This study showed that Oxitec's GE mosquitos did not function as planned with complete lethality; that is, biting and reproducing female GE mosquitoes were released, survived, and interbred and hybridized with local wild populations. This study raises concerns which have not been thoroughly addressed by US EPA or any independent scientist, and that should be addressed through a strong CEQA review. Many questions remain unanswered about the impact of female GE mosquitoes surviving and interbreeding, including: what is the biting behavior of the GE and hybridized females? could their survival and interbreeding result in greater risk of disease transmission? will the GE protein found in the modified mosquito's saliva affect humans and other animals who are bitten or animals who consume mosquitos?

While we recognize that an RA request is not the same as a full pesticide registration, we believe that the potential for irreversible impacts from releasing a genetically modified insect for the first time into California's environment merits a comparable level of scrutiny.

Research authorizations are discretionary and may be denied if "the research may involve a hazard to handlers and/or field workers, the public health, or the environment."[6] As summarized above and made clear in the attached documents, Oxitec's assurances that no female mosquitos will escape or survive are likely flawed because it is virtually impossible to ensure 100% success, particularly given how common tetracycline use is in California agriculture. There are valid concerns that GE mosquitoes could exhibit more aggressive biting behavior. Oxitec has refused to fully disclose the health effects of its OX5034 mosquitoes and still claims a significant part of its data as "confidential business information" that US EPA cannot release.[7] This raises the concern that field research involving the release of Oxitec's GE mosquitos may pose significant hazards to handlers and/or field workers, the public health, or the environment.

B. Need for robust public comment

On April 5, DPR announced a 15-day public comment period for the proposed Oxitec project. While we appreciate the opportunity for the public to comment early in the process, this public comment period is insufficient for several reasons. First, 15 days is not enough time for most people, particularly those in the potentially affected area, to learn about the public comment opportunity, read through the currently available materials (which are Oxitec's US EPA application), and write meaningful comments to DPR. US EPA's documents and communication are only available in English and are therefore likely inaccessible to many in the county where the release will take place because it has one of the highest levels of limited-English-proficiency in the state.[8] In addition, the locations of the proposed releases have not been disclosed, so residents of affected areas have no means to even know that the project will directly affect them. Because Tulare is a relatively large county of 4,839 square miles, it is not simple to speculate as to potential locations of the proposed releases. In addition, comments are being accepted only by email, to which many Tulare County residents do not have access.

Farm workers, low-income communities, and communities of color are at significantly greater risk from a project such as this one. These residents are heavily represented in the Visalia area (Tulare County) that is the only location so far to have been identified in Oxitec's public media releases; this raises environmental justice concerns about the proposed release. In addition, in Florida, Oxitec chose to keep the locations of research releases confidential until just before those releases were made. In California, this conflicts with CEQA's requirements to inform the public and decision makers about the risks of a proposed project. Moreover, in other studies of mosquito-borne diseases, it has been noted that residents of low-income communities

[5] Evans, B.R., Kotsakiozi, P., Costa-da-Silva, A.L., Ioshino, R.S., Garziera, L., Pedrosa, M.C., Malavasi, A., Virginio, J.F., Capurro, M.L. and Powell, J.R. (2019). Transgenic *Aedes aegypti* mosquitoes transfer genes into a natural population. *Scientific Reports*, *9*(1), pp.1-6.

[6] 3 CCR § 6260(d)(1).

[7] Environmental Protection Agency (2022). Human Health and Environmental Risk Assessment of OX5034 Aedes aegypti Containing Tetracycline-Repressible Transactivator Protein Variant (tTAV-OX5034, New Active Ingredient), DsRed2-OX5034 Protein (new inert ingredient), and the Genetic Material Necessary (Vector pOX5034) for Production of the Proteins in vivo. Data and Information Provided in Support of an Extension and Amendment to a FIFRA. Retrieved at https://www.regulations.gov/document/EPA-HQ-OPP-2019-0274-0465

[8] United States Census Bureau (2019) Limited English Speaking Households. https://data.census.gov/cedsci/table?q=S1602&tid=ACSST1Y2019.S1602; The data from this site was used to calculate the estimated percentage of LEP Spanish speaking householders. 13.1% of Tulare County are limited English Speaking households, putting it at the 3rd highest in the state. Imperial and Kings County are the highest in California.

are most likely to lack screens and therefore have greater exposure to biting mosquitoes than other populations, adding to the environmental justice concerns that should be taken into account in evaluating Oxitec's proposal.

DPR has said that more information may be available at a later date but so far has announced no definite plan or commitment for another public comment period before the agency makes a decision about the Oxitec application. Given that the public still does not have access to critical information, including the proposed locations for release in Tulare County, the timing of DPR's decision, key public health data, information about Oxitec's methodology to ensure that only male mosquitoes are produced, and data from Oxitec's previous field trial in Monroe County, Florida, there should be at least one additional public comment period, if not more, as DPR receives more information.

Early in CEQA's environmental review process, an agency consults with the public through the "scoping" process, to identify the range of issues pertinent to the proposed project and feasible alternatives or mitigation measures to avoid potentially significant environmental effects. *See* 14 C.C.R. § 15083. Because, as mentioned previously, Oxitec's anticipated application poses a novel situation never before considered by DPR, the agency should conduct a thorough and robust CEQA analysis in considering potential authorization of the proposed release of GE mosquitoes, including a meaningful opportunity for public input.[9] There should also be an environmental review, covering the potential impacts on workers and the environment, for the research and development facility that Oxitec has said it will build in Visalia. In a standard CEQA process, a subsequent 45-day comment period would be opened once DPR's analysis was complete but before a decision was made, enabling the public to provide input on the analysis. A 45-day period for review of a draft environmental impact report (EIR) is required when the EIR must be reviewed by state agencies through the State Clearinghouse. (14 Cal Code Regs §15105(a).) These requirements apply when a state agency is a lead, responsible, or trustee agency for the project; a state agency has jurisdiction by law over the project for other reasons; or the project is of statewide, regional, or areawide significance. (Pub Res C §21091(a); 14 Cal Code Regs §15205(b), (d).)

