



FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
COMMISSIONER NICOLE "NIKKI" FRIED

May 03, 2022

Nathan Rose, DPhil
Head of Regulatory Affairs
Oxitec, Ltd.
71 Innovation Dr.
Milton Park, Abingdon
OX14 4RQ
United Kingdom

SUBJECT: EXPERIMENTAL USE PERMIT OX5034 *Aedes Aegypti* (EPA EUP NO. 93617-EUP-2)
Active Ingredient: OX5034 *Aedes Aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein and the genetic material (from vector pOX5034)
For evaluation of the active ingredients' effectiveness in suppressing and eliminating *Aedes aegypti* mosquitoes in Monroe County, Florida.

On the basis of your application and data submitted, we hereby authorize the distribution and experimental use of the above-mentioned product in Florida. This permit has been assigned **EUP No. 93167-EUP-2** and is authorized for use in the state of Florida through **April 30, 2024**.

The following conditions are placed on this experimental use permit:

- 1) Oxitec, Ltd. (Permittee) is responsible for ensuring that distribution and use of this product shall be limited to authorized participants and cooperators.
- 2) Permittee is responsible for assuring that all requirements specified in sections 5E-2.031, Florida Administrative Code and 40 CFR 172, are adhered to.
- 3) Participants and cooperators shall be submitted to the Florida Department of Agriculture and Consumer Services (FDACS) prior to initiation of experimentation.

- 4) Specific treatment sites shall be submitted to the Florida Department of Agriculture and Consumer Services (FDACS) prior to initiation of experimentation.
- 5) The permittee shall inform FDACS 72 hours prior to each application. Notification should include the location, date, and time.
- 6) Permittee and/or authorized participants and cooperators shall make all applications in accordance with the approved submitted protocol, all applicable directions, restrictions, and precautions on the accepted EUP label and as is required on the Federal Experimental Use Permit.
- 7) A copy of this permit, labeling and the experimental protocol must be furnished to, and in the possession of the participants and cooperators before applications are made.
- 8) The permittee shall notify FDACS within 24 hours of any adverse effects, including but not limited to those defined in the Federal Experimental Use Permit.
- 9) The permittee shall submit an interim report for OX5034 *Aedes Aegypti* detailing the results of this experimental program must be submitted by May 31, 2023.
- 10) The permittee shall submit a final report for OX5034 *Aedes Aegypti* detailing the results of this experimental program by October 31, 2024.
- 11) Note that although this permit is authorized through April 30, 2024, all permits expire biennially on December 31 and must be renewed by payment of the applicable fees as required by payment of the applicable fees as required under Chapter 487, Florida Statutes. This means a \$200 fee is required by January 31, 2023, for continued use of OX5034 *Aedes Aegypti* in the state of Florida for the duration of the trial.

Please send any future correspondence regarding this matter to Laura Ritchie, Pesticide Coordinator, via telephone at (850)617-7947 or via email at laura.ritchie1@fdacs.gov.

Oxitec Ltd.
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Sincerely,

Rashmi Singh, Ph.D.
Environmental Administrator
Pesticide Registration Review Section

RS/lr

Attachments: EUP label, Federal Experimental Use Permit

cc: Mr. Alan Edwards
Ms. Kelly Friend
Ms. Courtney Frazier
Mr. Michael Bauman
Mr. Randy Dominy
Mr. Gerald Everton
Mr. Neil Richmond
Ms. Amy Brown
Dr. James Cooper
Dr. Trevor Smith
Ms. Marah Clark
PREC Members