PUBLIC SUBMISSION

As of: 9/26/17 5:01 PM
Received: September 19, 2017
Status: Posted
Posted: September 19, 2017
Tracking No. 1k1-8yr2-xn02
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-0023
Anonymous public comment

Submitter Information

General Comment

Please approve! We need everything we can get to decrease the use of pesticides!

PUBLIC SUBMISSION

As of: 9/26/17 5:17 PM
Received: September 25, 2017
Status: Draft
Tracking No. 1k1-8yv5-weue
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0030
Comment on EPA-HQ-OPP-2016-0205-0012

Submitter Information

General Comment

Wolbachia bacteria have been transmitted from blood sucking insects to humans for thousands of years. There is no evidence that Wolbachia pipientis can infect vertebrates, or cause diseases in humans. Yes, please register the ZAP mosquito with EPA as a biocontrol agent to control disease carrying mosquitoes. Field releases in Australia shows that Wolbachia sterilized male mosquitoes do reduce disease carrying mosquito populations.

Attachments

Assessing key safety concerns of a Wolbachia-based strategy to control dengue transmission by Aedes mosquitoes

PUBLIC SUBMISSION

As of: 9/26/17 5:03 PM
Received: September 20, 2017
Status: Pending_Post
Tracking No. 1k1-8yrw-665a
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0029
Anonymous public comment

Submitter Information

General Comment

Do not allow this chemical to be used. The current juvenile hormones work very well
To control mosquitoes.

PUBLIC SUBMISSION

As of: 9/26/17 5:04 PM
Received: September 19, 2017
Status: Pending_Post
Tracking No. 1k1-8yr5-i1sm
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0028
Anonymous public comment

Submitter Information

General Comment

Please do not approve! More research needs to be done on the biological and ecological effects the release of these mosquitoes will have on every ecosystem that they will be released into. Just one example is how they will effect struggling bat and fish populations that rely on mosquitoes and there larva for there main food source!

PUBLIC SUBMISSION

As of: 9/26/17 5:09 PM
Received: September 25, 2017
Status: Draft
Tracking No. 1k1-8yv9-3hu2
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0031
Comment on EPA-HQ-OPP-2016-0205-0012

Submitter Information

Submitter's Representative: Joseph M Conlon
Organization: American Mosquito Control Association

General Comment

The American Mosquito Control Association is pleased to post the attached comment to the docket in support of registration of the ZAP Strain in male Aedes albopictus.

Attachments

ZAP Registration

AMCA
THE AMERICAN MOSQUITO CONTROL ASSOCIATION

Individuals enhancing the health and quality of life through the suppression of mosquitoes, other vectors and pests of public health importance.

A Partner in the EPA's Pesticide Environmental Stewardship Program

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TECHNICAL ADVISOR
Joseph Conlon

26 September 2017

Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001

Attention Docket ID No. EPA-HQ-OPP-2016-0205.
Pesticide Product with a New Active Ingredient (*Wolbachia pipientis*, ZAP Strain in male *Aedes albopictus* (Asian tiger mosquitoes)

The American Mosquito Control Association (AMCA) is submitting these comments in response to an EPA issuance of a notice requesting comment on the porposed registration of a new biopesticide to help control the spread of Zika and other viruses.

The AMCA is a not-for-profit professional association of 1600 public health officials, academicians, county trustee/commissioners and mosquito control professionals dedicated to providing leadership, information and education leading to the enhancement of health and quality of life through the suppression of mosquito and other vector transmitted diseases and the reduction of annoyance levels caused by mosquitoes and other vectors and pests of public health importance. This is accomplished, in part, through the use of duly registered public health pesticides.

The vector control community represented by the AMCA requires an extensive range of tools in order to fully comport with integrated mosquito management strategies. As the number and type of vector control products increases, more options are available to officials charged to protect public health to do so in an effective and environmentally-compatible manner. Indeed, mosquito control organizations function most efficiently when a range of prevention/control alternatives is available - for the following reasons:

1. Public health officials require a variety of tools, including chemical control methods, for resistance management.
2. Innovation in control strategies and products should be encouraged so that manufacturers will take risks to bring them to market.

AMCA – American Mosquito Control Association
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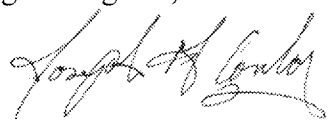
3. The 182 recognized mosquito species thrive in a variety of habitats across the breadth of the country – often requiring widely divergent prevention/control methodologies to effect proper control in addition to reducing environmental impact and effects on different non-targets.
4. Emerging control problems e.g. Chikungunya and Zika in the Caribbean, *Ae. albopictus* expanding its territory throughout the U.S. and dengue expanding globally will require product innovation to meet the challenges.
5. Effective community-based control programs are rare and the unique circumstances required for their success are only found in limited venues. Thus, a wide menu of options must be available to governmental mosquito control programs that cannot rely upon the full participation of comprehensive community-based mosquito prevention. This, in turn, argues for an expanded range of available control options and products to meet disease prevention needs.

