Message

From: Smith, Charles [Smith.Charles@epa.gov]
Sent: 11/16/2020 12:59:32 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
CC: Overstreet, Anne [overstreet.anne@epa.gov]
Subject: FW: November 12 Meeting
Attachments: presentation to Assistant Admin Dunn Nov 12 2020.pdf; ATT00001.htm

Mike,

I forwarded you this information earlier this am. I know you were able to be on the call on Thursday. Can we develop short responses to the claims that they have made? I'd say to shoot for having these together by end of day tomorrow if possible? Is there anyone else from the team who should be included?

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

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, November 16, 2020 7:27 AM
To: Smith, Charles <Smith.Charles@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: FW: November 12 Meeting

Billy/Anne

Alex would like to have a 30 min meeting to discuss some of the issues brought up during this meeting.
You may want to prepare some internal responses for them.
Not sure yet when this meeting will take place. Could be as early as this week.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
703-308-8157

From: Dunn, Alexandra <dunn.alexandra@epa.gov>
Sent: Monday, November 16, 2020 7:15 AM
To: Messina, Edward <Messina.Edward@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Tyler, Tom <Tyler.Tom@epa.gov>; Mills, Madeline <Mills.Madeline@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Lis-Coghlan, Kamila <lis-coghlan.kamila@epa.gov>; Cole, Joseph E. <cole.josephe@epa.gov>
Subject: Fwd: November 12 Meeting

Alexandra Dapolito Dunn, Esq.

Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

Sent from my iPhone

Begin forwarded message:

From: Ed Russo <erusso7404@aol.com>
Date: November 15, 2020 at 9:23:16 PM EST
To: "Dunn, Alexandra" <dunn.alexandra@epa.gov>, "Mills, Madeline" <Mills.Madeline@epa.gov>, "Bolen, Derrick" <bolen.derrick@epa.gov>, Barry Wray <support@fkec.org>, "Messina, Edward" <Messina.Edward@epa.gov>, "Smith, Charles" <Smith.Charles@epa.gov>, "Keigwin, Richard" <Keigwin.Richard@epa.gov>
Subject: November 12 Meeting

Assistant Administrator Dunn,

Please accept our sincere gratitude for your invitation to meet with you and the EPA team on Thursday, November 12, 2020. Attending members of the Florida Keys Environmental Coalition greatly appreciate your professional efforts in this important work, as well as the amicable atmosphere provided for hearing our concerns.

Thank you for hearing a fairly rapid presentation of our FKEC.org arguments and a new discovery presentation during the meeting. Attached herein you will find the narrative of Mr. Barry Wray's presentation for reference and future work. Also provided below, you will find a link to Dr. John Norris' more detailed presentation on Antibiotic Resistant and Bacterial Promotion concerns with Oxitec lab performance. For us, it still seems so unusual that such a simple low cost test would be met with resounding resistance from Oxitec, and no insistence for inclusion on the part of the EPA.

Dr. John Norris Presentation:

https://view.knowledgevision.com/presentation/f685f26257334969aae998765ae6a8a9

We are understanding of the relevance of emerging precedent making decisions. Due to the brevity of the meeting, this subject was not included in our discussions.

Clearly the scientific evidence provided directly impacts the quality standard associated with the evaluation process previously conducted,

which resulted in an unfortunate and premature approval of the EUP for the experimental trial of the Oxitec OX5034 mosquito in the United States.

We are eager to reconnect after your team has had several days to peruse the peer reviewed study from Yhao, Et. Al. which we share here again for your convenience (https://www.nature.com/articles/s41467-020-16807-3), versus the termination clause that activates if the emergence of any female GM Mosquitoes. We expect your team must also recognize the questionable reliability of the "DS-Red" fluorescent marker, which predictably will result in broad statistical error tolerances for any field data collection leaving scientifically credible conclusions unattainable.

It is difficult to see any scientific value remaining in this experiment, only risk to our community and our ecosystems in the Keys. These previously undisclosed characteristics of the OX5034 suggest that informed consent be required for any future considerations of Oxitec technology being released in the wild. This is, after all, the second version of Genetically Modified Mosquito that Oxitec produced where their claims of "No Females" were found to be mistaken, or untrue.

Science and data can be difficult to grasp, but perhaps more difficult to understand is how Oxitec could support such claims and were completely unaware that their technology would result in OX5034 females being produced in the wild. If they were unaware, then Oxitec's competence for assessing the performance and risks associated with their technology should not be trusted a third time. Regardless of the source of their numerous mistakes in the documentation provided to the EPA, deceit or incompetence, trusting any Oxitec submission without independent objective qualified investigation in the form of a properly designed and executed Environmental Impact Statement, should never occur.

This cautionary experience exposes the importance of proceeding into genetic engineering techniques and products with an escalated approach of holistic care for the technologies, the environment, and the communities to be exposed to risk.

We implore the EPA to exercise any and all efforts to assure the at-risk public that the EIS standard will be used to evaluate all new germ-line edited synthetic species that would be tested in the wild. Adopting a Precautionary Principle standard of "prove it is safe," given the complexity and risk associated with heredity based genetic modification

of organisms, is the only way to proceed responsibly in fulfilling the EPA's mission to protect the environment and our public.

It does now appear that the GE Salmon Ruling on Nov 5, 2020 from the US District Court for the Northern District of California, has direct bearing on the survivability of the OX5034 EUP, given that FDA approval also violated that the National Environmental Policy Act (NEPA) by underestimating the risk associated with that genetically engineered technology.

The media has begun contacting us for comments in light of growing awareness. We hope our presentations will assist the EPA in consideration of the new evidence and the court decision fulfilling the intent of NEPA. We have taken a lighter approach with the media for the short term, hopefully providing time for the EPA to act upon these discoveries in a proactive manner.

Please know that one of the most frustrating aspects of this process, from the public's perspective, has been Oxitec/MCB's avoidance to respond to simple straight forward questions with direct answers. For the most part, we receive gross generalizations and are directed to look at the approving documents. Unfortunately, the approval documents are silent regarding our important concerns. This behavior has resulted in growing citizen mistrust of this entire process.

We are available for a follow-up meeting this week. We are typically flexible and hopeful your team is available for a little longer discussion on Wednesday or Thursday. We look forward to our mutually evolving conversation as the new data we have presented to your team is studied by your team, in context with the existing EUP protocols.

Fundamentally, we are interested to be informed regarding what evidence is needed to have this Oxitec experiment not characterized as a "pesticide."

Again, thank you for providing us an opportunity to support the EPA with our work. It is our sincere hope that this level of discussion, which has historically been an ongoing and compelling component of prior EUP GM Mosquito applications targeted on the Keys, will now occur as part of the application reevaluation process. We all expect to learn more and to participate in this process, contributing and sharing in a two-way dialogue.

Sincerely,

Ed Russo

President

FKEC

Sent from my iPad