Even though this application is for an RA in one area of the state, because the outcome of this application process would set a precedent for evaluation of future GE animal releases in the state, the CEQA process for evaluating this RA should take into account the broad impact the decision could have beyond the specific locations proposed at this time.

Therefore, DPR should immediately inform the public that the current 15-day comment period is only the initial "scoping" piece of the ongoing public processes for this application, and that there will be additional opportunities for the public to participate, both through comment periods and public hearings, with an opportunity for live testimony.[10] As DPR receives and releases more information, including proposed locations for release sites, specific information and data about the technology used to produce and sort the GE mosquito eggs, and public health information, DPR should open additional public comment periods of at least 45 days. In order to appropriately include public comments from all potentially affected community members and with sensitivity to the environmental justice aspect of the location of the proposed releases, DPR should host public meetings and offer translation for the predominant languages spoken in Tulare County. The community meetings, held at different times of day and evening, and in various locations across Tulare County, should be run by a neutral body, such as DPR, not the local mosquito control district (which has already publicized its support for the field trial) or the local agriculture commissioner. The meetings should transcribe oral comments to be included part of the public record of comment on the proposal.

C. The Oxitec Application is a Discretionary CEQA "Project."

Oxitec seeks a Research Authorization permit pursuant to 3 Cal. Code Regs ("CCR") 6260. Since section 6260 grants DPR discretionary authority over the Research Authorization permit, and that action has potentially significant environmental impacts, CEQA review is required.

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[9] *Pesticide Action Network N. Am. v. Dep't of Pesticide Regul.*, 16 Cal. App. 5th 224, 240-43 (2017), *as modified on denial of reh'g* (Oct. 19, 2017).

[10] As you are aware, public participation is a hallmark of our democracy. Notice and comment periods have become the principal method for the public to participate in the administrative process, which is why laws like CEQA mandate public engagement opportunities. We understand from our prior discussion with DPR officials that the agency is refusing to extend the current 15-day commenting period. We must restate our position and strongly urge DPR to extend the current commenting period by an additional 30 days to meaningfully engage and hear from all affected stakeholders.

CEQA applies only to "discretionary projects proposed to be carried out or approved by public agencies." (Pub. Res. Code § 21080(a).) Section 15357 of the CEQA Guidelines defines a "discretionary project" as:

> [A] project which requires the exercise of judgment or deliberation when the public agency or body decides to approve or disapprove a particular activity, as distinguished from situations where the public agency or body merely has to determine whether there has been conformity with applicable statutes, ordinances, or regulations.

(14 C.C.R. §15357 ("CEQA Guidelines").) Section 15369 of the CEQA Guidelines defines "ministerial" as:

> [D]escrib[ing] a governmental decision involving little or no personal judgment by the public official as to the wisdom or manner of carrying out the project. The public official merely applies the law to the facts as presented but uses no special discretion or judgment in reaching a decision. A ministerial decision involves only the use of fixed standards or objective measurements, and the public official cannot use personal, subjective judgment in deciding whether or how the project should be carried out.

(CEQA Guidelines § 15369.)

If a project's approval involves both discretionary and ministerial acts, the project is subject to CEQA review. (CEQA Guidelines § 15258(d); *Friends of Westwood, Inc. v. City of Los Angeles* (1987) 191 Cal.App.3d 259.) The CEQA Guidelines further explain that "[w]hether an agency has discretionary or ministerial controls over a project depends on the authority granted by the law providing the controls over the activity." (CEQA Guidelines § 15002(i)(2).)

3 CCR 6260 provides that the Research Authorization permit:

> (b) may specify conditions under which the research must be conducted. The conditions may include, but are not limited to, handling of the treated commodity, safety equipment, reentry intervals, medical monitoring, and field posting.(c) Research requiring an approved human exposure protocol pursuant to section 6710, must be conducted in accordance with that protocol.(d) The Director may terminate, amend, or refuse to issue an authorization whenever it is determined that:(1) the research may involve a hazard to handlers and/or field workers, the public health, or the environment;(2) the research is used for purposes unrelated to pesticide data development; or(3) violations of the authorization, a previous authorization, or Divisions 6 or 7 of the Food and Agricultural Code, or regulations adopted pursuant to them, have occurred in connection with such research.(e) The research must be conducted in accordance with the conditions of the authorization and the research authorization regulations of this article.

This section provides ample discretion to DPR to impose conditions or to deny outright the Research Authorization. As such, the Research Authorization permit is a "discretionary project" within the meaning of CEQA.

D. DPR's Certified Regulatory Program Does Not Apply to The Oxitec Research Authorization.

DPR has adopted a Certified Regulatory Program ("CRP") that has been approved for purposes of CEQA compliance. (*Californians for Alternatives to Toxics v. Cal. Dept. of Pesticide Regulation* (2006) 136 Cal.App.4th 1049 ("*CATS v. DPR*").) The courts have held that DPR may follow the procedures set forth in its CRP, but that DPR must still comply with all substantive requirements of CEQA. (*Pesticide Action Network of North America v. Cal. Dept. of Pesticide Regulation* (2017) 16 Cal.App.5th 224 ("*PANNA v. DPR*").)

However, the CRP has been approved only for limited circumstances. DPR's CRP was approved in 1978 by non-codified urgency statute, Public Resources Code section 21080.5 (Chap. 308, Statutes of 1978, attached hereto as Exhibit A) ("Urgency Statute"). The Urgency Statute provides that the CRP applies to the "environmental review," of "***pesticides***." (PRC 21080.5, Sec. 1(d).). The legislation is expressly intended to "prevent disruption of California Agriculture." (PRC 21080.5, Sec. 5). DPR's CRP approval is codified in 14 CCR 15125(i), which states:

> (i) The pesticide regulatory program administered by the Department of Pesticide Regulation and the county agricultural commissioners insofar as the program consists of:
>
> (1) The registration, evaluation, and classification of pesticides.