The AMCA recognizes that suppression of *Aedes albopictus* populations in the northern tier of states is critical given pesticide resistance management concerns and the difficulty inherent in applying Ultra Low Volume treatments in urban areas. The use of ZAP males obviates these concerns and would be therefore a welcome addition to our control inventory. For this reason alone the AMCA fully supports the registration of MosquitoMate ZAP Males in accordance with EPA's label restrictions.

The AMCA fully supports a thorough, transparent, scientifically rigorous risk assessment and labeling process, from which regulators and pesticide users derive valid and reliable cost/benefit formulae that fully account for environmental impact while allowing appropriate vector-borne disease control. Critical to this process is a full realization of the unique properties that some adulticiding tools possess that make their application crucial in the control of mosquito-borne disease. The AMCA believes that *Wolbachia*-based mosquito population suppression fills a vital niche in our mosquito control inventory and the registration of ZAP males as a biopesticide constitutes a unique and much-needed adjunct to standard mosquito control methodologies.

Disease prevention through preparedness remains the mosquito control profession's primary focus, and is fully consistent with the very finest traditions of public health. We must remain prepared to accept and meet these challenges. The registration of ZAP Males for wide-area mosquito control is a definitive step in that direction.

Highest regards,



Joseph M. Conlon
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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 then 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,

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.

CENTER FOR
FOOD SAFETY

Date: September 27, 2017

TO: EPA via Regulations.Gov

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

FROM: Jaydee Hanson, Senior Policy Analyst

The Center for Food Safety has closely reviewed the data provided by the company MosquitoMate from trials in Kentucky, California, New York and Florida. We generally agree with the EPA's assessment that the ZAP Males® [active ingredient Wolbachia ZAP (also called wPip) strain], are not likely to cause significant human health or environmental effects when released in a larger trial. However, we do think that some additional tests should be required of the company prior to the EPA issuing an unconditional registration for this new biopesticide.

1. Gender separation review needs to evaluate robotic separation:

We agree that the current procedures for separating male from female mosquitoes appear to be sufficient. However, given that MosquitoMate is partnering with Google's Alphabet/Verily to use its Verily robotic processes to transfer the Wolbaccia to male mosquitoes[2], it seems prudent to require a future assessment of the efficiency of the robotic process. There is mention of a "mechanical" sorting device at 3.1.2 (see page 9 of 17 in EPA HQ OPP-2016-0205-0021)[3], but no discussion of the Verily robotic device now being used in a partnership between MosquitoMate and the Google owned robotics company. If the mechanical device is not the Verily robot, then a review of the efficacy of the robotic gender separation must be performed prior to the approval of these mosquitoes for wide use.

2. Geographical range of the trial is inappropriate:

Geographic restriction is one of the standards for biosafety review. In short, geography can serve to limit the spread of the new organism. The rationale used to determine in which states this five year trial would occur is inadequate. The report states: "BPPD [Biopesticides and Pollution

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Prevention Division] identified that efficacy data generated in more northern climate regions of the U.S. cannot be extrapolated to infer expected efficacy of this product in southern U.S. climate regions, which are considered high mosquito population pressure areas for Ae. albopictus." However, the proposed states for release include several states (TN, MD, DC, DE and KY) where all or a significant part of the state is situated in the south U.S. climatically. Even though Kentucky was one of the states where the early trials were conducted, the area of the state around the Mississippi River is very "southern" in climate and should be excluded from future trials. A better "mapping" of where this large trial could take place would assess the climatic conditions on a county, not state basis. Or alternatively, a standard source, such as the USDA plant hardiness zones, could be used a proxy for areas where hard freeze might prevent year around mosquito breeding.[4] Relying on state boundaries alone is insufficient. Either find a better method of selecting states for the trial, or exclude TN, MD, DC, DE and western KY. Moreover, much of California, especially the Central Valley and most of Southern California, should be considered "southern" areas, where there is a high likelihood of the mosquitoes breeding throughout the year.

3. BPPD's review of efficacy data on male releases of Ae. albopictus infected with ZAP strain Wolbachia to support homeowner use[5]:

The one small study examined by the BPPD on homeowner use of the ZAP strain males does not provide enough data to support the efficacy of having homeowners release the mosquitoes. The mosquitoes should be released only by a mosquito control district or a mosquito control professional company.

4. Clarify whether the suggestion of "IVM-integrated vector management" in the amended efficacy review [6]is a requirement of the approval:

The BPPD notes that, "A Wolbachia ZAP male release program for Ae. albopictus has the potential to reduce the female mosquito density over time and, therefore, can provide societal benefits. BPPD concludes that MosquitoMate should combine their ZAP male releases with an integrated vector management (IVM) approach (e.g., use sequentially with larvacide and/or adulticide treatments) in order to increase their efficacy (or % reduction in females) and to generate more consistent results. As an IVM tool, the proposed product would also provide environmental benefits because it could result in a reduction of chemical pesticide applications for mosquito control." Is this a requirement for further trials and registration of MosquitoMate's products or is this just a suggestion?

