CENTER FOR FOOD SAFETY

September 30, 2021

Center for Food Safety comments on EPA review of Oxitec Application 93267-EUP-2

(Docket EPA-HQ-OPP-2019-0274)

Oxitec, the GE insect company, is requesting a 2 year extension to its experimental trial in the Florida Keys and requests to expand the trial into California.

In a 2 page request to the EPA it proposes to:

1. Continue its releases of GE mosquitoes for 2 years in the Florida Keys on 6240 acres at a rate up to 20,000 male mosquitoes, per acre, per week.
2. Release its GE mosquitoes in 84,600 acres of California at a rate of 30,000 male mosquitoes per acre, per week.

The Center for Food Safety noted in its review of the original proposed release of Oxitec OX5034 GE mosquitoes that inadequate information was being provided to review proposed releases in Florida and Texas. That application, ironically, contained more specifics than does the current application. At least the original application indicated which counties in Florida and Texas would have mosquito releases. The two page extension to the application does not indicate which California counties would take the mosquitoes. A letter from 10 mosquito control districts posted to this docket suggests that the 11 counties where those mosquito control districts have operations are the likely sites of the releases.

Like the original application, no risk assessment and no review of the environmental or human health effects are provided for the public to review. After EPA approved the original trials in Florida and Texas, EPA posted to the docket nine (9) documents, including a risk assessment. Despite my having asked the EPA staff to post to the docket any materials that they have that would answer these questions for the California trials and any data on the Florida releases to date, the EPA staff insisted that this was all confidential business information of Oxitec. In essence, EPA is admitting that what should be a public review of a new technology is a SECRET discussion between EPA staff and Oxitec staff. The staff moreover told me and a colleague from another public interest group that we should be happy that they were having a docket for public comments at all as this in not legally required.

We hereby incorporate by reference our October 11, 2019, comments on the original Experimental Use Permit (EUP) for the release of Oxitec OX5034 GE mosquitoes, under this same Docket number. Our concerns raised in those comments remain as none of them have been properly addressed and are applicable to this proposed amendment and extension of the EUP.

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Given the proposed extension of time for trials in Florida and the proposed expansion to include releases in California, these mosquitos pose an increased risk to human health, the environment, and endangered species. And, thus there is even more need here for EPA to take a closer look and to require additional information and consult with other federal agencies prior to authorizing these expanded releases of experimental living organisms into the environment. As explained in previous comments, EPA must comply with other laws including the National Environmental Policy Act and the Endangered Species Act and thus should prepare an Environmental Impact Statement and consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service before deciding whether to approve the proposal at issue here. The necessity to do so is even more important with the expanded release proposed here, that includes a vast increase in the acreage for releases and expansion to releases in California, which is home to numerous federally threatened and endangered species, as well as areas of dense human populations.

RISK ASSESSMENT

As noted above, the risk assessment (EPA-HQ-OPP-2019-0274-0359) of the Florida/Texas trials were not made public for the earlier consultation. Even when it was released on May 28, 2020 key sections were claimed by Oxitec as Confidential Business Information and redacted: i.e. page 18 (mosquito rearing); page 21 (fecundity); page 22 (longevity) and, most troubling, a long section on p.28 which is the discussion of the allergenicity of the genetically engineered fluorescent protein inserted to track the mosquitoes (DsRed2-OX5034). Not redacted, but nonetheless inadequate, is the discussion of the amount of tetracycline exposure needed for female OX5034 mosquitoes to survive to mate and produce offspring. Given that both the environments of California contain many sources of tetracycline, this is an important fact to know. The risk assessment only points to secret Oxitec documents that the public is not given access to in the risk assessment and have not been published and peer-reviewed.