(2) The adoption, amendment, or repeal of regulations and standards for the licensing and regulation of pesticide dealers and pest control operators and advisors.

(3) The adoption, amendment, or repeal of regulations for standards dealing with the monitoring of pesticides and of the human health and environmental effects of pesticides.

(4) The regulation of the use of pesticides in agricultural and urban areas of the state through the permit system administered by the county agricultural commissioners.

Pesticides are defined as:

(a) Any spray adjuvant.

(b) Any substance, or mixture of substances which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in Section 12754.5, which may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment whatsoever.

Food and Agr. Code ("FAC") §12753.

Since GE mosquitoes are not a "substance, or mixture of substances," they are not a "pesticide" within the meaning of the Urgency Statute or pursuant to 14 CCR 15125. Also, 14 CCR 15125 does not apply to Research Authorizations at all. As such, they are not subject to DPR's CRP. DPR's CRP may not be expended beyond its express terms. (*Wildlife Alive v Chickering* (1976) 18 Cal.3d 190.) The fact that some agency activities come under a certified regulatory program does not exempt the agency from the requirement that an EIR or a negative declaration be prepared for other activities outside the scope of the certified program.

In the case of *Citizens for Non-Toxic Pest Control v Department of Food & Agric.* (1986) 187 Cal.App.3d 1575, 1588, the court addressed a very similar situation. In that case, the court held that the eradication effort for the apple maggot fruit fly was not within the strict terms of the Department's CRP for pesticides. As such, the court held that the agency was required to prepare a full CEQA document prior to approving the program.

Since CEQA review is required for the Oxitec Research Authorization, and since DPR's CRP does not apply, DPR must conduct full review under the standard provisions of CEQA, including preparation of an EIR. This will require a formal scoping period, preparation of a draft EIR, a minimum 45-day comment period, formal response to comments, preparation of a final EIR, and EIR certification, including formal written findings.

However, even if DPR's CRP applied to a research authorization for GE mosquitoes (which it clearly does not), the exemption provided by Pub Res C §21080.5(c) is not a blanket exemption from CEQA. When conducting its environmental review and preparing its documentation, a CRP remains subject to the provisions of CEQA outside the scope of the exemption, including CEQA's broad policy goals and substantive standards. (*PANNA v. DPR* (2017) 16 Cal.App.5th 224, 239; *POET, LLC v State Air Resources Bd.* (2013) 218 Cal.App.4th 681, 710; *City of Arcadia v State Water Resources Control Bd.* (2006) 135 Cal.App.4th 1392, 1422; *Environmental Protection Info. Ctr. v Johnson* (1985) 170 Cal.App.3d 604, 616. See also 14 Cal Code Regs §15250; *Californians for Native Salmon & Steelhead Ass'n v Department of Forestry* (1990) 221 Cal.App,3d 1419.) These include the fundamental duties set forth in Pub Res C §§21000 and 21002 to identify a project's adverse environmental effects, to mitigate those effects through adoption of feasible alternatives or mitigation measures, and to justify its action based on specific economic, social, or other conditions. (*Sierra Club v State Bd. of Forestry* (1994) 7 al.C4th 1215). This also includes the general principle that an agency may not "approve" a project until it has completed the CEQA review. (*John R. Lawson Rock & Oil, Inc. v State Air Resources Bd.* (2018) 20 Cal.App.5th 77, 100 (applying holding of *Save Tara v City of W. Hollywood* (2008) 45 Cal.4th 116, 130, to action by certified regulatory agency).)

Courts have characterized certified agencies' environmental documents as the functional equivalents of EIRs because the information required is in many respects the same as what is required in EIRs. (*Ebbetts Pass Forest Watch v Department of Forestry & Fire Protection* (2008) 43 Cal.4th 936, 943; *Environmental Protection Info. Ctr. v Department of Forestry & Fire Protection* (2008) 44 Cal.4th 459, 481.) Courts have interpreted the scope of the exemption from CEQA's requirements provided to CRPs particularly narrowly. Under the reasoning of these cases, because Pub Res C §21080.5(c) exempts agencies from the provisions of CEQA relating to preparation of EIRs, all other provisions of CEQA apply, including procedural requirements

for preparation of EIRs. (See *Joy Rd. Area Forest & Watershed Ass'n v Department of Forestry & Fire Protection* (2006) 142 Cal.App.4th 656, 667; *Ultramar, Inc. v South Coast Air Quality Mgmt. Dist.* (1993) 17 Cal.App.4th 689.)[11]

E. Department of Pesticide Regulation is the Wrong CEQA Lead Agency.

Since GE Mosquitoes are not "pesticides," but are in fact "pests," it is questionable whether DPR has jurisdiction over the project and would be the proper CEQA lead agency.

The distinction in CEQA between a lead agency and responsible agencies is critical. The lead agency is the agency that has principal responsibility for carrying out or approving a project and that prepares the appropriate CEQA review document for the project. (Pub Res C §21067; 14 Cal Code Regs §15050. See *Eller Media Co. v Community Redev. Agency* (2003) 108 Cal.App.4th 25, 38; *Planning & Conserv. League v Department of Water Resources* (2000) 83 Cal.App.4th 892, 903; *Friends of Cuyamaca Valley v Lake Cuyamaca Recreation & Park Dist.* (1994) 28 Cal.App.4th 419.)

Public agencies other than the lead agency that have discretionary approval authority over the project are referred to as "responsible agencies." (14 Cal Code Regs §15381.) Responsible agencies are bound by certain decisions made by a lead agency, including the decision whether an environmental impact report (EIR) or a negative declaration should be prepared for a proposed project. (See Pub Res C §21080.1(a); 14 Cal Code Regs §15050(c).) In certain circumstances, however, responsible agencies can challenge lead agency determinations, assume the lead agency role, and participate in other ways in the CEQA process. There can be only one CEQA lead agency for a particular project. (*City of Redding v Shasta County Local Agency Formation Comm'n* (1989) 209 Cal.App.3d 1169, 1174.)

