Message

From: Motilall, Christina [Motilall.Christina@epa.gov]
Sent: 5/13/2020 6:10:53 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]
CC: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Ingram, Earl [Ingram.Earl@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Schwarz, Stephanie [Schwarz.Stephanie@epa.gov]
Subject: RE: Urgent: Oxitec Press Follow-Up

Great, glad we have consensus. I will run this up the chain. Thanks!

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Wednesday, May 13, 2020 2:09 PM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Cc: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Don,

Sounds perfect to me!

Mike

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 1:36 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>
Cc: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: Re: Urgent: Oxitec Press Follow-Up

Mike --

Ex. 5 Attorney Client (AC)

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Wednesday, May 13, 2020 12:04 PM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Don,

Thanks. The question asked by the reporter was "I just would like to know if the data generated under this EUP are only produced by Oxitec or if a third party is involved in the evaluation."

This could be read two ways, e.g., data generated during the EUP or data submitted to support the EUP.

1. Ex. 5 Attorney Client (AC)

2. Ex. 5 Attorney Client (AC)

Mike Mendelsohn, Chief
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 463-7302 Mobile

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 9:15 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: Re: Urgent: Oxitec Press Follow-Up

Christina, per the email Mike just sent, my understanding of the facts was incorrect.

Mike, are you saying that the identity of the party who generated the data has already been claimed as CBI by Oxitec?

Donald A. Sadowsky
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From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Wednesday, May 13, 2020 9:12 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Morning Don,

That makes perfect sense. For simplicity, would this work?

The EPA allows submitters to claim Confidential Business Information (CBI). Under these regulations, information claimed as confidential may not be released until EPA has adjudicated the claim. EPA expects to hear back from Oxitec shortly on what they claim as CBI. the EPA must hold off on releasing information we believe might be claimed as confidential until we have that specification.

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 9:06 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: Re: Urgent: Oxitec Press Follow-Up

Good morning, Christina!

Because we are still waiting for Oxitec to tell us exactly what they are claiming as CBI, I would prefer not to make representations regarding what has been claimed. My suggested response (consistent

with Bob's input) is wordier, but lets the reporter know that the Agency is constrained for now rather than rubber stamping confidentiality claims:

> Oxitec has informed the Agency that it is making confidentiality claims for the information and will shortly be specifying exactly what is claimed as confidential. Under EPA confidentiality regulations we have to hold off on releasing information we believe might be claimed as confidential until we have that specification.

Also consider whether it would be helpful or not to also say

> Under these regulations, information claimed as confidential may not be released until EPA has adjudicated the claim.

Does this work for you?

Don

Donald A. Sadowsky
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From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Wednesday, May 13, 2020 8:51 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Morning Don,

Was drafting a message but I will shift it here! Thanks for your help on this, below is what we have:

Q: I just would like to know if the data generated under this EUP are only produced by Oxitec or if a third party is involved in the evaluation.

A: Due to confidentiality claims made under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA cannot answer this question at this time.

Please review and provide your input, thank you!

Best,
Christina

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 8:49 AM
To: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Motilall, Christina <Motilall.Christina@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike

<Mendelsohn.Mike@epa.gov>
Subject: Fw: Urgent: Oxitec Press Follow-Up

FYI, Chris.

A reporter has asked questions about the Oxitec submission where the answers may involve information claimed as CBI by Oxitec (who is supposed to tell OPP today exactly what they're claiming as CBI). OPP wants to get back to the reporter ASAP, and will be sending me a draft response for quick review.

I've cc'ed here some of the OPP staff working on this.

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From: Ingram, Earl <Ingram.Earl@epa.gov>
Sent: Wednesday, May 13, 2020 8:28 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

It's Don Sadowsky.

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Tuesday, May 12, 2020 6:17 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Thanks Earl! Can you put me in touch with your OGC contact so I can have them review a potential response asap?