Without fully addressing the many questions raised by the risk assessment, the US Environmental Protection Agency approved the release of genetically modified mosquitoes. Under a 2-year Experimental Use Permit, Oxitec was granted in the spring of 2020, permission to release over 1 billion genetically modified mosquitoes across 6,600 acres in Florida and Texas. Now it seeks two more years of research in Florida (Harris County in Texas withdrew from the study when its advocate for the trial became the mosquito district manager in Visalia, CA.) Without releasing any data from the Florida trial, Oxitec wants to expand to California. It proposes to release 30,000 males per acre per week over this large scale (with no explanation as to why this is higher than used in Florida), which equals the potential release of more then 2.5 billion mosquitos per week in the state. This hardly seems like a small experimental trial. Although no information is provided about the specific counties where these releases would occur, Oxitec's application indicates it could be as many as 20 counties, covering a significant portion of the state.

Oxitec hopes to demonstrate through field trials that their latest GM mosquito strain can reduce local populations of *Aedes aegypti* — the mosquito species that transmits dengue fever, yellow fever, chikungunya, and the Zika virus. When males of the OX5034 strain are continually released to mate in the wild, they pass on a lethal gene to their female offspring that causes female larvae to die before they can develop into biting adults. Male mosquito offspring survive, but male mosquitoes don't bite and without viable females, the population should eventually collapse. But a chief problem is that neither Florida nor California have significant cases of

these diseases. The only cases of yellow fever are from travelers from the few countries where it still is an active disease. Dengue is rare outside of Puerto Rico. Like yellow fever, almost all cases of Zika are brought to the US from foreign travel. The one mosquito borne disease that is more significant—West Nile is not carried by the *Aedes aegypti* mosquito that Oxitec is engineering.

EPA approval of the release of this new GE mosquito is just the first step toward Oxitec selling its proprietary mosquito to US mosquito-control boards, and by extension taxpayers who fund mosquito control. Its earlier trials of GE diamondback moths and GE boll weevils failed when farmers did not want to pay for the continued releases of the GE moths and GE weevils. Mosquito control has a more guaranteed source of funding. If the mosquito control districts of California join the Monroe County district in Florida, billions of GM mosquitoes could be released into the wild all summer in California and Florida next year. Since only one species of mosquito will be controlled, pesticide spraying will continue for the other species.

The environmental introduction of the first GM mosquito in the United States is a landmark decision. Its public health, ecosystem, and societal risks and benefits should be carefully reviewed. Oxitec claims its strategy is a "safe" and "environmentally sustainable" and "friendly" way to control mosquitoes that transmit disease. Yet the trial that the EPA is conducting is not one that assesses the control of disease. Oxitec would have to apply to the FDA for that review.

We have urged the EPA to convene a Scientific Advisory Panel to review this new "pesticide" as it has with many other new pesticides, i.e. Nanosilver as a pesticide. Yet the EPA did not convene an independent, external scientific advisory panel to review Oxitec's claim; the agency's risk assessment was only made publicly available after their approval decision and we know of no peer-reviewed articles on this particular GM mosquito strain.

We have also urged EPA to require caged trials that replicate the environments that the mosquitoes will be released into. The US Department of Agriculture required such caged trials for the GE Diamondback moth that Oxitec wanted to release in New York State. Only after the caged trials (one had to be repeated) did the USDA allow a very small open release. EPA should have required such environmentally specific caged trials for the GE OX5034 mosquito. During such trials more information on the effect of tetracycline on female survival could have been tested.

The risk assessment shows no evidence that EPA engaged with the Fish and Wildlife Service to consider the endangered species impacts in Florida and Texas. Instead, EPA made an unsubstantiated claim and misapplied the Endangered Species Act in concluding that these GE mosquitos would have no effect on endangered and threatened species. California has a tremendous number of endangered species that should be considered before billions of OX5034 mosquitoes are released in California. Without information about the specific counties in California where the mosquitos are proposed to be released, it is difficult to pinpoint which endangered species are of particular concern. However, there are likely to be many species that should be considered, such as listed species like the California red-legged frog, the California tiger salamander, and the vernal pool fairy shrimp

Meanwhile, GE mosquitoes are being released in the Florida Keys despite a vote by the people of the Keys that resulted in the people of Key Haven, where the GE mosquitoes were to be

released voting NO! by 78%. Perhaps because of that NO! vote, Oxitec this time did not reveal the exact locations of the release of their OX5034 mosquitoes and people are unknowingly sharing their environment with the OX5034 mosquitoes. EPA officials have told us that Oxitec is monitoring the mosquito releases to make sure that no female mosquitoes are released. EPA, however, is not doing their own independent assessment. The release of any females is grounds for stopping the trial, but EPA is just taking Oxitec's word that none have been released. President Ronald Reagan when negotiating with the Soviet Union had a saying: "trust, but verify". EPA is trusting Oxitec, but not doing its job of verifying.

