

Oxitec & Western States MCDs Tuesday 25 May 2021

OXITEC

With You Today





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Additional Resources Available at: <u>oxitec.com</u>

Introduction

Oxitec is pleased to announce that **10 mosquito control districts in California and one in Southern Nevada have registered their interest in hosting pilot projects** with Oxitec's Friendly™ Aedes aegypti technology in the near future. Oxitec looks forward to working with MVCAC and each of the districts to evaluate where such pilot projects might be implemented.

Key Facts:

- Oxitec's Friendly[™] Aedes aegypti technology was approved by the U.S. EPA for piloting in Florida and Texas; the EPA ruled that the technology is safe for humans, animals and the environment (information and resources are available <u>here</u>)
- Oxitec has submitted an amendment to its current permit requesting permission to expand the pilot area to California and Nevada
- 10 districts in California registered formal interest to host a pilot project
- The statutory timeline for a federal decision for the amendment is seven months
- This information will become public as part of the EPA's standard publication of application information in the Federal Register and a "public comment period", a 30-day period within which the public is invited to submit comments; we do not know when this will be published
- Oxitec has retained KP Public Affairs to assist districts and MVCAC in communications, public engagement and education efforts in the coming year relating to potential Oxitec projects in California and Nevada
- Oxitec has yet to determine where it will carry out pilot projects, but will work closely with EPA, California regulators, MVCAC and the interested districts to do so.
- The team at Oxitec is deeply thankful for the support it has received and looks forward to working closely with all key stakeholders as we progress in this effort.



Green districts represent counties served by mosquito control districts that have registered their interest in hosting an Oxitec pilot project.

Oxitec places trust and transparency at the center of all it does. As part of this, Oxitec has partnered with KP Public Affairs, a California firm that currently supports MVCAC, to support communications, public engagement and educational efforts relating to potential Oxitec projects in CA.



- Communications support for Western States districts, MVCAC and Oxitec
- Alignment on messaging and approaches
- Coordination of public engagement activities
- Liaison with state regulators and other important stakeholders



Goal: Delivering Positive Impact

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7 months statutory (PRIA) timeline

- Oxitec applied to EPA for EUP extension/ amendment (PRIA category B621).
- PRIA deadline for approval is Nov 2021.
- EUP extension/amendment application includes:
 - Field Trial Protocol ('Section G')
 - Updated deployment protocols
 - Location-specific updates to environmental analysis conducted as part of first EUP.

California State Approvals:



- Research authorization route possible.
- Research authorization route should take only a few weeks from submission.
- State decision would likely happen after the federal decision.

Timeline for Western States EUP





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Federal Register Notice of Receipt ("Public Comment Period")

- Name of the pesticide (incl active ingredient)
- Name of the submitter
- Purpose of the EUP (incl use patterns)
- Maximum application rate and use site
- Maximum number of treated acres requested
- Duration of EUP
- Location of site(s)
- Statement soliciting comments from any interested persons regarding the application

30-day Public Comment Period

- Oxitec has no input into comment responses that EPA generates
- Messaging from Districts or responses to inbounds can be standardized
- Comments are appreciated by EPA and can be actively solicited from third parties \sim
- Public comment period can be extended by 30 days subject to an EPA decision



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Project Design Elements

- 1. Single-point releases (households)
- 2. Multi-point releases (neighborhoods)
- 3. Trapping offspring to evaluate efficacy
- 4. Replicated and compared to untreated areas
- 5. Anticipated duration single mosquito season



Evaluation Elements

- 1. Male flight range and longevity
- 2. % kill of female mosquitoes
- 3. % of the wild population treated
- 4. Duration of effect (residual activity)
- 5. Evaluation of natural breeding sites

Scale and Locations still TBD

- The proposed EUP is flexible enough to permit projects of small to larger deployments (up to 5000 acre plots)
- Pilots will not be possible in all districts, but we will endeavour to work closely with all to generate a robust evaluation program.



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- There is no regulatory action for any of the Districts or Oxitec in response to comments
- The EPA receives and processes comments independently
- The EPA publishes responses in batches on their website

• A duration of 30 days (subject to extension by the EPA)

• As little as 24 hours notice before it is published

• Comments from organizations or individuals are welcomed by the EPA



- Increased inbounds from the public for information
- Inbounds from small but vocal group of opponents to GM technologies
- Media or journalist enquiries



Example Response Statement

The Mosquito Control District of ______ is committed to improving vector control for public health, which includes the evaluation of safe, promising, innovative technologies or approaches. Federal and State regulatory agencies will determine the safety of Oxitec's approach for people and the environment here in California/Nevada, and only after approval would an evaluation at the district level be considered. In addition to the Florida Keys and Harris County, Texas, we are one of 11 districts in California and Nevada that have expressed interest in evaluating this technology should federal and state regulators approve.

