Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 8/2/2018 12:04:01 AM
**To**: Barry Wray [Ex. 6 Personal Privacy (PP)]
**CC**: mcnally.robert@eps.gov; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Jack Norris [Ex. 6 Personal Privacy (PP) n]; Richard Keigwin (Keigwin.Richard@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=151baabb6a2246a3a312f12a706c0a05-Richard P Keigwin Jr]; Mendelsohn, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=720b16e1b31742738a728d8d2814beef-Mendelsohn, Mike]
**Subject**: RE: Follow up from Friday 13 meeting

Barry,
Thank you for taking the time to meet with us and for providing this follow-up information. I will make sure it is all passed along to our team.

Regards,
Nancy

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**From:** Barry Wray [Ex. 6 Personal Privacy (PP)]
**Sent:** Tuesday, July 24, 2018 11:42 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>
**Cc:** mcnally.robert@eps.gov; Baptist, Erik <Baptist.Erik@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Jack Norris <k Ex. 6 Personal Privacy (PP)
**Subject:** Follow up from Friday 13 meeting

Hi Nancy,

We wanted to reach out and thank you and your team for spending time with us on Friday July 13, to discuss our concerns and findings on Oxitec's application for EUP for the OX513A Genetically Modified Mosquito. As a follow-up I have attached several documents to this file that we were unable to submit on the "thumbdrive" we prepared. We also realize there were a few contact business card we did not have, so please pass along our comments where appropriate.

The Summary provided outlines the major concerns we feel prevent approval of and EUP for the OX513A. We also set out what we feel is important in evaluating GM Species for release. While it may be more pointed toward the Oxitec application and credibility concerns, it is important that our regulatory agencies develop a criteria and process of evaluation that will assure safety. Technology evolution is challenging to vet, we hope our seven years of history on this subject will provide guidance that will help the EPA's assure that these technologies are safe when approved.

In support of our concerns, below is a link to the second article in the past year that raises concerns over the actual outcome of the GM Species process. The number of unknown and uncharacterized mutations far exceeds the intended ones. While Oxitec will state that they do not use CRISPR-Cas9, they use a version of this splice and insertion method that is very similar and offers the same uncertainty of outcome.

https://www.nature.com/articles/nbt.4192.epdf?referrer_access_token=YYXlsJQYykP2090xPlGw7NRgN0jAjWel9jnR3ZoTv0Nys6VqCZNKLWLlQOUkpsgJD5BqGV2TQgujlWruW2r5PU9cbVtLfcEFSqK-n1CGPE8-R0o2losdkLLMb_vPZKhZxw3ZmTo0G6Rj2_Ejpra97Pxf-l3JEMmtTtVG75-NEcBqGWUu_kohPt2hxj2qB95dBWf84NUNMCshTTQi7xlBcl6Id-3IH6n58E-mqjHwjr7ffXp4KIR2Jd52Wv-k9B6WzJ-BydbTSPKJeeSdpXp-O-Vn9p9-7T95Tj659eP3mk%3D&tracking_referrer=www.scientificamerican.com

Referring back to the large variation in survivability, a term which Oxitec cannot actually define to any reasonable quantitative standard, after submitting the FDA application that suggest 2 day survivability, as does all of the marketing literature for the past number of years; they now suggest up to 5% can survive 40, or more, days, which is long enough for females to take 2 blood meals and lay 2 clutches of eggs. Together with their inability to control the number of females released, now somewhere between 9/500 and 1/1000, per the Cayman Trials, and purposefully misrepresented on the EUP application at 1/4300, this evidence is exactly why the Common Rule should be applied and Informed Consent must be obtained by Oxitec, or the Florida Keys Mosquito Control District (FKMCD), before any release can be considered.

In addition, for the benefit of the EPA, the safety of our citizens, and global health interest, we requested that Oxitec be required to provide statistically significant samples sets of OX513A genome sequences. The rigor required to understand what we are really testing, when we consider the release of a GM Species into the wild, especially a species that creates a hybrid wild colonies that bite humans and animals, is daunting. It is however necessary to vet this technology properly to assure we become smarter at how to qualify and disqualify products that are proposed.

Since Mila's petition is so large, we will invite you to look at the online version with 230,868 signatures (https://www.change.org/p/tell-the-epa-no-to-gmo-mosquitoes ) , and if needed to download the actual petition with signatures from the Google Drive address provided below. Included in the folder is a presentation that Dr Norris and I presented in May. The presentation goes over several issues with the test and talks about some of the allergen issues that have been raised, but below we provide. Slightly expanded discussion of this and access to the protein sequences and the SDAP database that matches the strings of proteins with known allergens. As I stated in our meeting my confidence is that there is an association, understanding the risk level, is something that needs to be clear before a release can be considered safe.