The Public is concerned that EPA is not doing its job.

Virtually, all public comments for the last review showed that the public is very worried that mosquito suppression, if it works, could affect the food chains and the ecosystems. Others feared that if the female mosquitoes are released GE hybrid mosquitoes would have hybrid vigor and could spread diseases more efficiently. More than 31,000 people have opposed the release of these mosquitoes.

The public is rightly worried that EPA is making secret deals with pesticide companies already. Bio-pesticides as a new class of pesticides should give EPA a chance to pilot a different way of doing business. Risks should not be assessed behind closed doors between company employees and EPA employees. EPA should publish on its website everytime its employees meet with advocates of any sort. The Office of Management and Budget already does this.

EPA must work to make the regulatory process more open, rigorous, and fair.

As mentioned above, an external independent group of experts (A scientific review panel) should be convened to review the first GE mosquitoes presented for release. But to address the complexity of such a decision, this group should consist of interdisciplinary experts representing diverse identities with expertise in ecology, genetics, vector biology, risk assessment, entomology, public health, ethics, and social science. External peer review is a cornerstone of good science and could ensure that all necessary risks are being addressed.

To ensure rigorous review, the EPA and other regulatory bodies must also fund independent third-party research on GM mosquitoes and their potential impact on US ecosystems and human health. Potential risks are too important to be left to corporations alone to research, and the American public needs to be assured that these decisions are made free of conflicts of interest.

EPA needs to develop new regulations for genetically engineered insects. Oxitec alone has engineered a dozen or so GE insects. Other companies are proposing to use gene-editing on insect vectors. EPA needs to have clear regulations and not rely on ad-hoc adoption of other pesticide authorities.

Most important, people who live in areas of release must be consulted for their specialized, on-the-ground knowledge and for their right to have input in decisions that will affect them. In California, State and local agencies must do their own review of these OX5034 mosquitoes and

decide based on public review whether to allow mosquito control districts to conduct the experiments. An independent group should host public conversations through local community venues, and it must make sure that structurally marginalized perspectives are at the center of those gatherings. But local community input should be consulted at every stage of the regulatory process, before not after permits have already been granted. And earmarked government funding from mosquito control districts, county boards, state agencies and EPA should support these local deliberations, as well as measures to amplify underrepresented people concerned about environmental regulation, biotechnology and human health. Otherwise, public trust will be eroded even more.

The public needs to know how the risks and benefits of these decisions will likely impact us all, and certain communities, especially those of BIPOC communities even more so. The COVID-19 pandemic has made it clear that robust public health depends on informed communities who feel that they are being invited to participate in collective actions. Release of GM mosquitoes is no different. For the health of ourselves, the nation, our planet, and future generations, environmental regulation of GMOs must be made more rigorous and just.

EPA should start its new regulations by addressing these four areas: 1. Antibiotic resistance promoted by the use of tetracycline to "sterilize" females. 2. Endangered species. 3. Allergenicity. 4. Transparency.