Conversely, the BPPD notes, "In future trials, MosquitoMate needs to assure that 1) control and treated sites are separated by approximately 800 m, 2) baseline (a priori) monitoring of mosquito pressures occurs in the presence of uniformly applied mosquito abatement, and 3) treated and control sites occur in the same general suburb with similar characteristics (e.g. socio economics, human density, mosquito abatement, etc.)." This reads like a requirement.

5. Human Health Assessment

The Human Health Assessment[7]only examines whether the MosquitoMate ZAP mosquito can transmit arboviruses as it is being presently raised. Given that there will be considerable variability in how conditions are established in a dozen states where the mosquitoes will be bred in the future, regular testing for arboviruses such as West Nile, known to be present in these states, should be a part of future trials. It is noted that the blood that female mosquitoes are fed during the rearing process is tested for the arbovirus vesicular stomatitis. This needs to be expanded to include testing for all arboviruses known to be in the area.

Thank you for your review of our comments.

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[2] https://www.technologyreview.com/s/608280/alphabet-has-built-a-robot-that-is-releasing-millions-of-sterile-mosquitoes-in-california/

[3]https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0205-0021

[4] http://planthardiness.ars.usda.gov/PHZMWeb/Images/All_states_halfzones_poster_300dpi.jpg

[5] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0205-0014

[6] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0205-0017

[7] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0205-0018

PUBLIC SUBMISSION

As of: 9/26/17 5:06 PM
Received: September 26, 2017
Status: Draft
Tracking No. 1k1-8yvv-kpwz
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0032
Comment on EPA-HQ-OPP-2016-0205-0012

Submitter Information

General Comment

To Whom It May Concern,

I am writing to you today on behalf of the more than 6,000 members of the Entomological Society of America (ESA) regarding the Notice of Public Comment Period for "Pesticide Product with a New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes) - FIFRA)," Docket Number EPA-HQ-OPP-2016-0205.

After consultation with Dr. Allan Felsot (Washington State University) - ESA's subject matter expert and liaison with the EPA's Office of Pesticide Programs, and other experts within the Society, ESA offers the comments below regarding the registration application.

Because Wolbachia, the product being registered, is a naturally occurring bacterium and because the registration of Wolbachia is not significantly different than the registration for any other biopesticide, the ESA does not have any findings of significant concern with regards to this registration. It is important to note that ESA is not endorsing the technology underlying the ZAP product nor the ZAP Strain as a product. Rather, we are endorsing the scientific approach which supports this registration application and regulatory evaluation process.

The ESA has long called for the development of additional methods to manage mosquitoes and other arthropod pests. We need to develop management systems that are sustainable over many decades as well as outreach programs that enlist individuals in every community at risk to engage in management efforts. This registration will provide one more tool in the mosquito management toolbox.

The ESA recently published a fact sheet on the topic of non-chemical approaches to mosquito management (http://www.entsoc.org/policy-initiatives/esa-fact-sheets) which may prove to be of value to you as you review this application.

We thank you for the opportunity to provide comments on this issue and seek to remain a resource for the Agency, should you need expert opinion on any topic of entomological importance.

Sincerely,

Susan J. Weller, Ph.D.
President, ESA

Attachments

ESA-comments-EPA-docket-registration-ZAP-males

ESA-Modern-mosquito-management-fact-sheet

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September 27, 2017

OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. N.W.
Washington, DC 20460-0001

Re: Public Participation for New Active Ingredient (*Wolbachia pipientis*, ZAP Strain in male *Aedes albopictus* (Asian tiger mosquitoes) – FIFRA)
(Docket No. EPA-HQ-OPP-2016-0205)

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We thank you for the opportunity to provide comments on this issue and seek to remain a resource for the Agency, should you need expert opinion on any topic of entomological importance.

Sincerely,

Susan J. Weller

Susan J. Weller, Ph.D.
President, ESA

Fighting Fire With Fire:

How Science is Turning Mosquitoes Against Themselves

There is no single "silver bullet" to adequately manage mosquitoes that carry viruses such as Zika, dengue, and West Nile, but today's mosquito management toolbox contains more than it did even just a few years ago. Entomologists and pest professionals use a broad array of tactics such as habitat manipulation and chemical insecticide in their integrated pest management (IPM) programs, and they may soon have three new options at their disposal to either manage mosquito populations or interfere with disease transmission.

Fine-Tune Mosquito Genes So They Can't Breed

Scientists have developed methods to precisely alter the genomes of male mosquitoes so that they pass a gene to their offspring that prevents them from becoming adults. Male mosquitoes do not bite, but they do mate with females (the ones guilty of biting and transmitting disease). Thus, when these modified males are released in large numbers and mate with wild females, their offspring die before becoming adults. Successful application of this technique has been shown to lower mosquito populations by over 90 percent.

