April 13, 2016

Center for Veterinary Medicine (HFV-2)
Food and Drug Administration
7500 Standish Pl.
Rockville, MD


Dear Dr. Brinda Dass,

The American Biological Safety Association (ABSA) International welcomes the opportunity to comment on the Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes. ABSA International provides critical expertise for this topic as many of its members are extensively involved in programs involving vector borne and zoonotic diseases.

ABSA International has reviewed the environmental assessment and provides the following comments for your consideration:

ABSA agrees with the preliminary finding of no significant impact and does not consider the proposed investigational release for field trial of recombinant mosquitoes in Florida to be a safety concern to humans or the environment. The investigational release of recombinant mosquitoes is an important trial which could have significant impact in controlling the spread of vector borne diseases. The risk assessment provided is thorough in addressing the environmental impact and acceptable controls are indicated to limit the spread of the new strain.

Concern: The goal of this trial is to decrease the population of *Aedes aegypti* mosquitoes, thereby reducing vectors of Zika and other viruses, such as Dengue and Chikungunya. It needs to be considered whether reduction in population of *Aedes aegypti* mosquitoes could result in an increase in the population of competing mosquito species such as *Aedes albopictus* that can also transmit these viruses.

Additionally, while not directly related to the evaluation of the safety of this proposed field trial, it may be questionable as to whether this is an economically practical method of ongoing control of mosquitoes that
can transmit these and other viruses compared with traditional chemical mosquito control methods.

Thank you again for the opportunity to comment on this matter. This letter is respectfully offered for your consideration.

Sincerely,

Melissa Morland, MS, RBP, CBSP
President, American Biological Safety Association