Tetracycline, the genetically engineered kill switch for the female mosquitoes, may not work to keep the female mosquitoes from surviving if they are released. In both Florida and California, tetracycline is sprayed on citrus and found in abundance in waste water treatment plants and Concentrated Animal Feeding Operations.
In addition, relative to female survival due to exposure to tetracycline (which can switch off the killing mechanism), there are also important gaps in evidence. The EPA states that "most" septic tanks in Florida are now gone (Response to Comments, p. 45) and other sources of tetracycline (e.g. cat feed, animal waste) not plausible (Response to Comments, p.46). However, concerns about potential exposure to tetracycline are sufficient for conditions to have been applied to the Florida trial in an attempt to limit such exposure – for example, Oxitec's Protocol (EPA-HQ-OPP-2019-0274-0358) states that, "The outer boundary of the trial area (denoted by the traps furthest from the central release point) will be greater than 500 m from commercial citrus growing areas and from sewage treatment plants". It is a matter of serious concern that no information has been supplied regarding potential tetracycline exposure at or near proposed release sites, particularly in the new proposed sites in California, including in commercial citrus growing areas or in septic tanks. Additional complexity needs to be considered in the light of recent studies showing that mosquito microbiomes (which can be influenced inter-generationally by the use of antibiotics) can influence vectorial capacity.15,16 The EPA has concluded that OX5034 "is not expected to establish within the test area" (p.94, Response to Comments). However, this conclusion seems to rely on a caged trial conducted in England to argue the transgene will not persist (p.38 to 39): this does not make sense because the caged population collapsed completely, which would not happen in the real world where wild mosquitoes are mobile and can move elsewhere. Further, in a caged trial the GE mosquitoes will not be exposed to tetracycline and the duration of the trial may not be sufficient to allow resistance to develop.

The trials in California and Florida may spread antibiotic resistance

In California, there is even more chance for the escaped females to get into water contaminated with tetracycline. In personal conversation with the staff of the EPA bio-pesticides branch, they seemed not to be aware of the extent of tetracycline spraying on citrus and other fruits in California. If the females get out they will be able to transfer their tetracycline tolerant genes to their offspring, bacteria they harbor, and perhaps even animals that consume them. In short, the kill switch may not work and may spread antibiotic resistance to microbes this antibiotic should kill in humans and livestock. I suggested to the EPA staff that 500m is too small a distance and no mosquitoes should be released within a mile of known operations using tetracycline as a spray or feeding it to animals.

Endangered Species and related harm to other animals

Section 7 of the Endangered Species Act (ESA) requires federal agencies such as EPA, in consultation with the expert wildlife agencies, to ensure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any threatened or endangered species, or result in the destruction or adverse modification of the critical habitat of such species.[i] If the action agency determines the action "may affect" a listed species or critical habitat, the action agency must formally consult with NMFS and/or FWS to "insure" that the action is "not likely to jeopardize the continued existence" of that species, or "result in the destruction or adverse modification of habitat … determined … to be critical…."[ii,iii] The threshold for a finding of "may affect" is extremely low. A triggering effect need not be significant; rather "any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement…."[iv] During consultation, EPA is prohibited from making any irreversible or irretrievable commitment of resources with respect to the agency action which may foreclose the formulation or implementation of any reasonable and prudent alternative measures.[v]

In approving the release of Oxitec's OX5034 GE mosquitoes with the original EUP, EPA made erroneous and unilateral assumptions that its action would have "no effect" on protected species and/or their critical habitat.[vi] Like its approval decision, EPA's conclusion concerning threatened and endangered species rests on an extremely limited inquiry that failed to adequately consider the significant risks of harm to listed species related to releasing more than a billion GE mosquitoes into the environment at the test trial sites in Monroe County and Harris County. Yet dozens of protected species that live or occur in the area of the release may have been affected by the approval.[vii] EPA's "no effect" decision for these species was contrary to law. Pursuant to its duties under the ESA, EPA was required to consult with the expert wildlife agencies before reaching any decision on the unprecedented GE mosquito. Now, in considering the proposed amendment and extension of that EUP, EPA has done no additional analysis under the ESA, despite the expansion of releases over a large swath of the state of California, which is home to numerous federally protected threatened and endangered species. EPA failed to conduct a proper ESA analysis for the original EUP application and has done nothing to correct that error, not to attempt to comply with the ESA with this proposed amendment and extension. EPA must work with the expert wildlife agencies, U.S. Fish and Wildlife Service and National Marine Fisheries Service, to properly examine potential impacts to protected species and to consult as necessary under the ESA.