Google Drive Folder:

**Ex. 6**

One of the concerns is that Oxitec may have chosen a longer protein sequence of 8, rather than the standard of 6 suggested by the SDAP database tool. This technique would undoubtedly yield fewer matches based on mathematical principles alone. If this is the case, it represents another example of Oxitec's pattern of obfuscation. We have to trust the applicants, or else it requires a different level of scrutiny to assure safe. Basically, it makes the EPA's job harder and should be a basis for disqualifying the Oxitec EUP application.

Below are the protein sequences and the SDAP allergen database tool to match the sequences to known allergens:

http://fermi.utmb.edu/SDAP/sdap_who.html

Amino Acid Sequence of the tTAV protein

MGSRLDKSKVINSALELLNEVGIEGLTTRKLAQKLGVEQPTLYWHVKNKRALLDALAIEM
LDRHHTHFCPLEGESWQDFLRNNAKSFRCALLSHRDGAKVHLGTRPTEKQYETLENQLAF

LCQQGFSLENALYALSAVGHFTLGCVLEDQEHQVAKEERETPTTDSMPPLLRQAIELFDH
QGAEPAFLFGLELIICGLEKQLKCESGSGPAYSRARTKNNYGSTIEGLLDLPDDDAPEEA
GLAAPRLSFLPAGHTRRLSTAPPTDVSLGDELHLDGEDVAMAHADALDDFDLDMLGDGDS
PGPGFTPHDSAPYGALDMADFEFEQMFTDALGIDEYGG

DsRed2 Amino Acid Sequence of the DsRed2 protein

MASSENVITE FMRFKVRMEG TVNGHEFEIE GEGEGRPYEG HNTVKLKVTK GGPLPFAWDI LSPQFQYGSK VYVKHPADIP
DYKKLSFPEG FKWERVMNFE DGGVATVTQD SSLQDGCFIY KVKFIGVNFP SDGPVMQKKT MGWEASTERL
YPRDGVLKGE THKALKLKDG GHYLVEFKSI YMAKKPVQLP GYYYVDAKLD ITSHNEDYTI VEQYERTEGR HHLFL

Here are some comments from recent observations from one of our science team regarding the SDAP results. We are still searching for a more studied allergen specialist to assess the results further. Once placed in the database tool, the results for tTav are in the range of 30 responses and the Florescent Marker are even greater. White Birch, Mung Beans, Castor Beans, Eastern Honey Bee, are some of the results that are noted. We will continue our efforts to obtain more specific qualified comments, but we hope the EPA has resources that can illuminate the true risks associated and determine if Oxitec's submissions were in compliance with industry standards in this field.

Comments from one of our science contributors:

It appears that anaphylactic shock has occurred from exposure to castor bean allergen.

Coattrenec, Y., Jaques, D., Jandus, P., Harr, T., & Spoerl, D. (2017). Anaphylactic shock following castor bean contact: a case report. Allergy, Asthma & Clinical Immunology, 13(1), 50. https://aacijournal.biomedcentral.com/articles/10.1186/s13223-017-0221-x

From what I can tell it appears that Bet v 1, affects over 100 million allergic patients and therefore could impact a large number of people exposed to GMO mosquitoes.

Asam, C., Batista, A.L., Moraes, A.H., de Paula, V.S., Almeida, F.C.L., Aglas, L., Kitzmüller, C., Bohle, B., Ebner, C., Ferreira, F. and Wallner, M., 2014. Bet v 1–a Trojan horse for small ligands boosting allergic sensitization?. Clinical & Experimental Allergy, 44(8), pp.1083-1093. https://s3.amazonaws.com/academia.edu.documents/44803421/Bet_v_1__a_Trojan_horse_for_small_ligand20160416-2528-14t471m.pdf?AWSAccessKeyId=AKIAIWOWYYGZ2Y53UL3A&Expires=1531593374&Signature=1wz357JNeTZjUeutFksWptfVTTw%3D&response-content-disposition=inline%3B%20filename%3DBet_v_1--a_Trojan_horse_for_small_ligand.pdf

Based on the Bet v 1. allergen it looks like as many as 1 in 70 or so people would be allergic so that is certainly a figure that would impact people in the trial area since there will be more than 70 people exposed.

We greatly appreciate the time, intensity and focus of the team contributing to this evaluation. We hope that our efforts provide a technical insight and depth that seven years of investigation and conversation provide. We are greatly disappointed in Oxitec. We truly believed in this technology as introduced, but we see no pathway, or attempt to prove this technology is safe by the manufacturer. This technology cannot be released in Europe because it cannot be proven safe. Oxitec has had to stop efforts to release other GM Species because they cannot prove they are safe. Why not? We think there is a pathway. We have expressed it to them, but again, Oxitec chose to pitch their tent in the marketing camp, not the science camp.

Thank you again for your time.

Sincerely,

Barry Wray
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