The CEQA Guidelines include detailed provisions for determining the lead agency when more than one public agency will approve a project. (14 Cal Code Regs §§15051–15053.) When more than one public agency is involved in a project, "the public agency that shoulders primary responsibility for creating and implementing a project is the lead agency, even though other public agencies have a role in approving or realizing it." (*Planning & Conserv. League v Castaic Lake Water Agency* (2009) 180 Cal.App.4th 210, 239. See *Covington v Great Basin Unified Air Pollution Control District* (2019) 43 Cal.App.5th 867, 883 (air district was proper lead agency for approval of power plant on federal land when county had jurisdiction over only small part of project); *Habitat & Watershed Caretakers v City of Santa Cruz* (2013) 213 Cal.App.4th 1277, 1298 (as one of two qualifying lead agencies for project, city was properly designated by agreement as lead agency); *AquAlliance v U.S. Bureau of Reclamation* (ED Cal 2018) 287 F Supp 3d 969, 992 (local water authority was proper lead agency for series of water transfers). Conversely, an agency with a collateral role in approving or carrying out the project should not be designated as the lead agency. *Planning & Conserv. League v Department of Water Resources* (2000) 83 Cal.App.4th 892, 904 (local water authority was improper lead agency for statewide water policy document). For a private project, the lead agency is the public agency that has the greatest responsibility for supervising or approving the project as a whole. (14 Cal Code Regs §15051(b); *Eller Media Co. v Community Redev. Agency* (2003) 108 Cal.App.4th 25, 38.)

Since GE Mosquitoes are not "pesticides," DPR has little jurisdiction over the project. Therefore, DPR is not the proper CEQA lead agency.

F. **Inadequate Comment Period**

DPR has provided a patently inadequate 15-day comment period for the Oxitec Research Authorization. This comment is so brief that it violates both the substantive and procedural requirements of CEQA and deprives the public of procedural due process.

The environmental documents of a certified program must be available for review and comment by the public and other agencies for a "reasonable time." (Pub Res C §21080.5(d)(3)(B); *Ebbetts Pass Forest Watch v Department of Forestry & Fire Protection* (2008) 43 Cal.4th 936, 943*; Ross v California Coastal Comm'n* (2011) 199 Cal.App.4th 900, 1610; *Schoen v Department of Forestry &*

[11] C.f. *Ross v California Coastal Comm'n* (2011) 199 Cal.App.4th 900; *Californians for Alternatives to Toxics v Department of Pesticide Regulation* (2006) 136 Cal.App.4th 1049, 1059; *City of Arcadia v State Water Resources Control Bd.* (2006) 135 Cal.App.4th 1392, 1421.

Fire Protection (1997) 58 Cal.App.4th 556.) CRPs require public notice, and notice to persons who requested notice, of the filing of the plan or other written documentation, allowing sufficient time for review and comment (Pub Res Code §21080.5(d)(2)(F)).

In the case of *Ultramar, Inc. v South Coast Air Quality Mgmt. Dist*. (1993) 17 Cal.App.4th 689, the court addressed the CRP of the South Coast Air Quality Management District ("SCAQMD"). The court held that SCAQMD violated CEQA by providing a public comment period that was only one day short of the 30 days required by CEQA. The court held that CEQA's requirement that "[t]he public review period for a draft [EIR] shall not be less than 30 days," (Public Resources Code section 21091, subdivision (a)) applies equally to certified regulatory programs. The court stated, "We conclude that an interpretation of Public Resources Code section 21080.5 which contracts the public comment period would thwart the legislative intent underlying CEQA." (Id. at 700.)

As one commentator has noted, "the 'privileged position' that members of the public hold in the CEQA process ... is based on a belief that citizens can make important contributions to environmental protection and on notions of democratic decision-making...." (Selmi, The Judicial Development of the California Environmental Quality Act (1984) 18 *U.C.Davis L.Rev.* 197, 215–216.) "CEQA compels an interactive process of assessment of environmental impacts and responsive project modification which must be genuine. It must be open to the public, premised upon a full and meaningful disclosure of the scope, purposes, and effect of a consistently described project, with flexibility to respond to unforeseen insights that emerge from the process." (*County of Inyo v. City of Los Angeles* (1984) 160 Cal.App.3d 1178, 1185.) In short, a project must be open for public discussion and subject to agency modification during the CEQA process. (*Ibid.*) This process helps demonstrate to the public that the agency has in fact analyzed and considered the environmental implications of its action. (*No. Oil, Inc. v. City of Los Angeles* (1974) 13 Cal.3d 68, 86; *Concerned Citizens of Costa Mesa, Inc. v. 32nd Dist. Agric. Assn*., 42 Cal. 3d 929, 936 (1986).) DPR's 15-day comment period is simply too short to allow the "meaningful" public participation required by CEQA. The 15-day comment period is simply unreasonably short and deprives the public of a meaningful comment period.

Because DPR has provided only a 15-day comment period, it has violated CEQA section 21091(a), as did SCAQMD in the *Ultramar* case. The agency must provide the full 45-day comment period required by CEQA.[12] The 15-day comment period simply cannot be deemed to be a "reasonable time period" given the complex nature of the proposed action. Experts are unable to provide meaningful comments in a mere two weeks, and the public is unable to review and comment meaningfully on the proposal. DPR must reopen the public comment period for a minimum of 45 days.

G. Inadequate Project Description

CEQA requires the CEQA document (including any document prepared pursuant to a CRP) to contain an adequate project description. (14 Cal.Code Regs. 15252(a)(1).) The document the agency prepares must include a description of the proposed activity, its significant adverse impacts, and a discussion of alternatives and mitigation measures, and must be made available for review and comment by the public and other agencies. (Pub Res C §21080.5(d)(3). See *Sierra Club v. State Bd. of Forestry* (1994) 7 Cal.4th 1215*; Conway v State Water Resources Control Bd.* (2015) 235 Cal.App.4th 671, 680). To comply with the technical and formal requirements of 14 Cal Code Regs §15124(a), a project description must include: The precise location and boundaries of the proposed project; A detailed map, preferably topographical, and a map showing the project's location in a regional perspective.