Best,
Christina

From: Ingram, Earl <Ingram.Earl@epa.gov>
Sent: Tuesday, May 12, 2020 4:38 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

The company made a confidentiality claim son some of that information in your response. Under the direction of OGC, I sent the company an email asking they clearly indicate the information they are claiming confidential. They have until COB tomorrow to respond. BPPD will let you know what information in your response that Oxitec is making confidentiality claims on if any.

If they do maintain claims of confidentiality, we will have them to substantiate their confidentiality claims. OGC will make the final determination on the claims. It could be a sometime before OGC makes its determination.

Earl Ingram, Chief
Public Information & Records Integrity Branch
Information Technology & Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-5456

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Tuesday, May 12, 2020 4:13 PM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

If not, Mike's group can help. Earl Ingram in ITRMD handles these as does Sharon McBride in ITRMD.

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Tuesday, May 12, 2020 4:10 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Thanks, that makes sense. I will see if we have some pre-approved language on it.

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Tuesday, May 12, 2020 4:08 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

I think the answer is fine, but will likely lead to a follow-up: "What do you mean it's confidential?" The notion of confidentiality sounds suspicious to a reporter without context under the law.

We could expand with a sentence or two about how registrants are allowed to make confidentiality claims under FIFRA and what role EPA plays in refereeing that process.

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Tuesday, May 12, 2020 3:56 PM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

The answer to the question below is: EPA cannot answer the question because of confidentiality claims.

Let us know if we need to discuss further. Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Tuesday, May 12, 2020 3:45 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Hi all,

Any word on this?

Best,
Christina

From: Motilall, Christina
Sent: Tuesday, May 12, 2020 11:59 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Urgent: Oxitec Press Follow-Up

Hi there,

We got a follow-up Oxitec question, in yellow, deadline is ASAP. Below the follow-up question is what we originally provided.

I just would like to know if the data generated under this EUP are only produced by Oxitec or if a third party is involved in the evaluation.

EPA previously provided:

Question 1: Why do the releases not occur within 500 meters of sewage treatment facilities and any farm producing citrus crops?
Response 1: This restriction is to ensure female OX5034 Aedes aegypti mosquitoes do not encounter levels of tetracycline in the environment that will result in survival of adult OX5034 female mosquitoes. Female OX5034 Aedes aegypti mosquitoes can survive when exposed to a high enough dose of tetracycline.

A compilation of release recapture studies around the world found that most Ae. aegypti mosquitoes are recovered within 20 to 50 meters of the release point, with a small percentage found at 170 meters but generally not more than 200 meters from the release point. Therefore, a restriction of 500 meters from potential sources (200 m for released OX5034 males + 200 m for mated Ae. aegypti females + 100 m of additional buffer) provides a conservative buffer zone to prevent OX5034 mosquitoes from encountering tetracycline in the environment. Additional detailed discussion can be found in EPA's

Response to Comments in Part VI.B. in the response to comment document (document ID: EPA-HQ-OPP-2019-0274-0355).

Question 2: How are you controlling the effectiveness of the Oxitec technology?
Response 2: The purpose of the Experimental Use Permit is for Oxitec to determine the efficacy of the OX5034 Aedes aegypti mosquitoes for controlling populations of wild Ae. aegypti mosquitoes. EPA reviewed the proposed protocol to determine efficacy, thus ensuring the methods used to evaluate efficacy are appropriate and scientifically valid. EPA would evaluate the data generated under this EUP in a future application to support a product registration under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Question 3: Why does EPA decide to restrict the release (20 000 mosquitoe / week / acre) ?
Response 3: Oxitec proposed 20,000 adult male mosquitoes/week/acre as the maximum application rate. EPA's evaluation of the application was based on this proposed maximum application rate.

Christina Motilall *(she/her/hers)*
Acting Team Leader, Communication Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Desk: (202) 564-1287 | Cell: (202) 860-5122