Message

From: Smith, Charles [Smith.Charles@epa.gov]
Sent: 11/3/2021 5:45:19 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]
CC: Reynolds, Alan [Reynolds.Alan@epa.gov]; Welch, Kara [welch.kara@epa.gov]; Welch, Kara [welch.kara@epa.gov]; Kirk, Cassandra [kirk.cassandra@epa.gov]; Striegel, Wiebke [Striegel.Wiebke@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Subject: RE: Updated Oxitec 1 Pager
Attachments: Oxitec_updated 1 Pager 11 3 2021.docx

Mike,

I made some pretty big changes to this. I added the info from our March one pager about the human health/eco analysis we did. I also moved some stuff around and have a few questions about stuff to add. Please remember that Jake knows little about the specifics of this action. He wasn't here when we briefed Michal. He suggested that once we sent him the one-pager that he might want to have a brief discussion. Please take a look at what I added/changes and let me know if there are any issues. Thanks.

Charles "Billy" Smith
Acting Division Director
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Wednesday, November 3, 2021 12:26 PM
To: Smith, Charles <Smith.Charles@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: Updated Oxitec 1 Pager

Billy and Anne,

As discussed. Thanks!

Mike M.

OXITEC'S GE MOSQUITO EXPERIMENTAL USE PERMIT (EUP) OX5034 11/3/2021

BACKGROUND:

- In March 2019, EPA received an application for an Experimental Use Permit (EUP) for two years to assess the efficacy of OX5034 *Aedes aegypti* mosquitoes in the United States. The registrant proposes to release the genetically engineered mosquitoes on 6,600 acres in Texas and Florida. These mosquitos possess the tTAV trait, which causes their offspring to die before adulthood.
- In April 2020, EPA approved an Experimental Use Permit (EUP) for this technology to enable field testing to occur during 2020 in Florida and Texas. We understand releases have been limited to Florida.
- In March 2021, EPA received an amendment application to extend and expand the EUP in Florida by another 24 months on up to 6,240 acres and in California on up 84,600 acres. The EUP amendment would allow generation of additional data in different climatic zones for consideration of whether to approve a full FIFRA section 3 registration of OX5034 mosquitoes.
- On August 31, 2021, EPA announced receipt of Oxitec's amendment application in the Federal Register and issued a pesticide announcement with a 30-day opportunity the public to submit comments on the proposed extension and expansion. EPA's risk assessment and comment response to the original EUP remained in the docket and available to the public during this time. *The amended risk assessment will focus on issues related to the new sites and acreage but rely primarily on the previous assessment.* → **Not public.** California specific comments are among those submitted.
- EPA has been meeting with mosquito control districts since 2017 and prior to the COVID-19 pandemic visited districts in Florida, Texas and California.
- During the comment period for the EUP granted in 2020, the public raised concerns regarding potential allergic reactions from mosquito bites, exposures to novel proteins, and disease transmission of escaped GE female mosquitoes.
- As part of the EUP, genetically engineered mosquitoes breed with wild mosquitoes and pass on some of their genetic characteristics. As part of EPA's evaluation of the initial EUP, the Agency determined that no significant adverse impacts are expected from this introgression into the gene pool of the wild mosquito population.

KEY POINTS:

- No genetically modified female OX5034 mosquitoes have been detected under the current EUP.
- *Genetically engineered male OX5034 mosquitoes (which are released under this EUP) have been detected at the border of the treatment area and additional monitoring is taking place.* → **Not public.**
- OX5034 GE male *Ae. aegypti* mosquitoes with the tTAV trait are released into the environment to mate with wild female *Ae. aegypti* mosquitoes. (Male mosquitoes do not bite.)
- All female offspring from matings of GE male mosquitoes with wild female mosquitoes die.
- All male offspring from matings of GE male mosquitoes with wild female mosquitoes survive, and half of those offspring contain the trait for tTAV and can pass it on to subsequent generations.
- Over time, *Ae. aegypti* mosquito populations are reduced in areas where OX5034 mosquitoes are released.
- OX5034 contains the marker DsRed2 protein, which turns red under visible light, making the mosquitoes trackable for measuring the effectiveness of the trials.
- The marker DsRed2 is substantially similar to "Akane," a protein from coral that at one time had been listed as an allergen in the allergenicity databases AllergenOnline and Compare.
- Removal of Akane from the two databases does not resolve the potential risk of DsRed2 allergenicity.
- The Oxitec mosquitoes have significant potential to advance the protection of public health. EPA will review data on the effectiveness of Oxitec's mosquitoes from the testing under the EUP to determine how well the Oxitec mosquitoes work in reducing the number of *Ae. aegypti* mosquitoes in treated areas.

TALKING POINTS:

- EPA takes its role of protecting the public from insect-borne diseases very seriously.

- EPA carefully considered the original Experimental Use Permit (EUP) application for a genetically engineered mosquito by Oxitec designed to reduce the number of mosquitos and is currently doing the so with the pending EUP amendment application.
- EPA's decision is based on the science, specifically, a risk assessment that determined that unreasonable adverse effects risks to human health or the environment are expected as a result of the proposed testing under the EUP granted in 2020.
- If approved, the EUP amendment request extending the testing period and adding California test sites would be subject to many of the same requirements that are in place for the current EUP. For example, EPA currently requires that Oxitec not release OX5034 mosquitoes near potential environmental sources of tetracyclines, which could impact the OX5034 female mosquito-lethal trait. EPA also mandates that Oxitec monitor for OX5034 mosquito offspring. In the unlikely event Oxitec finds genetically modified female offspring, they are required to immediately cease releases, apply conventional pesticides targeting the adult and larval mosquito stages, and continue monitoring until no female OX5034 mosquitoes are found for two consecutive generations.