For over 40 years the courts have consistently held that an accurate and stable project description is a bedrock requirement of CEQA—the *sine qua non* (that without which there is nothing) of an adequate CEQA document:

> Only through an accurate view of the project may affected outsiders and public decision-makers balance the proposal's benefit against its environmental cost, consider mitigation measures, assess the advantage of terminating the proposal (i.e., the "no project" alternative) and weigh other alternatives in the balance. An accurate, stable and finite project description is the sine qua non of an informative and legally sufficient EIR.

(*County of Inyo v. City of Los Angeles* (1977) 71 Cal.App.3d 185 at 192-93.)

[12] DPR as a state agency is subject to a minimum 45-day review period (14 Cal Code Regs §15105(a)), while SCAQMD as a local agency was subject to a 30-day comment period.

The ability of informed citizens to participate in environmental review is a key component of CEQA. (*Washoe Meadows Cmty. v. Dep't of Parks & Recreation*, 17 Cal. App. 5th 277, 285 (2017) ["Informed public participation is essential to environmental review under CEQA."]; Inyo, supra, 71 Cal.App.3d at 192 ["The EIR process facilitates CEQA's policy of supplying citizen input."].) Through the EIR process, CEQA "provide[s] public agencies and the public in general with detailed information about the effect which a proposed project is likely to have on the environment." (*Washoe*, supra, 17 Cal.App.5th at 286 [quoting Pub. Res. Code § 21061].)

In *Inyo*, the court first articulated that "[a] curtailed or distorted project description may stultify the objectives of the [CEQA] process." (*Inyo, supra*, 71 Cal.App.3d at 192.) The court of appeals recently noted that the requirement for an accurate, stable, and finite project description has been "reiterated in a number of cases since County of Inyo." (*Stopthemillenniumhollywood.com v. City of Los Angeles* (2019) 39 Cal. App. 5th 1, 17, [citing *Communities for a Better Envt. v. City of Richmond* (2010) 184 Cal.App.4th 70, 85-89; *San Joaquin Raptor Rescue Ctr. v. County of Merced* (2007) 149 Cal.App.4th 645, 653].)

i. The Project Description is Inadequate Because it Fails to Disclose Release Locations.

The Project Description is abjectly inadequate. The description fails entirely to disclose the locations where Oxitec intends to release the GE mosquitoes. CEQA is clear that at a bare minimum, an adequate project description must describe the location of the proposed project. The Oxitec project description does not describe where Oxitec intends to release the mosquitoes, other than somewhere in Tulare County, and possibly other locations in as many as 3 other California counties. There is no map and no formal disclosure of the proposed release locations.

Without knowledge of the precise location of mosquito releases, the public cannot assess and intelligently comment on the proposed project. For example, it cannot be known if the release locations are near sensitive receptors such as schools, senior citizen homes, day care facilities, or other receptors. It also cannot be known if the release locations are near any sources of tetracycline, such as citrus orchards or confined animal feeding operations ("CAFOs"). If GE mosquitoes are released near such areas where tetracycline is applied in large quantities, it is possible that colonies of female GE mosquitoes may persist and reproduce for extended periods of time or indefinitely – contrary to the limited and inadequate project description. The lack of information concerning the proposed release locations renders the Oxitec CEQA document inadequate as an informational document since it precludes meaningful public comment and participation.

ii. The Project Description is Inadequate Because if Fails to Describe all Phases of the Project, Including Releases in Other California Counties.

The project description is also inadequate because the Oxitec CEQA document discusses only releases in Tulare County (albeit entirely inadequately). The US EPA EUP allows release in at least four California counties. An adequate CEQA document must include a description of all foreseeable phases of the proposed project. (14 Cal Code Regs §15126 (EIR's impact analysis must consider all phases of project).)

For example, in *Laurel Heights Improvement Ass'n v. Regents of Univ. of Cal*. (1988) 47 Cal.3d 376, the Supreme Court found an EIR's project description to be inadequate when it described a proposed medical research facility to be 100,000 square feet, but evidence indicated that the facility was likely to include a second phase increasing the ultimate size to 340,000 square feet. The EIR was required to disclose and analyze the later phases of the project. Similarly, the Oxitec CEQA document is inadequate since it discusses only the Tulare County phase of the GE mosquito release despite the fact that evidence makes clear that Oxitec intends later phases that may involve releases in 4 California Counties.

The entire project being proposed for approval (and not some smaller aspect of it) must be described in the CEQA document. This requirement reflects the CEQA Guidelines' definition of a "project" as "the whole of an action" that may result in either a direct physical environmental change or a reasonably foreseeable indirect change. (14 Cal Code Regs §15378. See *Habitat & Watershed Caretakers v City of Santa Cruz* (2013) 213 Cal.App.4th 1277, 1297; *Banning Ranch Conservancy v City of Newport Beach* (2012) 211 Cal.App.4th 1209, 1220). A complete project description is necessary to ensure that the environmental impacts of the entire project are considered. (*City of Santee v County of San Diego* (1989) 214 Cal.App.3d 1438, 1454). A lead agency may not split a single large project into smaller ones resulting in piecemeal environmental review that fails to consider the environmental consequences of the entire project. (*East Sacramento Partnership for a Livable City v City of Sacramento* (2016) 5

Cal.App.5th 281, 293; *Banning Ranch Conservancy v City of Newport Beach* (2012) 211 CA4th 1209, 1222; *Communities for a Better Env't v City of Richmond* (2010) 184 CA4th 70, 98.)

The Oxitec CEQA document's project description is woefully inadequate since it fails to disclose the proposed release locations, and it fails to describe all phases of the project, including likely releases in up to 4 California Counties. A new CEQA document is required with an adequate project description.

