Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 12/15/2017 4:59:24 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]
Subject: follow-up Q --- FW: LINDA/OPP: Key West Citizen - 12/12 - genetically modified mosquito proposal

OK to go?

Below is OPP's response to the follow-up question about Oxitec from the *Key West Citizen*. This has been approved by Rick.

> Q. So I can say it is too early to say if the EPA is going to require an environmental impact statement or relying on the environmental assessment Oxitec worked on with FDA?
>
> R. EPA will conduct an environmental risk assessment under FIFRA, and will review the FDA impact statement as supplemental information to help inform our risk assessment.

From: Keigwin, Richard
Sent: Thursday, December 14, 2017 6:50 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: Re: LINDA/OPP: Key West Citizen - 12/12 - genetically modified mosquito proposal

As with all experimental use permits, we will be conducting a risk assessment to assess any potential human health and environmental risks prior to making a decision to issue the permit.

Rick Keigwin
Director, Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: 703-305-7090
Website: www.epa.gov/pesticides
Sent from my iPhone

On Dec 13, 2017, at 9:08 PM, Strauss, Linda <Strauss.Linda@epa.gov> wrote:

> Yes, sorry it went, and we just got this follow-up Q. OPP will draft an answer.
> "Thanks. So I can say it is too early to say if the EPA is going to require an environmental impact statement or relying on the environmental assessment Oxitec worked on with FDA?"
>
> ---
>
> **From:** Beck, Nancy
> **Sent:** Wednesday, December 13, 2017 7:32 PM
> **To:** Strauss, Linda <Strauss.Linda@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
> **Cc:** Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
> **Subject:** RE: LINDA/OPP: Key West Citizen - 12/12 - genetically modified mosquito proposal
>
> I'm guessing this went already, but if not one suggestion below. Not a showstopper..

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
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From: Strauss, Linda
Sent: Wednesday, December 13, 2017 10:04 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: FW: LINDA/OPP: Key West Citizen - 12/12 - genetically modified mosquito proposal

Per our discussion this am, here's what I will send for this. Also added background info from OPP.

Response:

~~We only got~~ The application for the experimental use permit was received last week. We are completing a screen of the application to ensure that it is complete. Once it is complete, we will begin the scientific evaluation. Under PRIA, the application has a review period of several months.

For the environmental impacts, we will consider all available information in making a safety determination consistent with the FIFRA risk/benefit standard.

Background:

EPA registers pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process of registering a pesticide is a scientific, legal, and administrative procedure. In evaluating a pesticide registration application, we assess a wide variety of potential human health and environmental effects associated with use of the product. We consider all available information in making a safety determination and evaluation of environmental impacts consistent with the FIFRA risk/benefit standard.

EPA requires that a pesticide product undergo extensive chemical, toxicological, and on occasion field-testing before being registered as a pesticide. Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, EPA sometimes must first authorize the distribution and sale for testing purposes by means of an experimental use permit (EUP) under FIFRA.

From: Daguillard, Robert
Sent: Friday, December 08, 2017 11:16 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Lantz, Tracy <Lantz.Tracy@epa.gov>
Subject: LINDA/OPP: Key West Citizen - 12/12 - genetically modified mosquito proposal

OUTLET	**KEY WEST CITIZEN**
REPORTER	**TIM O'HARA**

DDL **APPROX. TUESDAY 12/12**

Good morning team,

The reporter says he reached out directly to OXITEC, which told him we are not requiring a full environmental impact assessment before registering their product. However, the head of a popular initiative that opposed testing OXITEC's GE mosquitoes in Key West, tells him we are. The reporter wants to know who is right, and where the registration process for this particular product stands.

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I am a reporter with the Key West Citizen newspaper. We are the daily paper here in the Florida Keys. The EPA has taken over responsibility for approving or rejecting a proposal by a company called Oxitec, which wants to release millions of genetically modified mosquitoes as part of mosquito eradication or suppression effort here in the Keys. The Food and Drug Administration had been handling the approval of the test release but it has been passed along to the EPA.

I have a few questions about where in the process Oxitec's request is and whether your agency is requiring them to perform a full blown environmental impact statement or rely on the environmental assessment conducted when FDA was handling it.

Also, I wanted to establish a regular media contact for this issue.
If someone can call me or email me back I would appreciate it.