wiley

ALERT

EPA's Biopesticides and Pollution Prevention Division Grants Experimental Use Permit for Oxitec's Novel Genetic Mosquito Larvacide Technology

May 6, 2020

On May 1, the U.S. Environmental Protection Agency's (EPA) Biopesticides and Pollution Prevention Division (BPPD) granted Oxitec, Ltd. an Experimental Use Permit (EUP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for trial releases of a novel genetically engineered mosquito that significantly reduces populations of the Zika vector mosquito *Aedes aegypti*. The Oxitec mosquito, OX5034 *Aedes aegypti,* uses novel genetic technology that causes all female progeny to die, thus resulting in significant decreases in *Aedes aegypti* populations. Oxitec's new *Aedes aegypti* technology represents a ground-breaking advance in efforts to protect the U.S. from mosquito-borne diseases. Oxitec's technology has been safely and successfully deployed in Central and South America, and the OX5034 EUP is the first step in bringing this life-saving technology to the United States.

The *Aedes aegypti* mosquito vectors pathogens causing Zika, Dengue, Chikungunya, and Yellow Fever. *Aedes aegypti*-vectored diseases have caused untold suffering in tropical and sub-tropical areas of the globe. As global warming causes higher ambient temperatures to expand northward from the equator, the range of *Aedes aegypti* is expanding, including in the United States. Mosquito-borne diseases are vectored entirely by female mosquitoes – male mosquitoes cannot bite and do not take blood meals. Oxitec has developed a novel genetically engineered *Aedes aegypti* that does not produce female offspring: when an Oxitec male mosquito mates with a female, the resulting progeny are 100% male; when these male

Practice Areas

Environment & Product Regulation

Novel Products and Technologies Regulation

progeny mate, again all female progeny die; over time this 100% male reproductive effect leads to a severe diminution of the number of female *Aedes aegypti*, which causes a significant decrease in the population of *Aedes aegypti* mosquitoes. Oxitec mosquito technologies have been successfully deployed in tropical regions for over a decade. The OX5034 technology represents a significant advance from earlier Oxitec technologies, which required that small numbers of female mosquitoes be separated out of the population prior to release (which meant that there was a very small, but greater than zero, possibility that someone might be bitten by an Oxitec female mosquito). With OX5034 *Aedes aegypti* mosquitoes, all females die as larvae, so there is no need to cull females – and there is zero possibility that someone might be bitten. Oxitec has successfully deployed this new *Aedes aegypti* technology in Brazil.

Oxitec has sought approval for release of its genetically engineered mosquitoes in the United States for well over a decade. While the technology was being successfully deployed in Central and South America, Oxitec patiently navigated the labyrinthine U.S. regulatory process. (Oxitec was first directed to seek U.S. approval of its mosquitoes by the U.S. Food and Drug Administration (FDA) as new animal drugs; then, at the end of the Obama administration, regulatory jurisdiction over genetically engineered insects that are intended to diminish pest insect populations was formally established with EPA.) EPA's regulatory review of the OX5034 *Aedes aegypti* EUP application raised a number of novel and unique issues and data requirements. Oxitec was able to work with EPA to address all such issues and requirements such that EPA could determine that trial releases of the OX5034 *Aedes aegypti* mosquito will have no adverse effects to human health or the environment.

That Oxitec now has achieved the first step towards regulatory approval and deployment of this technologically advanced mosquito control technology in the United States is a remarkable achievement and promises significant public health benefits in the battle against Zika and Dengue in the United States. The EUP and supporting regulatory documents are available in Regulations.gov in Docket ID EPA-HQ-OPP-2019-0274.