H. Alternatives Analysis

The courts have held that a CEQA document prepared pursuant to a certified regulatory program must include an adequate alternative analysis. (14 Cal.Code Regs. §15252(a)(2); Pub. Res. Code § 21080.5, subd. (d)(3); *Citizens for Non-Toxic Pest Control v. Department of Food & Agriculture* (1986) 187 Cal.App.3d 1575, 1586.) DPR's standards of review and evaluation state that before allowing a pesticide to be registered for a proposed use, the director must consider all feasible alternatives and make a written determination that any significant adverse impact (such as health dangers, potential for environmental damage and toxicity to wildlife) is outweighed by the anticipated benefit. (Cal. Admin. Code, tit. 3, § 6158; *Citizens for Non-Toxic Pest Control v. Department of Food & Agriculture* (1986) 187 Cal.App.3d 1575, 1586.) A CRP must require denial of a proposed activity if feasible alternatives or mitigation measures that would substantially lessen any significant adverse environmental impact are available. (Pub Res Code §21080.5(d)(2)(A)). DPR's regulations state that "The director shall not approve an activity which would cause a significant adverse environmental impact if there is a feasible alternative or feasible mitigation measure available which would substantially lessen any significant adverse impact which implementation of the proposal may reasonably be expected to have on the environment." (3 Cal.Code Regs. 6254(a).)

Alternatives to the proposed activity, including the "no project alternative," must be described in an environmental document prepared for a certified program. (Pub Res C §21080.5(d)(3)(A); 14 Cal Code Regs §15252(a)(2)(A)). This requirement applies even if the project's significant environmental impacts will be avoided through mitigation measures. (*Friends of the Old Trees v Department of Forestry & Fire Protection* (1997) 52 CA4th 1383, 1404). The fact that mitigation measures will avoid significant impacts may, however, be considered in identifying the range of reasonable alternatives to the project. (*Center for Biological Diversity v Department of Forestry & Fire Protection* (2014) 232 CA4th 931, 947.)

Although DPR's pesticide registration program is a certified state regulatory program exempt from some procedural requirements of CEQA, DPR is still obligated to comply with the "broad policy goals and substantive standards of CEQA."[13] This includes the need to identify and meaningfully assess feasible alternatives to a proposed project: "[u]nder CEQA, the public agency bears the burden of affirmatively demonstrating that, notwithstanding a project's impact on the environment, the agency's approval of the proposed project followed meaningful consideration of alternatives."[14] The alternatives analysis must include the option of a "no-project" alternative. Public Resources Code section 21002 states that "it is the policy of the state that public agencies should not approve projects as proposed if there are feasible alternatives available which would substantially lessen the significant environmental impacts of such projects, and that the procedures required by this division are intended to assist public agencies in systematically identifying feasible alternatives which will avoid or substantially lessen such significant effects." This is reflected in the Department's own program regulations which state that "[e]ach public report [prepared by the Department] shall also contain a statement and discussion of reasonable alternatives which would reduce any significant environmental impact."[15]

One of CEQA's fundamental requirements is that the CEQA document must identify the "environmentally superior alternative," and require implementation of that alternative unless it is infeasible. (14 Cal.Code Regs. §1526.6(e)(2); *Burger v. County of Mendocino* (1975) 45 Cal.App.3d 322; Kostka & Zischke, *Practice Under the California Environmental Quality Act* §15.37 (Cont. Educ. Of the Bar, 2008).) A CEQA analysis must identify the environmentally superior alternative, which is analyzed in detail, while other project alternatives receive more cursory review. "CEQA's substantive mandate that public agencies refrain from approving projects for which there are feasible alternatives or mitigation measures is effectuated in section 21081. Under

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[13] *Pesticide Action Network N. Am. v. Dep't of Pesticide Regul.*, 16 Cal. App. 5th 224, 242 (2017), *as modified on denial of reh'g* (Oct. 19, 2017).
[14] *Mountain Lion Foundation v. Fish & Game Com.*, 16 Cal.4th 105, 134 (2007)
[15] Cal. Code Regs., tit. 3, § 6254.

this provision, a decision making agency is prohibited from approving a project for which significant environmental effects have been identified unless it makes specific findings about alternatives and mitigation measures." (*California Clean Energy Comm. v. City of Woodland* (2014) 225 Cal. App. 4th 173, 203.) An agency's rejection of an alternative as "infeasible" or otherwise "unworthy of more in-depth consideration" must be supported by "substantial evidence." (*Center for Biological Diversity v. County of San Bernardino* (2010) 185 Cal.App.4th 866, 885.)

Of prime importance in this case is that California does not have any endemic cases of the diseases associated with the *Aedes aegypti* mosquito (dengue, zika, yellow fever, chikungunya),[16] so it seems that Oxitec's GE mosquitos are a solution looking for a problem that does not exist.[17] In this regard, any alternatives analysis carried out under CEQA must weigh the relative risks of a no-project alternative compared to the proposed project, with the CEQA-mandated aim of minimizing environmental harm. If there is no *Aedes aegypti*-borne disease problem to solve, what could be the justification for undertaking the proposed project with its attendant potential adverse and significant environmental impacts? In addition, publicly available data on Oxitec's previous GE mosquito trials do not demonstrate that they have significantly reduced mosquito populations. Cayman Islands regulators challenged Oxitec's high estimate of the reduction in mosquito populations.[18] Is this research project advisable given the track record of the technology so far, weighed against the potential harm to California's environment? The California Supreme Court has repeatedly held that CEQA must be interpreted to "afford the fullest possible protection to the environment." If the evidence indicates that technology does not successfully reduce *Aedes aegypti* populations, then there would be no real "benefit" from the program, and the benefits could not outweigh the environmental risks.[19] DPR therefore could not make the required finding that any significant adverse impact is outweighed by the anticipated benefit. (Cal. Admin. Code, tit. 3, § 6158; *Citizens for Non-Toxic Pest Control v. Department of Food & Agriculture* (1986) 187 Cal.App.3d 1575, 1586.)

