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ALERT

EPA's BPPD Extends and Expands the Experimental Use Permit Authorizing Trial Releases of Oxitec's Genetically Engineered *Aedes aegypti* Mosquito

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A May 6, 2020 Wiley Alert discussed the granting of an Experimental Use Permit (EUP) by the Biopesticides and Pollution Prevention Division (BPPD) in the U.S. Environmental Protection Agency's (EPA's) Office of Pesticide Programs to Oxitec, Ltd. (Oxitec) for trial releases of a genetically engineered mosquito that significantly reduces populations of the Zika vector mosquito *Aedes aegypti*. As explained in that earlier alert, the Oxitec mosquito, OX5034 *Aedes aegypti*, uses novel genetic technology that causes 100% of female progeny to die during the larval stage of development, thus resulting in significant decreases in *Aedes aegypti* populations. The Oxitec technology has been safely and successfully deployed in Central and South America to reduce disease vector mosquito populations.

On March 7, 2022, EPA approved an expansion and extension of the OX5034 *Aedes aegypti* EUP. EPA BPPD's action extends the 2020 EUP until April 30, 2024 (it had been scheduled to expire in April 2022), and expands the EUP to include four counties in California (Stanislaus, Fresno, Tulare, and San Bernardino). The significance of this action is that Oxitec is now permitted to continue to gather information on the efficacy of the OX5034 *Aedes aegypti* mosquito in reducing mosquito populations in south Florida (which has the greatest mosquito pressure of any area in the contiguous United States). In addition, Oxitec is permitted to begin to gather data on the efficacy of the OX5034 mosquito in California counties that have a different climate than south Florida, but that also have significant mosquito populations.

Practice Areas

Environment & Product Regulation

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The *Aedes aegypti* mosquito is an invasive species from Africa that arrived in the Western Hemisphere during the slave trade. *Aedes aegypti* is a vector for pathogens that cause Zika, Dengue, Chikungunya, and Yellow Fever in tropical and sub-tropical areas. *Aedes aegypti* was the vector for the 2016 Zika outbreak in Florida. Elimination of disease vectors can be an important public health tool in preventing outbreaks. Moreover, as ambient temperatures increase, the range of *Aedes aegypti* in the United States is expanding northwards, which places additional areas at risk of *Aedes aegypti*-vectored diseases.

Mosquito-borne diseases are transmitted entirely by female mosquitoes – male mosquitoes cannot bite. Oxitec's OX5034 *Aedes aegypti* is genetically engineered to not produce female offspring: when an Oxitec male mosquito mates with a female, the surviving progeny are 100% male. As part of the EUP, Oxitec must monitor and sample the test areas to ensure that there are no female OX5034 mosquitoes present (as expected, there were zero detections of females during the first two years of releases in Florida). As the 100% male OX5034 mosquitoes proliferate, there will be a significant decrease in the population of *Aedes aegypti* mosquitoes (including, over time, the OX5034 mosquito). Oxitec's mosquito technologies have been successfully deployed in tropical regions for over a decade.

BPPD conducted a complete risk assessment of the Oxitec OX5034 *Aedes aegypti* release program, including examining whether there would be ecological impacts (including impacts to endangered species) or toxicological impacts. BPPD concluded that, similar to OX5034 release program in South and Central America, no adverse environmental or toxicological impacts are anticipated. However, before the OX5034 mosquitoes can be released in the areas permitted by EPA's EUP, Oxitec must obtain approval for the releases from the Florida Department of Agriculture and Consumer Services and the California Department of Pesticide Regulation.

The progress of the Oxitec OX5034 *Aedes aegypti* mosquito towards regulatory approval in the United States continues to promise significant public health benefits in the battle against Zika and Dengue in the United States. The EPA EUP and supporting regulatory documents are available in Regulations.gov in Docket ID EPA-HQ-OPP-2019-0274. Also, EPA posted a webinar discussing the original EUP risk assessment and approval here.