WOLBACHIA AND OXITEC MOSQUITO REGISTRATIONS

ISSUE/TOPIC: Biotechnology, Pesticides, Wolbachia, Bacteria and Genetically Engineered Mosquitos

BACKGROUND:

- The EPA registers biopesticides, which include alterations of mosquito species to reduce mosquito populations. Two technologies involve release of sterilized male mosquitos. When the altered mosquitos are released and mate with wild female mosquitos, the offspring are not viable.

- One technique introduces Wolbachia bacteria, found naturally in many insect species, into male mosquitos. On November 3, 2017, EPA announced the registration of the new mosquito biopesticide, ZAP Males®, that can reduce local populations of the type of mosquito (Aedes albopictus, or Asian Tiger Mosquitoes) that can spread numerous diseases of significant human health concern, including the Zika virus. ZAP Males® are live male mosquitoes that are infected with the ZAP strain, a particular strain of the Wolbachia bacterium. Infected males mate with females, which then produce offspring that do not survive.

- The time-limited registration allows MosquitoMate, Inc., to sell the Wolbachia-infected male mosquitoes for five years in the District of Columbia and the following states: California, Connecticut, Delaware, Illinois, Indiana, Kentucky, Massachusetts, Maine, Maryland, Missouri, New Hampshire, New Jersey, Nevada, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Vermont, and West Virginia. When the five-year time limit ends, the registration will expire, unless the registrant requests further action from EPA.

- The EPA is also reviewing an experimental use permit (EUP) amendment/extension for Wolbachia WB1 strain in *Aedes aegypti* mosquitoes to add new sites in Texas and Florida where Zika could be present, as well as a new manufacturing process for producing male mosquitoes for release. The EPA anticipates being able to make a decision in April 2018.

- Another technique involves genetically engineered *Aedes aegypti* mosquitoes. This so-called "Oxitec" mosquito is now regulated by EPA as a pesticide and has yet to be approved for general use. FDA finalized guidance on 10/4/2017 that provided information on FDA and EPA jurisdiction over the regulation of mosquito-related products intended to function as pesticides, including those produced through the use of biotechnology., [HYPERLINK "https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm578420.htm"].
- At present, EPA can accept any Oxitec pesticide related application, e.g. fora pesticide experimental use permit, for a pesticide registration, etc.

- Congressional Inquiries: Sen. Inhofe submitted an inquiry to the EPA supporting approval of the "Oxitec" mosquito.

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TALKING POINTS:

- The EPA recently registered Wolbachia ZAP Males®, that can reduce local populations of Aedes albopictus, or Asian Tiger, mosquitoes and is reviewing an experimental use permit (EUP) amendment/extension application for Wolbachia WB1 strain in *Aedes aegypti* mosquitoes.EPA is also nvolved in discussions with a potential registrant of a product using Oxitec Male Mosquitoes.
- Oxitec's genetically engineered mosquitos and MosquitoMate's Wolbachia mosquitoes are emerging biotechnology pesticides that could be used to combat the spread of vector-borne diseases, such as Zika.

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