Message

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Sent: 10/29/2018 10:38:18 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]
CC: Ellis, Frank [Ellis.Frank@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Mendelsohn, Mike [mendelsohn.mike@epa.gov]
Subject: Oxitec -- Renegotiation

Rick,

BPPD staff met separately last week with Brad Shurdut from Intrexon/Oxitec and Ben Beard of CDC. We have a briefing scheduled for you next Monday , 11/5/18, on the Oxitec EUP status, but I wanted to update you now since the PRIA date for this action is 11/9/18 and we will need to renegotiate.

- CDC has provided funds to FL for hurricane relief. The appropriations for this funding required novel and traditional mosquito control technology and FL chose to fund Oxitec $1.5 million. CDC indicated that the funding was emergency response funds and had to be implemented this coming season or they would lose the funding. They asked if November 2018 was a viable plan for an EUP approval. They had heard from Oxitec that January 2019 was likely. We have communicated with Susan Jennings today that November is not viable and she heard from CDC that their drop dead date is early January. I understand if the Oxitec EUP is not off the ground by early January, CDC may have the option of using their funds for Wolbachia EUPs in Florida. As I understand it, they may not lose the money but merely shift it to fund other technology if this option is available to them.

- CDC has medical entomologists on staff and offered help with data analysis. We appreciate CDC's willingness to help; we feel CDC's input on BPPD's analysis regarding peptide signaling motif analysis would be helpful. However, we need to pass this through an ethics check because of CDC's interest in granting the EUP due to the funding issues.

- Intrexon/Oxitec has decided to do a mass spec analysis of mosquito saliva in lieu of the study protocol we have been discussing with them for several months. They may or may not do a protocol review and/or talk with us further about this. They hope to get the data in to us in 2 months.

- Our review of the EUP is ongoing, but it now looks like submission of the saliva expression data will be in late December or January. This pushes our review timeline estimates that we discussed internally this summer out to May/June 2019. I will forward our earlier roadmap to you ASAP. We are just taking the earlier estimates and projecting them out accordingly to reach May/June 2019. However, as I think Michelle A has conveyed to you, we do not at present have the info to go before HSRB re: the Kato study.

- The COMPARE database is set to discuss potential allergens this November. We understand (based on input from John Kough that has not been shared with Oxitec) that COMPARE will not change the status of GFP-like protein Akane unless new info. appears in Scientific Lit. However, Brad from Intrexon/Oxitec indicated last week that they had discussed this issue with COMPARE and he expects COMPARE to discuss further. So, we will see what happens next month after the

COMPARE meeting. As I understand it, this is a regularly scheduled COMPARE meeting, not one set up to discuss just the Oxitec issue. If for some reason COMPARE changes the designation from their current call as an "identified" allergen, we will let you know. Doing so would present OPP with some challenges.

Given these developments, we plan on proposing a renegotiation with Oxitec for June 1, 2019. We could also propose March 1, 2019 based on a late December or January submission of the saliva data, but we would have to caveat this date and say the EUP decision is unlikely to be completed by this date. We would have to integrate that data into our overall assessment. In addition, although Mike's staff has made real progress on many of the substantive comments, we still do not have a contract to help us with the 200,000 plus comments, and OGC has not had a chance to review our work.

Do you agree with us reaching out to the company to renegotiate the Nov. 9 date? I suspect they will go for a date in January/February, not May or June. We can live with a winter 2019 date as an interim PRIA date, as long as we convey to them that we will likely have more work to do that could push the date out into spring.

Bob