UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 30, 2020

Keith A. Matthews, Agent
C/O Oxitec, Ltd
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Subject: Experimental Use Permit Issued for 93167-EUP-2 to Allow for Releases of *OX5034 Aedes aegypti* in Florida and Texas.

Experimental Use Permit No.: 93167-EUP-2
OPP Decision No.: 549240
Effective Dates: For OX5034 *Aedes aegypti*: Immediately until April 30, 2022 (pesticide applications and associated activities, e.g., post-release monitoring activities).
Quantity Authorized: 1,266,720,000 OX5034 *Aedes aegypti* mosquitoes, containing 0.012 pounds (5193.56 mg) of tTAV-OX5034.
Acres Involved: 6,600 acres

Dear Mr. Matthews:

On the basis of the information furnished by you, the subject Experimental Use Permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is hereby issued for the release of OX5034 *Aedes aegypti* mosquitoes containing Tetracycline Trans-Activator Variant (tTAV-OX5034) protein and the genetic material (from vector pOX5034) necessary to produce the protein *in vivo*. The EUP, which is authorized only in the states of Florida and Texas, will evaluate efficacy of release of adult and eggs of OX5034 *Aedes aegypti* mosquitoes against wild *Aedes aegypti* mosquitoes within Monroe County, Florida and Harris County, Texas. Shipment and/or use under this permit are subject to the provisions of 40 CFR Part 172.

Prior to shipment and/or use of this material, you must consult with the pesticide regulatory officials of the states in which you will conduct your experimental program and obtain a state permit or license if such is required. Issuance of this Federal permit does not negate the need for permission from individual states. Prior to initiating this experimental program in any state, you are required to notify the lead agency of the states in which you will conduct your experimental program of the specific testing program (when, where, how much, etc.). Failure to obtain that permission may result in revocation or modification of the EUP.

You must provide notice to the state pesticide regulatory agency at least 72 hours prior to the application of this experimental pesticide product. You must also provide a copy of this authorization letter and the stamped, accepted EUP labeling to all cooperators, participants, and users prior to the initial pesticide application made in accordance with this EUP. The U.S. Environmental Protection Agency (EPA) will notify the relevant EPA

Regions of the approval of this EUP by sending copies of this EUP authorization letter and the stamped, accepted EUP labeling to them.

Based on the experimental program submitted, this product may be shipped for use under this EUP to the states of Florida and Texas for the next experimental period, effective immediately until 04/30/2022. Post-release activities (e.g., data collection and post-release monitoring) may continue afterwards as necessary in accordance with the experimental program and terms and conditions below. The acres and amounts permitted per state are as follows:

STATE	ACRES	NUMBER OF MOSQUITOES	POUNDS OF ACTIVE INGREDIENT (mg)
YEAR April 30, 2020 – April 29, 2021			
Florida	3120	508,560,000	0.0046 (2,085.10 mg)
Texas	0	0	0
TOTAL (YEAR 2020-2021)	**3120**	**508,560,000**	**0.0046 (2085.10 mg)**
YEAR April 30, 2021 - April 30, 2022			
Florida	3120	508,560,000	0.0046 (2,085.10 mg)
Texas	360	249, 600,000	0.0023 (1,023.36 mg)
TOTAL (YEAR 2021-2022)	**3480**	**758,160,000**	**0.0069 (3,108.46 mg)**
OVERALL PERMIT TOTAL	**6,600**	**1,266,720,000**	**0.0115 (5193.56 mg)**

You will immediately notify (within 24 hours) the EPA of any findings from the experimental uses that have a bearing on safety (i.e., the EPA requires reporting of any adverse effects from the use of or exposure to pesticides). This includes, among other findings, any violation of the required 500 meter release distances from citrus orchards or municipal sewage treatment plants and detection of female mosquitoes containing the OX5034 genetic construct surviving to adulthood. You will also keep records of production, distribution, and performance, and make the records available on request to any authorized officer or employee of the EPA.

Prior to registration under FIFRA section 3, all data requirements must be satisfied.

The labeling submitted in connection with the application for the EUP is acceptable, and a stamped, accepted copy is enclosed for your records. This labeling must be used for all shipments under this EUP and must be in possession of the user at the time of pesticide application. The following Confidential Statements of Formula (CSF) are acceptable:

Basic CSF dated: 04/28/2020
Alternative CSF dated: 04/23/2020

You must provide a final report at the conclusion of the experiment. This final report shall include all of the items set forth in 40 CFR § 172.8(b)(2). In addition, you must adhere to the following terms and conditions:

1) Releases must not occur within 500 meters of sewage treatment facilities and any farm producing citrus crops.

2) Oxitec must conduct continuous weekly monitoring for fluorescent larvae at release sites as indicated in the section G experimental program (sections 5.2.6.1 and 5.9.4.1). From the reared field-collected individuals, Oxitec must determine the presence of the genetic cassette (vector pOX5034) in a minimum of 150 non-fluorescent adult female *Ae. aegypti* following the standard operating procedures QD-R-00109 or QD-R-00108 once per month. If at any time during the course of the EUP Oxitec finds female individuals containing the OX5034 genetic construct surviving to adulthood Oxitec must take the following remediation actions: immediately cease releases of all OX5034 mosquitoes, as soon as practicable apply adulticide and larvicide pesticides to the treated area where the surviving females were detected and continue to monitor for the presence of the OX5034 genetic construct in female *Ae. aegypti* until OX5034 mosquitoes are no longer found for at least two successive mosquito generations, a minimum of 10 weeks. EPA may require additional applications of adulticides and larvicides if fluorescent mosquitoes continue to be found in the treated area after the initial detection.

3) If evidence is found of invasive *Aedes* spp. or arboviruses principally vectored by *Ae. aegypti* becoming established in the UK, colony related testing will be required.

4) As indicated in the section G experimental program (sections 5.3.1 and 5.10), Oxitec must conduct post-release monitoring until no fluorescent OX5034 mosquitoes have been found for at least two successive generations, a minimum of 10 consecutive weeks.

If you have any questions regarding this permit, please contact Eric Bohnenblust by phone at (703) 347-0426 or via email at Bohnenblust.eric@epa.gov.

Sincerely,

Richard P. Keigwin, Jr., Director
Office of Pesticide Programs

Enclosure

cc: Randy Dominy, EPA Region 4 (Florida)
Kenneth McPherson, EPA Region 6 (Texas)