An important advantage of this tactic is that it can target only one species in a localized area. (In its lifetime, an *Aedes aegypti* male mosquito's range is typically just 30-100 meters). However, once the males are no longer released, the population will return. To keep populations suppressed, modified male mosquitoes must be released on a recurring basis.

The U.S. Food and Drug Administration has conducted a thorough assessment of the risks to people and the environment of releasing genetically engineered male mosquitoes, and it published a finding of no significant impact, concluding that their use "is not expected to cause any significant adverse impacts ... beyond those caused by wild-type mosquitoes."

Infect Mosquitoes With Bacteria So They Can't Breed

While harmless to humans, the bacterium known as *Wolbachia* naturally infects more than half of all known insect species. *Wolbachia* is naturally common because it manipulates the reproduction of insect hosts: When an uninfected female mates with a *Wolbachia*-infected male, her eggs will not hatch. However, a female infected with *Wolbachia* will pass it down to her offspring after mating with any male mosquito of the same species. This natural phenomenon can be employed by entomologists to establish *Wolbachia* infections in several mosquito species, including those of medical importance.

One technique using *Wolbachia* is similar in concept to the genetic-modification method in that it relies on releasing specially raised, *Wolbachia*-infected male mosquitoes to breed with wild females causing them to produce eggs that do not hatch. The mosquito population is therefore reduced.

Although effective, this method of population reduction is sustained only through ongoing introduction of *Wolbachia*-infected males.

In the U.S., *Wolbachia*-based methods are currently regulated by the Microbial Pesticide Branch of the Environmental Protection Agency. To date, the population replacement method has not been used in the U.S., but it has been regulated and used in Australia, Brazil, and other countries.

Infect Mosquitoes With Bacteria So They Can't Transmit Disease

Wolbachia has also been shown to interfere with the ability of mosquitoes to carry pathogens and transmit diseases by boosting the mosquito immune response or by competing for the resources available to a virus inside a mosquito. A second technique uses this *Wolbachia* trait to replace a wild mosquito population with *Wolbachia*-infected mosquitoes that have reduced capacity to transmit disease. It does, however, require that at least some of the introduced, *Wolbachia*-infected mosquitoes be females, which will bite and feed on blood.

Because mosquito offspring acquire *Wolbachia* from their mother, a *Wolbachia* infection that is established and spread into a population of mosquitoes can be maintained, meaning additional introductions of *Wolbachia*-infected mosquitoes are not required.

Infected females can successfully reproduce with both infected and uninfected males; however, uninfected females can only produce offspring if they mate with uninfected males. Since uninfected males become increasingly rare over time, eventually the mosquito population will be unable to transmit viruses. This population replacement technique does not significantly reduce the number of mosquitoes, but it does interrupt disease transmission.

The Entomological Society of America is the largest organization in the world serving the needs of entomologists and other insect scientists. ESA stands as a resource for policymakers and the general public who seek to understand the importance and diversity of earth's most diverse lifeform—insects. Learn more at www.entsoc.org.

Photo credit: James Gathany, CDC Public Health Image Library

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September 27, 2017

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Submitted Electronically to http://www.regulations.gov

Re: Submission to Docket EPA-HQ-OPP-2016-0205

Dear Dr. Tapken:

Oxitec Ltd. (Oxitec) submits the accompanying comments on the proposal to register ZAP male mosquitoes as an end-use pesticide product (File Symbol 89668-U). Oxitec appreciates the opportunity to submit these comments as part of the Office of Pesticide Program's public participation process for new pesticide active ingredients.

Please do not hesitate to contact Tricia Whitmore (tricia.whitmore@oxitec.com) or myself if you have any questions about Oxitec's comments.

Sincerely,

Keith A. Matthews

Oxitec, Ltd. Submission to Docket EPA-HQ-OPP-2016-0205
27 September 2017

Oxitec, Ltd., (Oxitec) hereby submits comments on EPA's documents posted to Docket Number EPA-HQ-OPP-2016-0205 on September 12 and 19, 2017. The documents posted provide additional information on EPA's scientific conclusions and proposed regulatory action concerning pesticide registration application file symbol 89668-U, submitted by MosquitoMate, Inc. Pesticide registration application 89668-U seeks registration pursuant to FIFRA Section 3(c)(5) of an end-use pesticide product containing an active ingredient that is not included in any currently registered pesticide product. The active ingredient in application 89668-U is *Wolbachia pipientis*, ZAP strain, which is proposed to be used in male *Aedes albopictus* mosquitoes.