Center for Food Safety previously expressed concerns about potential impacts to threatened and endangered species in Monroe County, Florida. These concerns remain, and the same concerns apply to those protected species in California. Given the large amount of acreage proposed for releases in California and a potentially large number of counties where releases

may take place (up to 20 based on Oxitec's application) there are many more species that may be put at risk through approval of these additional releases. California is a state with a wide variety of habitat types, high levels of biodiversity, and home to many threatened and endangered species. Thus, we are greatly concerned about the additional potential impacts raised here.

Clear consultation with both other federal agencies and with local agencies that know about endangered species should be a part of regulatory requirements for GE insects.

Oxitec claims, "The consequences of escape, survival, and establishment of OX513A in the environment have been extensively studied: data and information from those studies indicates that there are unlikely to be any adverse effects on non-target species, including humans. There are also unlikely to be any adverse effects on foreign countries or the global commons. Risk of establishment or spread has been determined to be negligible. The trial is short in duration and any unanticipated adverse effects are unlikely to be widespread or persistent in the environment. Most importantly, the status of the environment is restored when releases are stopped (i.e., the released mosquitoes all die, and the environment reverts to the pretrial status)."[viii] While this claim was made about OX513A it is also applied to OX5034. There is no data provided to support this claim, hence it is an unsubstantiated claim at best and cannot be assumed to be true without data.[ix] Oxitec withdrew an application for another of their genetically engineered insects when regulators asked similar questions the company could not answer.[x] Oxitec told Olive Oil Times that Spain's National Biosafety Commission requested that predator studies be held. Oxitec stated they would conduct the studies requested.[xi] If Oxitec is willing to conduct these studies for Spain they must be willing to conduct them for the U.S. as well. Since reproducibility is one of the main principles of the scientific method, these studies must be reproduced by independent experts. Once Oxitec has conducted these necessary studies and they are replicated by independent experts, then Oxitec must reassess and include this new information. Until Oxitec has conducted such studies and they are replicated by independent experts, their GE mosquitoes cannot be considered safe. Nine species of dragonflies and three species of damselflies found in the Keys can eat mosquitoes, the bat *Molossus molossus*, carnivorous plants like small butterwort, lizards like the green anole and amphibians like green tree frog tadpoles, etc. all can eat mosquitoes. Dragonfly larvae, for example, may consume large amounts of *Aedes aegypti* larvae.[xii] If GE mosquito larvae are deposited in pet dishes, a dog, cat, etc. may drink the water and consume some larvae in the process. A young child might even drink from a cup left inside or outside with OX5034 x wild *Aedes aegypti* larvae in it. So, what happens if the transgene is consumed by any or all of these species? Nobody knows, because there have been no studies published on the subject. Without testing of actual species in the Keys and California counties where mosquitoes might be released, Oxitec is basing their assessment on speculation, not science.

Oxitec states in SECTION G PROPOSED EXPERIMENTAL PROGRAM that, "Season of Application: May-December (but could be deployed any time of year)". Oxitec has not provided adequate evidence to conclude there is no toxicity for insectivores in the Keys (and we have no evidence that any studies have been done in California) especially for a duration of potentially all year for at least 24 months, and now even longer for potentially another 2 years. The only studies Oxitec has provided are a 14 day acute toxicity study using *Poecilia reticulata* and a 96 hour study using *Pacifastacus leniusculus*. These studies are of insufficient duration and insufficient parameters to assess sub-chronic and chronic toxicity or carcinogenicity. These studies also have little to no relevance for insects, lizards, amphibians, carnivorous plants, etc. that may consume OX5034 as larvae, pupae, or adults. These studies have little to no relevance for mammals, including humans that may consume or otherwise be exposed to OX5034. Oxitec must therefore perform toxicity studies using insectivores present in the Keys (and each California county

considered for the trial) for a duration of at least 48 months, or the life of the subject if the subject does not live for 48 months. These toxicity studies should not be limited to mortality, appearance, size, and behavior, but should include examination of all major organ systems, including histological examination of organs as well as all other health parameters typical of toxicity studies. Multigenerational exposure, as well as transgenerational effects must also be considered since a large number of environmental factors have been shown to promote the epigenetic transgenerational inheritance of disease or phenotypic variation in a variety of different species, including humans.[xiii] Until Oxitec conducts such studies their GE mosquitoes cannot be considered safe for any insectivores in the Keys or California.

