



BEYOND PESTICIDES

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September 27, 2017

Environmental Protection Agency
Office of Pesticide Programs
Docket Center (EPA/DC), (28221T),
1200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001.

Re: Pesticide Product with a New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes). Docket Number EPA-HQ-OPP-2016-0205

With recent threats from the Zika virus and other mosquito-borne diseases there have been nationwide discussion on how best to contain and eliminate these threats. Naturally, there are elevated concerns regarding mosquito-borne diseases and the subsequent aerial and ground adulticiding to control mosquito populations. Current chemical control options have been shown to be hazardous to human health and threatening to non-target species. Organophosphate and pyrethroid adulticides are commonly used for vector control management. Organophosphate agents like naled are neurotoxic cholinesterase inhibitors (an important enzyme needed for the proper functioning of the nervous system), which causes rapid twitching of muscles, paralyzed breathing, convulsions, and in extreme cases, death. Permethrin and other synthetic pyrethroids used as adulticides are associated with cancer, hormone disruption, and reproductive effects, and thus have hazard and exposure concerns regarding widespread application for mosquito control. It is paramount that the public's health is safeguarded from unnecessary exposures to such neurotoxins.

We have learned that in pest management there are typically no quick fixes that are sustainable and fully protective of public health. In this context of a new proposed biological control for mosquitoes, we want to: (i) ensure complete testing of the potential range of adverse biological effects (A naturally occurring bacterium that is known to have several different effects on an insect's reproductive system and is considered a "symbiont" certainly has possibilities for coevolving with its host in ways that benefit the mosquito and the bacterium.); and (ii) forcefully advance an integrated approach to mosquito management that supports prevention strategies, which manage breeding areas in communities and around homes, and educates on steps individuals can take, including protection from mosquito bites (Any program that suggests there is a silver bullet strategy to controlling mosquitoes will suppress important community-wide efforts that are needed to prevent mosquito breeding.)

This new proposed mosquito management tool will utilize the microbial pesticide, *Wolbachia pipientis* ZAP strain (ZAP Males®), to render a reduction in successive mosquito generations. This bacterium will be applied to male mosquitoes that will then be released to mate with wild females. The subsequent larvae will be unable to mature into adult mosquitoes, thus reducing populations. According to the agency, *Wolbachia pipientis* is naturally present in many arthropod species and was first discovered in the mosquito, *Culex pipens*. This strain (ZAP *W. pipientis*) will be used to specifically infect *Aedes albopictus* mosquitoes- a mosquito that is known to carry and transmit dengue, chikungunya, and even Zika, but to a lesser extent than its cousin *Aedes aegypti*.¹

There is promise in this novel technique in reducing mosquito populations without the reliance on hazardous chemical controls. We must continue to find novel strategies to combat vector-borne diseases without chemicals that pose further risks to human and wildlife populations. However, there are still questions regarding the use of this new product that we believe should prompt the agency to take a precautionary approach. There is little independent data on the overall efficacy of the *Wolbachia pipientis* ZAP strain, and we therefore do not know how effective the release of significant numbers of *W. pipientis*-infected mosquitoes will have on competing with wild males and successfully breeding with females. How many females would need to encounter an infected male to render a sufficient reduction in healthy larvae? Will these mosquitoes be applied to areas that will continue adulticiding activities, thereby eliminating *W. pipientis*-infected mosquitoes from the area and reducing efficacy?

There are questions around the use of naturally-occurring bacterium to suppress insect populations and the onset of resistance. This has been seen previously with *Bacillus thuringiensis* (Bt) in other species. Does the agency have a plan to mitigate the onset of resistance?

Further, while male *Aedes albopictus* are to be released, there is a possibility of the unintended release of infected females. The registrant estimates there may be a female contamination factor of one female per 250,000 males,² but since visual checks are to be employed to identify female contamination, we can expect this number to be much higher. Female mosquitoes bite and infect their human host with viruses, and whether there is a human risk from being exposed to *W. pipientis* is not known or has been considered. EPA believes the gender separation technique employed by the registrant to be “highly efficient” and that there will be “negligible exposure” to infected females and subsequent human health

1 CDC. Estimated range of *Aedes aegypti* and *Aedes albopictus* in the United States, 2017
<https://www.cdc.gov/zika/vector/range.html>

2 EPA. 2017. Human Health Assessment, Review of the MosquitoMate Inc., Updated Manufacturing Process, ZAP strain Origin Validation, and Sex Separation data to the Section 3 Registration of the ZAP strain *Wolbachia pipientis* in *Aedes albopictus*. Office of Pesticide Programs. Washington DC.

risk.³ We believe a thorough human health assessment for *W. pipientis* is still warranted and must be conducted.

The registrant, MosquitoMate Inc., has submitted a section 3 registration petition, including the ZAP strain Wolbachia-infected male mosquitoes for the product, ZAP Males®. Under the *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA), EPA has a responsibility to ensure that this product does not pose unreasonable adverse effects to the environment. In EPA's response document to comments received in 2016,⁴ several commenters raised valid concerns we believe the agency has to address. There is concern for potential non-target ecological effects where Wolbachia may affect insects in the environment by changing behavior, disease transmission, gene expression and biology. More information is needed on any unintended ecological impacts.

Overall, we are optimistic about this new mosquito control method. Paramount is the need for strategies to reduce our reliance on toxic pesticides for vector control. If used in tandem with other non-chemical methods and community-based participation, the *Wolbachia pipientis* ZAP strain could be part of an effective strategy to reduce mosquito populations. However, we urge EPA to remain vigilant and use caution with this new technology, conduct a full human health assessment, and consider the potential for resistance and ecological impacts. We look forward to working with the agency on finding new least-toxic options for mosquito control to safeguard human health and that of the environment.

Respectfully,

A handwritten signature in blue ink, appearing to read 'NH', is positioned above the name of the signatory.

Nichelle Harriott
Science and Regulatory Director

³ Ibid

⁴ EPA. 2017. EPA's Response to Comments Received on the April 28, 2016 Notice for the Pesticide Product Application with a New Active Ingredient Wolbachia pipientis ZAP strain in Male Aedes albopictus (Asian Tiger Mosquito)(EPA File Symbol 89668-U)-(Docket ID Number: EPA-HQ-OPP-2016-0205; FRL-9945-49). Office of Pesticide Programs. Washington DC.