As is set forth in detail below, Oxitec has serious concerns regarding EPA's proposed registration decision for application 89668-U and the draft "User Manual" that has been placed in the docket. The proposed registration decision and draft User Manual are either inconsistent in significant respects with the findings and recommendations of EPA's science reviews, or lack sufficient clarity to demonstrate how certain recommendations will be addressed. Moreover, as Oxitec has detailed in previous comments submitted on the record in this matter, the potential for release of *Wolbachia pipientis*, ZAP strain (ZAP) females could potentially result in serious and significant adverse environmental effects. The materials released to the docket on September 12 and September 19 do not adequately address the issue of how the production methods proposed by the applicant MosquitoMate will ensure that ZAP females are not released to the environment. All that is apparent from the materials released to the docket are EPA's conclusions that the applicant has in place production methods to limit release of ZAP females, but there is not any information that explains what those conclusions are based on, or that the public may comment on. Oxitec requests that EPA make available the actual information on ZAP mosquito production methods that will enable informed comment on the Agency's conclusions.

Notwithstanding whatever information was the basis on which EPA drew its conclusions regarding release of ZAP females, the potential adverse consequences of release of ZAP females are significant and substantial. If EPA registers the ZAP mosquitoes for geographically limited release under FIFRA Section 3(c)(5), Oxitec strongly urges EPA to include post-release monitoring requirements to ensure that ZAP females are not being released. The proposed registration decision is time limited for five years. It is entirely reasonable and justified by the potential adverse effects that could result from release of ZAP females for EPA to impose mandatory post-release monitoring requirements for the duration of the time limited registration.

Moreover, if monitoring of any releases of ZAP mosquitoes reveals that female ZAP mosquitoes have been released, the registration should include a term and condition mandating that EPA immediately be informed of such release and that the ZAP mosquito registration be suspended immediately and releases halted until a full investigation has been conducted to determine the circumstances that led to release of ZAP females. If female ZAP mosquitoes are released and the ZAP strain is found in wild type mosquitoes, EPA must immediately initiate cancellation proceedings for the registration.

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Finally, we note that MosquitoMate included with its registration application a request that ZAP mosquitoes be approved for sale and distribution to homeowners for domestic use. The record does not to any extent support such use, and EPA should under no circumstances approve this product for homeowner use. EPA's science reviews and decision documents make clear that proper use of ZAP mosquitoes is complex, and involves significant preparatory and monitoring work. No ordinary homeowner is equipped to carry out these preparatory and monitoring functions. The draft label must be revised so that it cannot be interpreted as permitting homeowner use of ZAP mosquitoes.

Specific Concerns Regarding the Proposed ZAP Registration and Draft Registration Materials

Oxitec has serious concerns regarding specific aspects of the proposed ZAP mosquito registration decision and the draft registration materials. First, the bases of the recommendations and conclusions regarding gender sorting are not apparent. Because of significant concern regarding whether the asserted gender sorting can be accomplished at production scale, the registration must include mandatory monitoring for released ZAP females. If ZAP females are detected, the registration must be immediately suspended and all releases halted. If ZAP *Wolbachia* mosquitoes are determined to be established in any area, the registration must be cancelled. Second, MosquitoMate's so-called User Manual is unclear, confusing, and out of date. It should not be publicly released until it is corrected and substantially revised. Third, sales and distribution of ZAP mosquitoes to homeowners for domestic use should not be permitted under any circumstances. The ZAP mosquito label should be revised to make clear that homeowner use is not intended or permitted.

Oxitec's concerns are set forth in detail below.

Gender Sorting

The most likely failure of the ZAP *Aedes albopictus* control program is through the release of ZAP females resulting in replacement of the wild *albopictus* population with mosquitoes carrying the ZAP *Wolbachia* strain. If this occurs the ZAP mosquito product can no longer be efficacious, and the ZAP *Wolbachia* strain, which is not naturally found in *Aedes albopictus*, could potentially spread throughout the United States. Moreover, in such circumstances, the spread of ZAP *Wolbachia* mosquitoes would not necessarily be limited to the States where the registration may be approved.

In addition, were there to be widespread dissemination of ZAP *Wolbachia* mosquitoes, the human health risks that were proposed to be mitigated by the 'negligible risk' exposure of ZAP females would have to be completely re-evaluated. As stated in EPA's *Human Health Assessment* (EPA-HQ-OPP-2016-0205-18), 'the evaluation of the unintended release of females is the critical factor for the purposes of exposure assessment'.

MosquitoMate quotes a female release rate of 1:250,000 males, based on size sorting pupae, and then visual inspection of adults from very small scale releases performed in 2013 and 2015. At small scale this may be achievable, but at the scale of production proposed in the Section 3

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application, to cover entire States, this is unrealistic and unprecedented. We are unaware of any data or information posted that support a conclusion that the necessary female sorting can be accomplished at that scale of production. Moreover, without any available quality control procedures reported or able to be confirmed, one cannot adequately address the potential deficiencies in the MosquitoMate production protocols.

Female ZAP mosquitoes that are released will carry the ZAP *Wolbachia* strain in their eggs, and such offspring will survive to adulthood. The female offspring from such eggs will also inherit the ZAP *Wolbachia* strain and their offspring can survive, whether they mate a ZAP male or a wild-type male. In typical Malthusian dynamics, this will lead to the ZAP strain spreading throughout an *Aedes albopictus* population. When this occurs, the ZAP males are no longer effective and this leads to a failure of control. In addition, and of significant concern, humans, pets, and wild animals (including endangered animals), which are all targets of the *Aedes albopictus* mosquito species, will then be exposed to the ZAP *Wolbachia* from bites by infected females.

