



September 30, 2021

OPP Docket
Environmental Protection Agency Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Docket ID No. EPA-HQ-OPP-2019-0274. Pesticide Experimental Use Permit; Receipt of Application; Comment Request

Dear Sir or Madam:

The Biotechnology Innovation Organization (BIO) submits these comments in response to the U.S. Environmental Protection Agency's (EPA) request for public input on the receipt of an application, 93167-EUP-2, from Oxitec Ltd requesting to amend and extend of an experimental use permit (EUP) for the OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant protein.¹ The mosquitoes are proposed to be released in Florida and California to evaluate the efficacy of the mosquitoes as a tool for suppression of wild *Aedes aegypti* mosquito populations. The release would be an amendment and extension of an EUP authorized in April 2020.

BIO is the world's largest bioscience trade association representing roughly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents many of the agricultural biotechnology product developers in North America.

BIO strongly supports the development of innovative products to address issues of critical importance to society, including those like the product developed by Oxitec with the potential to provide benefits to human and animal health in the fight against vector-borne diseases. Regulatory oversight of products of biotechnology should be science-based and risk-proportionate in order to protect human health and the environment, and should allow timely entry into the marketplace of innovative products with potential benefits to human health and the environment.

Thank you for the opportunity to provide comments on this application. Please feel free to contact me directly if you have any questions about our comments.

¹ 86 FR 48692 (August 31, 2021).



Sincerely,

A handwritten signature in black ink, appearing to read "Clint Nesbitt", with a long horizontal stroke extending to the right.

Clint Nesbitt
Senior Director, Science and Regulatory Affairs, Agriculture and Environment, BIO
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