Message

From: Daguillard, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BBE9682B940C4F2C90732E4D37355DD4-DAGUILLARD,]
Sent: 10/12/2017 8:02:15 PM
To: Abby Olena Ex. 6
CC: Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b293283291dc44e0b5d1c36be9281d8a-Press]
Subject: RE: Comment for The Scientist about mosquitoes. Deadline: Monday Oct 9 at 5 pm ET.

Abby, for attribution to "an EPA spokesperson," please:

1. **Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?**

EPA will regulate GE mosquitoes in the same way the agency regulates other pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives EPA the authority to regulate the distribution, sale, and use of pesticide products to ensure they do not cause unreasonable adverse effects on people or the environment.

Background:
More specifically, FIFRA generally requires that, before a pesticide may be sold or distributed in commerce, it must be registered (licensed) based on sufficient scientific data for EPA to conclude that the use of the pesticide will not cause unreasonable adverse effects on people or the environment. FIFRA also gives EPA the authority to issue experimental use permits to allow the testing of a pesticide in the environment for the purpose of generating data to support the registration of the pesticide, and to control the distribution and use of a pesticide post-registration and to monitor its production.

2. **Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?**

Yes. These products will now be regulated under FIFRA; thus the company must show EPA that their product meets FIFRA established safety standards.

3. **If so, what is the timeline and basic structure of that sort of process?**

From start to finish, the FIFRA statutory timeframes can be as short as 7 months to as long as about 2 years, depending on the type of registration application submitted to the Agency.

Background:
FIFRA establishes a statutory framework creating timelines within which EPA must make a determination on an application. The timelines applied depends on the type of application submitted by the company.

At this point, EPA has not received an application from Oxitec. However, in general under FIFRA, an applicant typically applies first for an Experimental Use Permit (EUP) to generate the data necessary to support the registration. Should Oxitec request an EUP, once a complete EUP application has been submitted, the agency would have 7 months to reach a decision. After sufficient data have been collected in field testing (this may take from a few months to several years depending on the types of data to be generated), the applicant typically then applies for a registration under FIFRA. Once a registration application is received, the agency has 13-25 months to complete its review, depending on the nature of application. The 25-month estimate provides for input from nationally recognized technical experts via the EPA's FIFRA Scientific Advisory Panel when the Agency deems such input appropriate.

4. **Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?**

If Oxitec applies for a registration, they may submit information generated in another country which may or may not be used by the EPA in its evaluation of the Oxitec mosquito product under FIFRA.

5. **Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?**

Over the past few years, EPA has regulated several field trial releases of *Wolbachia* bacteria that are contained within mosquitoes and are being evaluated for control of mosquito populations.
More information on these trials can be found at:

- www.epa.gov/pesticides/epa-grants-extension-experimental-use-permit-wolbachia-mosquito

www.regulations.gov/docket?D=EPA-HQ-OPP-2017-0392

Regards, R.

Robert Daguillard
Office of Media Relations
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (O)
Ex. 6 (M)

From: Abby Olena [mailto Ex. 6
Sent: Friday, October 06, 2017 1:57 PM
To: Press <Press@epa.gov>
Subject: Comment for The Scientist about mosquitoes. Deadline: Monday Oct 9 at 5 pm ET.

Hello EPA Press team,

I spoke with Robert Daguillard yesterday afternoon about a story I'm writing for The Scientist about the oversight of Oxitec mosquitoes shifting to the EPA. I hadn't heard from him, and I think he mentioned he was out today, so I wanted to try this avenue as well.

I've included some questions below my signature. If someone can help me find answers, that would be great. My story will be a short one (500 or words) headed for the Daily News section. Deadline is Monday at 5 pm ET.

All the best,

Abby Olena
—
Science Writer
www.abbyolena.com
Ex. 6

Does the EPA have a plan in place for regulating the use of the genetically engineered (Oxitec) mosquitoes?

Is there still an approval process that needs to take place since the FDA handed oversight over to EPA?

If so, what is the timeline and basic structure of that sort of process?

Will the EPA be looking to other countries in which the Oxitec mosquitoes have already been used for guidance in evaluating the mosquitoes' approval?

Are there other examples of the release of living insects or other kinds of animals that EPA has overseen?