EPA has assessed the chances of population replacement through the release of ZAP females as negligible. However, the assessment of risk to humans and animals changes dramatically if ZAP mosquitoes become established in any area.

There are two critical processes that must be evaluated to mitigate this risk:

1) The ZAP mosquito application claims 1 in 250,000 sorting efficiency. Therefore, any registration of ZAP mosquito should require quality control procedures for every batch of ZAP males produced to ensure that ZAP females are not released. If there are more than 1 female in every 250,000 males it should be reported to the EPA. If this occurs the releases should be stopped and the sorting process assessed and corrected.

2) The establishment of the ZAP *Wolbachia* strain in the wild. This can be assessed through BG sentinel traps and the testing of female *Aedes albopictus* for the presence of the ZAP *Wolbachia* strain. If female *Aedes albopictus* are found with the ZAP strain, all releases of ZAP mosquitoes must be halted and monitoring for females continued for at least 8 weeks to determine if the ZAP strain has established in the wild. If establishment of the ZAP strain is confirmed, through the detection of more females infected with the ZAP strain, the registration should be immediately cancelled and no further releases should be allowed.

Post-Release Monitoring

It is imperative that EPA impose mandatory post-release monitoring requirements that will ensure the detection of any ZAP female mosquitoes in the environment.

For the reasons set forth above, Oxitec requests that EPA include an explicit term and condition of registration requiring post-release monitoring of *Aedes albopictus* populations to determine if any ZAP females have been released.

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Monitoring for female release should include, at a minimum, implementation of quality control procedures to ensure no more than 1 female in every 250,000 males produced. To maintain adequate and appropriate manufacturing practices, the quality control procedure should be performed independently from the mass rearing team. If this female contamination level is exceeded for 2 or more batches, then the releases are stopped, reported to the EPA and the sorting process assessed and corrected before further releases can occur.

At a minimum, the post-release monitoring must include adult traps (such as BG sentinel traps) that are deployed weekly, with a minimum of 20 adult traps deployed at a density of between 20-30 traps per square mile. All *Aedes albopictus* females caught in such traps must be tested for the presence of the ZAP *Wolbachia* strain. If female *Aedes albopictus* are found with the ZAP strain then releases should be stopped and monitoring for females continued for at least 8 weeks to determine if the ZAP strain has established in the wild.

Registration Suspension and Cancellation

It is imperative that EPA impose mandatory registration suspension requirements in the event that ZAP female mosquitoes are detected in the environment.

If post-release monitoring detects the presence of ZAP females, all releases must be halted and the ZAP registration immediately suspended. EPA should include a term and condition of registration that, if ZAP *Wolbachia* females are detected in the environment, the registration will be suspended under FIFRA Section 6(c); if the ZAP strain is found to have become established in the wild, EPA will initiate cancellation proceedings under FIFRA Section 6. Discovery of an established population of ZAP mosquitoes would constitute a serious adverse environmental effect; therefore, the ZAP registration must be immediately cancelled and action on any pending registration applications immediately suspended, as the ZAP strain would no longer be effective at controlling *Aedes albopictus* and additional releases could result in this non-wild type strain becoming more established in the environment.

The ZAP Mosquito Draft User Manual

Oxitec finds the draft "User Manual" to be confusing, misleading, and out of date. EPA should require a complete re-write of this document, starting with a determination as to what is its intended purpose. Is this document intended to be distributed to public health and vector control specialists? If so, it is likely to be of no benefit or utility to such professionals at all. To the extent that such professionals would need education on *Aedes albopictus* (which is unlikely), more reliable and useful information may be easily obtained from the Centers for Disease Control website. If the document is intended to inform the public, as currently drafted, it fails that purpose.

Oxitec respectfully suggests that the User Manual not be approved for any use related to the proposed ZAP mosquito registration. To the extent that the User Manual is allowed to be distributed, EPA must require the following corrections and revisions:

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The User Manual must incorporate the 2017 CDC *Aedes albopictus* range map, not the outdated 2016 range map.

The User Manual must explicitly state the limited geographic scope of the registration, so that readers are not confused as to where the product may lawfully be used.

The User Manual should explicitly state that release of ZAP mosquitoes in States other than those expressly identified on the label is a violation of Federal law.