Oxitec should also conduct feeding trials using rodents and non-rodents to assess toxicity as it may relate to humans, since humans may also accidentally swallow Oxitec's mosquitoes. The studies should also be for the life of the rodents and 48 months in duration for non-rodents and should not be limited to mortality, appearance, size, and behavior, as their previous studies are limited to, but should include examination of all major organ systems, include histological examination of organs as well as all other health parameters typical of chronic toxicity/carcinogenicity studies. Since reproducibility is one of the main principles of the scientific method, these studies must be reproduced by independent experts. Once Oxitec has conducted these necessary studies and they are replicated by independent experts, then Oxitec must reassess and include this new information. Until Oxitec has conducted such studies and they are replicated by independent experts, their GE mosquitoes cannot be considered safe for endangered species or indeed any human or animal life.

Allergens from the mosquitoes or the genetically engineered proteins in them.

GE female mosquitoes will be present at some point in the Keys or California[xiv] What happens when people are bitten? While Oxitec previously claimed there are no proteins unique to the GE mosquito in the saliva of the OX513A mosquito, no data is presented for OX5034. Even if Oxitec provided data for a few hundred or thousand OX5034, it is still possible that some unknown percent of OX5034 mosquitoes do have these proteins in their saliva. Therefore, toxicity and allergenicity studies must be conducted to determine what happens if people are bitten by OX5034 with the transgenic proteins expressed in their saliva. Such data, if it exists, does not appear to have been published in a peer reviewed journal, or replicated by independent experts. Since reproducibility is one of the main principles of the scientific method, these studies must be reproduced by independent experts.

Oxitec does not indicate if there are or will be differences in the levels of proteins in the saliva of the GE mosquitoes compared to wild mosquitoes in the Florida Keys or California. Since there are at least 8 allergens that have been found in *Aedes aegypti* saliva, [xv] an increase in these levels of allergens in GE mosquitoes may increase allergic responses or increase severity of allergic responses in people in the test area bit by these GE female *Aedes aegypti*. Oxitec must therefore also conduct studies to determine if there are differences in the allergen levels of their GE *Aedes aegypti* compared to wild *Aedes aegypti* currently found in the Keys and in California. Oxitec must also conduct studies to determine if the saliva of wild female *Aedes aegypti* in the Keys and California is altered once they are inseminated by GE *Aedes aegypti* males as it is unknown if this may alter the saliva of the wild female and perhaps even cause the wild female to have unique proteins in their saliva.

Also, allergen databases are often incomplete and therefore the risk of an allergic response in residents exposed to the GE mosquitoes is a possibility and residents must be informed of and consent to such a risk. If all residents in the test area do consent Oxitec must provide a physician, as a part of the test, who will monitor the health of the residents that are exposed to Oxitec's

mosquitoes. In the case of an adverse event being reported during this trial Oxitec must have a plan in place to recall the mosquitoes and/or evacuate the residents. This would involve erecting temporary structures outside of the test area, in case of an adverse event being reported, to evacuate residents to. An immediate response plan to eradicate the mosquitoes must also be in place since the lethality trait cannot be fully relied on considering 50% of all male offspring can survive and an even greater percent when they exposed to pet food, a likely scenario, or environmental tetracyclines.[xvi]

Even in the absence of tetracyclines Oxitec's mosquitoes are likely to remain in the environment due to the offspring that survive to adulthood without exposure to tetracycline. The Food and Agriculture Organization of the United Nations agrees on their website stating, "The transgenic approaches instead can have potentially unforeseen consequences because the released insects are not sterile and therefore will reproduce and become established."[xvii]

Oxitec was asked whether health studies were conducted on humans who were bitten by GE mosquitoes, they replied in a town hall meeting in Monroe County that many of the scientists working with the GE mosquitoes had been bitten and no adverse health effects were reported.[xviii] This is anecdoctal and insufficient evidence when human health is potentially at risk.

The proteins expressed by the transgenes may be toxic.

