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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

April 30, 2020

MEMORANDUM

SUBJECT: EPA's Response to Comments Received on the September 11, 2019, Notice for an Experimental Use Permit Application for OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) Protein.

FROM:

Elizabeth Milewski, Ph.D., Senior Policy Advisor
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

ELIZABETH MILEWSKI Digitally signed by ELIZABETH MILEWSKI Date: 2020.04.30 15:52:10 -04'00'

Eric W. Bohnenblust, Ph.D., Senior Biologist
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

ERIC BOHNENBLUST Digitally signed by ERIC BOHNENBLUST Date: 2020.04.30 15:10:37 -04'00'

Wiebke T. Striegel, Ph.D., Senior Scientist
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

Digitally signed by WIEBKE STRIEGEL Date: 2020.04.30 16:00:30 -04'00'

Amanda A. Pierce, Ph.D., Biologist
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

Kara Welch, M.S. Biologist
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

Chris A. Wozniak, Ph.D. Biotechnology Special Assistant
Immediate Office
Biopesticides and Pollution Prevention Division

THROUGH: Mike Mendelsohn, Chief
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division

TO: Robert McNally, Director
Biopesticides and Pollution Prevention Division

BACKGROUND

On September 11, 2019, the Environmental Protection Agency (EPA) in the Federal Register (84 FR 47947) announced receipt of an application 93167-EUP-E from Oxitec Ltd., requesting an experimental use permit (EUP) for the OX5034 *Aedes aegypti* mosquitoes expressing tetracycline trans-activator (tTAV-OX5034) protein. Pursuant to 40 CFR 172.11(a), the Agency determined that the application may be of regional and national significance and sought public comment on the application.

EPA's September 11, 2019 announcement indicated that Oxitec is proposing to test OX5034 *Aedes aegypti* mosquitoes expressing tTAV-OX5034 protein in the states of Florida and Texas on up to 6600 total acres at a maximum rate of 0.000056 g active ingredient (tTAV-OX5034), equivalent to 20,000 male OX5034 mosquitoes, per acre per week. The proposed experiments are to evaluate the efficacy of OX5034 mosquitoes as a tool for suppression of wild *Aedes aegypti* mosquito populations. Female offspring of the OX5034 mosquitoes in the environment are expected to die before they mature into adults and therefore exposure to biting female mosquitoes is not anticipated.

Thirty-one thousand, two hundred thirty-five comments were received in response to the September 11, 2019 Federal Register Notice. Three hundred and forty eight comments were posted for public view at www.regulations.gov. One of the posted comments carried 25,577 signatures (submitted by Friends of the Earth 0345). In addition, another 5,310 comments were received as part of a mass mail campaign but were not made available in public view at www.regulations.gov; these comments were identical to comment 0329, that is posted in public view. In the attached *Response to Comments* document EPA treats comment 0329 as representative of the 5,310 mass mail campaign comments received but not posted in the public view. In the attached *Response to Comments* document EPA is providing a summary of comments received on the announcement, and EPA's response to those comments.

ORGANIZATION OF RESPONSE TO COMMENT DOCUMENT

The attached *Response to Comments* document is organized into several main sections, overview of comments including those supporting issuance and expressing opposition to issuance, comments pertaining to the characteristics of OX5034, the potential for introgression of OX5034 genetics into local wild *Aedes aegypti* populations, whether OX5034 female mosquitoes will be present in test areas, human health considerations, environmental risk considerations, ability of OX5034 to produce the desired result including efficacy, trial parameters, calls for additional testing prior to approval, and recommendations on actions that could be taken by EPA. Each of these main sections is divided into subsections of topics of additional specificity. Within specific topics, EPA grouped text from comments pertaining to the topic, illustrated the topic using quotes taken from comment and generated one response to each group of comments.

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