For more information, the following external resources may be helpful: The Florida Keys Oxitec Mosquito Project website – <u>http://www.keysmosquitoproject.com</u> Oxitec's website – <u>http://www.oxitec.com</u> The U.S. EPA's publications relating to Oxitec's EUP permit (including their risk assessment and detailed documentation) – <u>https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0274</u>

What We Would Ask of You

- 1. Share with us any question, concern or comment at any time we stand ready to support you
- 2. To liaise with the Oxitec team and Lisa Yarbrough at KP Public Affairs on any matter (lyarbrough@ka-pow.com)
- 1. To kindly provide:
 - Your PIO contact details to aid information exchange
 - Your technical point of contact to discuss project details and design
 - Any key stakeholders who may have specific requirements
- 2. To submit comments and solicit others to do so via the EPA website during the public comment period

What we would not ask of you:

- 1. To endorse Oxitec or its technology
- 2. To provide your time (e.g. participation in meetings) when not convenient for you

Communications and Outreach for CA/NV EUP signatories

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Communications, Public Outreach, and Resources



We invite you to visit our website dedicated to the Florida Keys project keysmosquitoproject.com

Latest Project Updates:

Throughout all release locations less than 12,000 mosquitoes are expected to emerge each week for app





Beginning in spring 2021, the Florida Keys Mosquito Control District (FKMCD) and Oxitec will evaluate the effectiveness of Oxitec mosquitoes to control the invasive, disease-spreading Aedes aegypti mosquito in the Florida Keys.

- Oxitec mosquitoes are safe and self-limiting.
- Like all male mosquitoes, Oxitec's male mosquitoes do not bite. Femo spread disease.
- The Aedes aegypti mosquito is the known vector of diseases includir becoming more resistant to traditional pesticides.

Please visit keysmoquitoproject.com for additional resources.

PLEASE TURN OVER TO LEARN MORE



Project to Control Disease-Carrying Mosquitoes Kicks...





FKMCD - #Oxitec Mosquito Project Update: Emergenc...

0:53

2.1K views • 1 week ago



FKMCD - #Oxitec Public Educational Webinar #13

64 views • 3 weeks ago



FKMCD - #Oxitec Public Educational Webinar #12

48 views • 1 month ago



JUST-ADD-WATER

Educational Webinar #11

82 views • 2 months ago



What are the risks if a female Oxitec mosquito bites someone?

0%.

There will be no Oxitec female mosquitoes and thus no risk.

We release only male mosquitoes because the self-limiting gene prevents females from surviving in the pre-release production stage.

Oxitec male mosquitoes are safe and non-toxic.





Are self-limiting mosquitoes an environmentally sustainable control tool?

Yes.

Self-limiting mosquitoes work by finding and mating with invasive pest *Aedes aegypti* females and the suppression effect is specifically targeted to this species of mosquito. This specificity leaves non-target species, such as bees and butterflies, unharmed.





Will Oxitec mosquitoes harm birds, bees, bats, fish, turtles, or other wildlife?

No.

The EPA and State of Florida confirmed this, and Oxitec has carried out exhaustive research (part of submissions made available to the EPA) on this topic.





Is Oxitec going to be using tetracycline for US deployments?

No.

Tetracycline is only used in our facilities in the UK. The *total* amount used to produce the eggs in the UK is less than three normal therapeutic doses in humans – *for the entire 2-year Florida project*. This is roughly equivalent to the contents of a single sugar packet.





Will Oxitec's mosquitoes replace insecticides and other control measures?

No.

Insecticides are a valuable option available to mosquito control authorities but they have limitations. Over-reliance has led to the development of resistance.

Integrated pest management approaches rely on a suite of technologies. Oxitec mosquitoes are intended to be one of these valuable tools and can offer the potential to reverse insecticide resistance.



Will this technology be expensive compared to others?

No.

The benefits of egg-releases and in-built sexing offer dramatic reductions in production and delivery costs. This will ensure affordability and in conjunction with the benefits of improved and sustainable mosquito management at cost-effective levels.