Consistent with BPPD's Geographic Restriction memorandum, the User Manual should note that not all of the 21 States included on the label that have climatic conditions similar to the States where efficacy testing was conducted actually have *Aedes albopictus* populations

Consistent with BPPD's efficacy review, the User Manual must accurately state the typical and maximum extent of *Aedes albopictus* dispersal

Proposed Homeowner Use

Document EPA-HQ-OPP-2016-205-14, *BPPD's review of efficacy data on male releases of Ae. albopictus infected with ZAP strain Wolbachia to support homeowner use* indicates that the applicant also requested registration of ZAP mosquitoes for homeowner use. EPA has not included a proposed label for homeowner use in the public docket, nor has EPA indicated an intent to register the product for homeowner use. Information included in the public docket does not support registration of ZAP mosquitoes for homeowner use. Moreover, EPA's science reviews include numerous use requirements for ZAP mosquitoes that are wholly incompatible with sale and distribution to untrained homeowners for domestic use.

Document EPA-HQ-OPP-2016-205-21, *Proposed Registration Decision for the New Active Ingredient Wolbachia pipientis ZAP (wPip) strain in Aedes albopictus* states that "ZAP Males must be released in excess of wild males (10 ZAP Males per 1 wild male), and these ratios must be empirically determined by the applicator for each geographic area throughout the months of the mosquito season, including its peak season." Well, this determination is, of course, beyond the means of homeowners. Determinations of this sort must be conducted by vector control professionals – not by ordinary homeowners. Document EPA-HQ-OPP-2016-205-17, *Amended BPPD review of efficacy data on male releases of Ae. albopictus infected with ZAP strain Wolbachia pipientis and modeling analyses for population dynamics of Ae. albopictus* recommends that "a *Wolbachia* ZAP male release program be made part of an integrated vector management (IVM) program" that is a "multi-tactic strategy consisting of e.g., larvicide and adulticide applications in addition to ZAP male releases with considerations given to appropriate timing of each application." Conduct of an IVM program in concert with proper releases of ZAP mosquitoes is beyond the capability of homeowners.

Also, permitting homeowner use may significantly increase the risk that ZAP mosquitoes may be intentionally released in States where such releases are not approved. This may be a particular concern in unapproved areas bordering States where the registration is approved, e.g., Virginia, South Carolina, North Carolina, Georgia, Alabama, Mississippi, Oklahoma, and Arkansas. These

concerns will be entirely eliminated if use of ZAP mosquitoes is restricted to vector control and public health bodies.

Finally, we note that the proposed label permits use by "persons under direct contract with MosquitoMate, Inc., for the purpose of application of this pesticide." EPA must make clear that this language is not intended, and cannot be used, to permit MosquitoMate to contract directly with homeowners to permit use of the product by such homeowners on individual properties. Given the express recommendations of EPA's science reviewers regarding proper use of ZAP mosquitoes, and the proposed use requirements in EPA's proposed decision, it must be made unequivocally clear that this product is only to be used by trained professionals.

There is no basis in the public record that supports registration of ZAP mosquitoes for domestic homeowner use. EPA should not, under any circumstances, approve ZAP mosquitoes for homeowner use. EPA's science reviews and decision documents make clear that proper use of ZAP mosquitoes is complex, and involves significant preparatory and monitoring work. No ordinary homeowner is equipped to carry out these preparatory and monitoring functions.

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PUBLIC SUBMISSION

As of: 9/27/17 3:58 PM
Received: September 27, 2017
Status: Draft
Tracking No. 1k1-8ywj-j82j
Comments Due: September 27, 2017
Submission Type: Web

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

Comment On: EPA-HQ-OPP-2016-0205-0012
Public Participation for New Active Ingredient (Wolbachia pipientis, ZAP Strain in male Aedes albopictus (Asian tiger mosquitoes)

Document: EPA-HQ-OPP-2016-0205-DRAFT-0033
Comment on EPA-HQ-OPP-2016-0205-0012

Submitter Information

General Comment

This comment was submitted by the Western IPM Center. An excerpt from the comment is included below and the entire comment can be viewed in the attached file.

Asian tiger mosquito has been reported to occur in eight counties in California including San Diego, Orange, Los Angeles, San Bernadino, Kern, Santa Clara, San Joaquin, San Mateo. Hawaii also has reported Asian tiger mosquito trap captures over the past several years. The Center for Disease Control predicts that Asian tiger mosquito is unlikely to be widely distributed in California, Nevada, New Mexico and Washington, but the CDC maps suggest that Asian tiger mosquito may be a more significant threat to some counties in Oregon.

Within California, several major metropolitan areas are in counties where Asian tiger mosquito has been captured. The Los Angeles Metropolitan area is one of the most populous areas in the country with over 13 million people (U.S. Census Bureau). San Mateo County is within the bay area and the bay area has more than 7.6 million inhabitants (U.S. Census Bureau).

Mosquitoes can be managed with applications of organophosphate and pyrethroid insecticides, and these applications pose a low risk to human and environmental health (Peterson 2010). From 2014 to 2015, more than 200,000 pounds of organophosphate and pyrethroid insecticides were applied for adult mosquito control in California. But the use of these products may be limited in the future. The public response to the use of these products was negative in Los Angeles and Orange counties in the face of the West Nile virus threat. A second concern with these products is their age. Organophosphate and pyrethroid insecticides were developed many decades ago and may not continue to provide adequate control because mosquito populations rapidly develop physiological or behavioral resistance to them.