Although Oxitec claims, "tTA and its variants, such as tTAV, have been used in fungi, rodents, plants, and mammalian cultures with no known non-target adverse effects on the environment or human health"[xix], signs of toxicity [xx] and neurotoxicity[xxi] have been reported in mice expressing the tTA protein. Oxitec should therefore attempt to replicate these studies, finding toxicity and until Oxitec has conducted such studies and they are replicated by independent experts their GE mosquitoes cannot be considered safe.

Transparency

Any new regulations must require that all information about the human health effects and the effects on the environment and animals in the environment must be available for public review. In many other countries, health and environmental effects cannot be claimed as “confidential business information”. The EPA can only restore public trust in its judgements if it starts making all of its decision making fully transparent. If companies need legal protections for their inventions, that is what the US Patent and Trademark Office provides. EPA should get out of the business of making behind closed doors deals with biopesticide companies like Oxitec.

In summary:

EPA should not proceed with these trials until it:

Convenes a Scientific Review Panel composed of multidisciplinary specialists to independently review these genetically engineered “biopesticides”.

Develops a program of independent review of all aspects of the trials, including the sterile insect strategies being used.

Develops new regulations appropriate for the oversight of these new bio-pesticidal insects, including removing claims of confidential business information for environmental and human health effects.

Prepares an Environmental Impact Statement.

Consults with other federal and state agencies with more expertise in endangered species in the locations where GE insects will be released, and specifically conduct a proper ESA consultation with the U.S. Fish and Wildlife Service and National Marine Fisheries Service for the releases currently proposed in Florida and California.

Holds public hearings in each of the counties proposed for the release of the genetically engineered insects.
Releases in a timely manner all data from trials already conducted with GE insects and related trials such as those involving Wolbachia infected mosquitoes.

Thank you for your consideration of these comments.

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[i] 16 U.S.C. § 1536(a)(2).
[ii] 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a).
[iii] "Jeopardize" means taking action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species." 50 C.F.R. § 402.02. A species' "critical habitat" includes those areas identified as "essential to the conservation of the species" and "which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).
[iv] Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986); Final ESA Section 7 Consultation Handbook at xvi (Mar. 1998) (defining "may affect" as "the appropriate conclusion when a proposed action may pose *any* effects on listed species….").
[v] 16 U.S.C. § 1536(d).
[vi] *See* EPA, Response to Comments to the Notice of Receipt of an Application for an Experimental Use Permit Number 93167-EUP-E, ID: EPA-HQ-OPP-2019-0274-0355, 139 (May 1, 2020) (hereinafter Response to Comments), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0355; *see also id.* at 73-74.
[vii] *See* FWS, Species By County Report: Monroe, Florida, https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=12087 (last visited May 16, 2020). *See* FWS, Species By County Report: Harris, Texas, https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=48201 (last visited May 16, 2020) (Note that not all federally threatened and endangered species are listed for Harris County); Texas Parks & Wildlife, Rare, Threatened, and Endangered Species by County Map, Harris County Report, https://tpwd.texas.gov/gis/rtest/ (last visited May 16, 2020) (This report includes all federally listed threatened and endangered species in Harris County, including listed species not included in FWS's species by county report for Harris County, Texas.).
[viii] Draft Environmental Assessment for Investigational Use of Aedes aegypti OX513A https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM487377.pdf

[ix] ibid
[x] Sustainable Pulse Dec 9 2013 Oxitec Cancels GM Flies Release after Government Health Questions http://web.archive.org/web/20150928081937/http://sustainablepulse.com/2013/12/09/oxitec-cancelsgm-flies-release-government-health-questions/

[xi] JULIE BUTLER (2014) Oxitec Still Pursuing Trial Release of GM Olive Flies in Spain http://web.archive.org/web/20150205062034/http://www.oliveoiltimes.com/olive-oil-making-and-milling/oxitec-still-pursuing-release-gmo-olive-flies-spain/38079
[xii] Sebastian, A., Sein, M.M., Thu, M.M. and Corbet, P.S., 1990. Suppression of Aedes aegypti (Diptera: Culicidae) using augmentative release of dragonfly larvae (Odonata: Libellulidae) with community

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