In this case, the "no project" alternative would be "environmentally superior" to the proposed project because the proposed project provides few, if any environmental benefits but poses significant risks to the environment and human health. The no project alternative is clearly "feasible" since it is being implemented now without release of genetically modified living creatures. Since the no project alternative is environmentally superior and feasible, DPR is legally obligated to select the no project alternative.

Another feasible and superior alternative would be to test the mutant mosquitoes in caged studies. This would provide a far greater level of control and prevent their release into the environment with potentially unforeseen impacts. Cage studies are plainly "feasible" and "environmentally superior." Cage studies could be designed to achieve most if not all project objectives.

I. Environmental Setting or Baseline

Another relevant CEQA requirement is the need to adequately define an environmental setting or baseline against which a proposed project's effects are measured. Every CEQA document must start from a "baseline" assumption. The CEQA "baseline" is the set of environmental conditions against which to compare a project's anticipated impacts. (*Communities for a Better Environment v. So Coast Air Qual. Mgmnt. Dist.* (2010) 48 Cal. 4th 310, 321. Section 15125(a) of the CEQA Guidelines (14 C.C.R., § 15125(a)) states in pertinent part that a lead agency's environmental review under CEQA:

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[16] Centers for Disease Control and Prevention. (2021) Table 1: Dengue cases reported to ArboNET by state or territory of residence – United States, 2021 (as of February 1, 2022).
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TravelAssociatedCasesofDengueVirusinCA.pdf; https://wwwn.cdc.gov/arbonet/Maps/ADB_Diseases_Map/index.html

[17] Among the documents we share with you here are several which show population numbers for the *Aedes aegypti* mosquito and local transmission numbers for Zika and Dengue. Although *Aedes aegypti* have been documented in 22 counties in California as of February 4, 2022, data from the CDC show that there has been no local transmission of Zika or Dengue in California. The small number of cases that are reported by the CDC were associated with travel, not with local mosquito populations.

[18] http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Failed_in_the_field_fin.pdf
In emails from the Cayman Islands government obtained through freedom of information requests, GeneWatchUK learned that the reduction of Aedes aegypti mosquitoes was significantly less than the 90 to 95% that Oxitec had claimed.

[19] Evans, B.R., Kotsakiozi, P., Costa-da-Silva, A.L., Ioshino, R.S., Garziera, L., Pedrosa, M.C., Malavasi, A., Virginio, J.F., Capurro, M.L. and Powell, J.R. (2019). Transgenic *Aedes aegypti* mosquitoes transfer genes into a natural population. *Scientific Reports*, *9*(1), pp.1-6; GeneWatchUK http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Failed_in_the_field_fin.pdf

> "…must include a description of the physical environmental conditions in the vicinity of the project, as they exist at the time [environmental analysis] is commenced, from both a local and regional perspective. This environmental setting will normally constitute the baseline physical conditions by which a Lead Agency determines whether an impact is significant."

(See, *Save Our Peninsula Committee v. County of Monterey* (2001) 87 Cal.App.4th 99, 124-125.) As the court of appeal has explained, "the impacts of the project must be measured against the 'real conditions on the ground,'" and not against hypothetical permitted levels. (*Save Our Peninsula*,87 Cal.App.4th 99, 121-123.) Further, as the court has explained, using such a skewed baseline "mislead(s) the public" and "draws a red herring across the path of public input." (*San Joaquin Raptor Rescue Center v. County of Merced* (2007) 149 Cal.App.4th 645, 656; *Woodward Park Homeowners v. City of Fresno* (2007) 150 Cal.App.4th 683, 708-711.)

Because the survival of this mosquito depends on the presence of tetracycline, and because tetracycline is widely used in agriculture, especially on citrus, as well as in treating human disease which results in residues in sewage, it is critical that we understand the levels of environmental tetracycline that could contravene the Oxitec "kill switch" strategy in the mosquito. We do not know the levels of tetracycline used to rear the Oxitec mosquitoes because that information has not been disclosed, but in publications describing the development of tetracycline as a promoter in cell lines, researchers saw effects from tetracycline on the transgene at extremely low levels of 0.01 microgram/milliliter of substrate. In transgenic fruit flies, gene induction is seen at a concentration of 1 microgram per ml.[20, 21]

In light of the key role of tetracycline in the survival or death of the Oxitec mosquitoes, it is crucial that, as part of the evaluation of a potential permit for their release, the levels of tetracycline be documented in the environment where the release would take place. The Tulare County area where the first experimental release is proposed is an area where significant numbers of citrus crops are grown.

Evaluation should also include the impact of potential use of pesticides to treat for any escaped female mosquitos. The US EPA's required mitigation of surviving females were found is 10 weeks of pesticide treatments, which represent a potentially significant environmental impact of the research project.

J. Consultation with Other Agencies

An agency with a CRP must consult with the responsible agencies and provide an opportunity for responsible agencies to participate in the review process and to inform the certified program of its concerns before release of the EIR substitute. (14 Cal Code Regs §15253(b); See *Lexington Hills Ass'n v State* (1988) 200 Cal.App.3d 415, 436.) If the lead agency fails to adequately consult with all responsible agencies, then the responsible agencies may not rely on the CRP, and must prepare a full environmental impact report in compliance with CEQA. (14 Cal Code Regs §15253(c)(1)–(2).)

DPR has stated its intention to consult with the California Department of Public Health in regard to relationships with other mosquito programs and the local mosquito district and agricultural commissioner. However, given the cross-cutting nature of an environmental release of this type, which has potential to affect human health, wildlife, and agriculture, we believe that a much broader multi-agency approach is needed, including, but not necessarily limited to, the California Department of Natural Resources, Department of Fish and Wildlife, and Department of Food and Agriculture

K. Flaws in US EPA Review Process

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[20] Gossen, M and Bujard, H. (1992) Tight control of gene expression in mammalian cells by tetracycline-responsive promoters. *Proceedings of the National Academies of Science.* Vol. 89, pp. 5547-5551.