Continued management of mosquito adults will require new products - especially those that are efficacious, target specific, and unlikely to cause significant environmental or human health impacts. Originally proposed by Edward Knipling in 1955, the sterile insect technique (SIT) has been highly successful in eradicating or controlling a variety of pests including primary screwworm and boll weevil in the United States. Given this track record of success, it seems likely that the ZAP-males product can manage or eradicate Asian tiger mosquito in the West.

Although Asian tiger mosquito represents a limited threat in the West, it will be important to register this product for use to set precedent. This precedent will allow SIT products targeting other mosquitoes species that currently pose a threat to public health to be registered quickly.

Attachments

centerComment

Western IPM Center

Western Integrated Pest Management Center

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September 27, 2017

Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-001

RE: Revised Ecological Risk Assessment for the Section 3 registration of the microbial pesticide end-use ZAP mosquito larvae: PC Code: 069035; EPA File Symbol 89668-U; Decision No. 513757; Submission Nos. 980717, 985153; DP Barcode No: 432413, 433706. MRID Nos: 49530604, 49830704-06, Federal Register Docket number: EPA-HQ-OPP-2016-205-0019

About us

The Western IPM Center works with stakeholders in the public and private sectors in the West to promote the development and adoption of IPM to solve pest problems. We gather information from the IPM network to provide federal agencies with information to assist the decision-making process. Our network includes comment coordinators in the Pacific Northwest, the arid southwest, the intermountain west, and the pacific island territories and Hawaii. Comments reflect the principles of IPM.

The Center will only provide a comment from California because California and Nevada are the only states in the West listed on the proposed label.

California uses

Aedes albopictus has been reported to occur in eight counties in California including San Diego, Orange, Los Angeles, San Bernadino, Kern, Santa Clara, San Joaquin, San Mateo (Hahn et al. 2017), and has been recorded in three or more years in San Bernadino, Los Angeles and Orange Counties. Hawaii has also reported *Ae. albopictus* trap captures over the past several years (Hahn et al. 2017). The Center for Disease Control predicts that *Ae. albopictus* is unlikely to be widely distributed in California, Nevada, New Mexico, and Washington but *Ae. albopictus* may be a more significant threat to some counties in Oregon (CDC 2017).

Within California, several major metropolitan areas are in counties where *Ae. albopictus* has been captured. The Los Angeles Metropolitan area is one of the most populous areas in the country with over 13 million people (U.S. Census Bureau). San Mateo County is within the bay area and the bay area has more than 7.6 million inhabitants (U.S. Census Bureau).

Aedes mosquitoes can be managed with applications of ULV organophosphates or pyrethroids, and these applications pose little risk to human and environmental health (Peterson 2010). From 2014 to 2015, more than 200,000 pounds of organophosphate and pyrethroid insecticides were applied for adult mosquito control in California (Table 1). But the use of these products may be limited in the future. The public response to the use of these products has been negative in large urban centers such as Los Angeles and Orange counties (Baur et al. 2017). The public responded negatively to aerial treatment of urban centers for mosquito management in the face of the threat of West Nile virus. A second concern with these products is their age. Organophosphate and pyrethroid insecticides were developed many

decades ago and may not continue to provide adequate control because mosquito populations rapidly develop physiological or behavioral resistance to them (Cui et al 2006, Ponce-Garcia 2009).

Continued management of mosquito adults will require new products – especially those that are efficacious, target specific, and unlikely to cause significant environmental or human health impacts. Originally proposed by Edward Knipling (1955), the sterile insect technique (SIT) has been highly successful in eradicating or controlling a variety of pests including primary screwworm and boll weevil in the United States. Given this track record of success, it seems likely that the ZAP-males product can manage or eradicate *Ae. albopictus* in the West.

Although *Ae. albopictus* represents a limited threat to California and other states in the West, it will be important to register this product for use in California and Nevada to set precedent. This precedent will allow SIT products targeting other *Aedes* and *Culex* mosquitoes that currently pose a threat to human health to be registered quickly.

Table 1. Amount (in pounds active ingredient or lbs a.i.) of pesticide applied in California for control of adult mosquitoes (California Department of Pesticide Regulation, Pesticide Use Reporting Database)

	2014	2015	Total
Organophosphate	79,005	103,052	182,057
Pyrethroid	8,473	10,962	19,435
Total	87,478	114,015	201,492

Please contact me if you have any questions about the comment. The Western IPM Center comments are archived at http://www.westernipm.org/index.cfm/searchable-data-sources/information-request-replies/

Sincerely,

Matthew Baur, Associate Director
530-750-1270
mebaur@ucanr.edu

References:

Baur ME, Crump A, Elliott SF, Farrar JJ. 2017. Integrated pest management of mosquitoes: A case study of West Nile virus in California. Western IPM Center Publication. Available at westernipm.org

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