[21] Stebbins,M.J., Urlinger, S., Byrne, G., Bello, B., Hillen, W., and Yin, J. C.P. (2001). Tetracycline-inducible systems for Drosophila. *Proceedings of the National Academies of Science*. Vol 98, no. 19, pp. 10775-10780.

As expressed to DPR in our April 5th and March 2nd meetings, we believe that the EPA review process was incomplete and that it is, frankly, premature for the state of California to be evaluating the Oxitec proposal without more diligent federal view having taken place. We summarize the flaws in the US EPA process here to point out the additional information, not addressed by US EPA in its review, that we believe that DPR should require. During US EPA's public comment period, insufficient data were available for the public to comment on, and key public health information about allergenicity was redacted from public documents.

For a scientifically complete review, EPA should have:

1. Required Oxitec to fully disclose its sterilization techniques and how Oxitec can guarantee that no female OX5014 mosquitoes will be released from the mosquito boxes. This public disclosure needs to be reviewed by experts in the field of sterile insect technology.
2. Mandated that Oxitec release all data on the environmental and health effects of this mosquito, instead of redacting much of it, including data on allergenicity, as "confidential business information."
3. Mandated that Oxitec conduct caged trials appropriate to all of the potential California release sites' environments in a step-wise fashion, i.e., small cages that start to model the local ecosystem, and larger cages where the company can test whether there is introgression of the GE mosquitoes' DNA into wild type mosquitoes if female mosquitos get released. Caged trials could test how little tetracycline is needed to keep the female mosquitoes alive and could then be used to inform assessments about tetracycline presence. It would be prudent to measure whether the wild female offspring, resulting from the GE males mating with wild females, can survive due to the level of tetracycline in the local environment. There is federal precedent for this process. For trials involving their GE Diamondback Moth in New York State, and at the urging of the USDA, Oxitec hired a researcher at Cornell University to conduct two cage trials. State and federal agencies assessing Oxitec's application for a field trial should encourage independent researchers to do caged trials in California ahead of a field trial.
4. Convened a Scientific Advisory Panel to assess the need for this new mosquito.
5. Required independent monitoring for any field trials (rather than allowing Oxitec to perform monitoring). DPR must put in place measures to monitor and verify that mosquito trapping is done according to scientific standards for numbers of traps, area covered, etc. to ensure that escaped females are detected.
6. Named the specific sites where Oxitec is considering a release so there could be independent review of the presence of tetracycline in the environment.
7. Included in the US EPA's endangered species assessment an evaluation of the impacts of the mitigation measures that the EUP requires. For instance, US EPA's approval requires Oxitec to spray pesticides for a minimum of 10 weeks if any female mosquitos are found to survive. Pesticides, including those that are used for mosquitoes, are harmful to numerous threatened and endangered species and thus there are likely effects to these species that were not considered by EPA.[22]

Our recommendation is that DPR conduct a comprehensive scientific review of Oxitec's proposal, including a full CEQA analysis, in considering potential approval of an RA permit for a release in California. A comprehensive review process should:

- Establish robust regulatory structures for responsible assessment, monitoring and oversight of GE insects, per the National Academy of Science's recommendations;[23]
- Conduct a site-specific analysis for each site where release of the mosquitoes is proposed;
- Establish an independent scientific advisory panel 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;
- Require public review of the Florida field trial data ahead of DPR's consideration of an approval; and

[22] In DPR's review of the RA application, it must consider the impact to species listed under California's Endangered Species Act and California species of special concern, as well as federally-protected threatened and endangered species. In conducting this review, DPR must consider all of the potential impacts of the action, including the impacts of the mitigation measures imposed by EPA that include vast amounts of pesticide spraying.

[23] National Academies of Sciences, Engineering, and Medicine. 2016. *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*. Washington, DC: The National Academies Press. https://doi.org/10.17226/23405

- 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. Meetings should be available in Spanish as well as other languages predominantly spoken in the areas where releases are proposed.

CEQA's overarching purpose to preserve and enhance the state's public health, safety, and the environment – coupled with the unprecedented nature with critical outstanding questions about the health and environmental safety of releasing GE mosquitos into an uncontrolled environment – requires DPR to conduct a thorough environmental review, including opportunity for public review and comment, prior to making a determination on Oxitec's anticipated application for an RA.

Thank you for your attention to the above and the attached materials (listed below). We appreciate that DPR continues to be in dialogue with us and considers our comments and recommendations. We understand that DPR is working to get the necessary information that currently is missing, and that there is an intention to prioritize transparency and thorough analysis.

We look forward to further engaging with DPR on these important issues.

Sincerely,

Dana Perls, Emerging Technology Program Manager, Friends of the Earth

Nan Wishner, Board Member, California Environmental Health Initiative

Sarah Aird and Jane Sellen, Co-Director, Californians for Pesticide Reform

Rebecca Spector, West Coast Director, Center for Food Safety

Asha Sharma, Organizing Co-Director, Pesticide Action Network

California Environmental Health Initiative

Science at the intersection of human health and agriculture

Attached documents:

California Department of Public Health. (2021). Aedes aegypti and Aedes albopictus Mosquitoes in California by County/City. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/AedesDistributionMap.pdf

Center for Food Safety. (2021). Center for Food Safety comments on EPA review of Oxitec Application 93267-EUP-2 (Docket EPA-HQ-OPP-2019-0274). https://www.centerforfoodsafety.org/files/final-cfs-comments-on-epa-review-of-oxitec-proposal-to-expand-mosquito-releases-to-california_92324.pdf.

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Exhibit A. Chap. 308, Statutes of 1978. Public Resources Code section 21080.5.

Friends of the Earth. (2021). Comments for the EPA's consultation on application 93167-EUP-2 from Oxitec. https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/Friends-of-the-Earth-EPA-public-comments-GE-mosquito-EUP-FL_CA.pdf

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Macer, Darryl. "Ethical, Legal and Social Issues of Genetically Modifying Insect Vectors for Public Health." Insect Biochemistry and Molecular Biology 35.7 (2005): 649-60.

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.

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