Message

From: Ingram, Earl [Ingram.Earl@epa.gov]
Sent: 5/11/2020 4:23:32 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
CC: McBride, Sharon Y [Mcbride.Sharony@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: Detailed Confidentiality Claims Request as Follow Up to Our Call Today

I saw it and as Don and discussed, we will follow the FOIA law and the Agency procedures for releasing records.

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, May 11, 2020 11:59 AM
To: Ingram, Earl <Ingram.Earl@epa.gov>
Cc: McBride, Sharon Y <Mcbride.Sharony@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: FW: Detailed Confidentiality Claims Request as Follow Up to Our Call Today

Earl,

In light of our discussion about DERs earlier this morning, I just wanted to make you aware of this email from Oxitec if you are not already.

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: Matthews, Keith <KMatthews@wiley.law>
Sent: Tuesday, May 5, 2020 2:23 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Nathan Rose <nathan.rose@oxitec.com>; McNally, Robert <Mcnally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: Detailed Confidentiality Claims Request as Follow Up to Our Call Today

Mike,

In response to your request, please note that Oxitec is not raising additional or more extensive claims of confidentiality than have been raised previously in the context of the OX5034 EUP application, or than Oxitec is entitled to under FIFRA Section 10. While Oxitec has authorized EPA to discuss publicly certain information related to the OX5034 EUP application – specifically information contained in the public version of the Section G document, Oxitec has not authorized the release or discussion of any information that is entitled to confidential protection that is not included in either the public Section G or other documents clearly marked as public.

As you know, FIFRA provides strong protections for confidentiality of business, commercial, and trade secret information. FIFRA Section 10(b) mandates that EPA not disclose <u>any</u> information, which, in EPA's "judgment contains or relates to trade secrets or commercial or financial information" that is obtained from a person subject to FIFRA. With respect to the OX5034 EUP application, Oxitec has clearly identified information that it

claims as confidential on the basis that in contains or includes business, commercial, or trade secret information. That includes all information identified as confidential in the EUP application and supporting materials, and the letter and attachment that I provided to you on Friday, 01 May.

In addition, with respect to information that may be contained in EPA's Data Evaluation Reports, please note that any discussion, information, or reference contained in any such report that concerns the objectives, methodology, standard operating procedures, results, or significance of any test or experiment performed on or with tTAV-OX5034, DsRed2-OX5034, or OX5034, and any information concerning either the effects of tTAV-OX5034, DsRed2-OX5034, or OX5034 on humans or any other organisms, or the behavior and effects of tTAV-OX5034, DsRed2-OX5034, or OX5034 in the environment, including any data and information related to human health and environmental effects, is Oxitec business confidential information. FIFRA strictly protects and explicitly prohibits disclosure of such information when it concerns or is related to a pesticide or pesticide active ingredient prior to registration. Until such time as OX5034 and/or tTAV-OX5034 are registered pursuant to FIFRA Section 3, Oxitec claims as confidential any data, information, or discussion described in this instant paragraph.

Therefore, in the context of our discussion on Monday morning, in the event that BPPD receives a FOIA request that seeks release of any DERs prepared with respect to OX5034, tTAV-OX5034, or DsRed2-OX5034, and BPPD intends to release in any information in such DERs in response to the FOIA request, Oxitec requests that BPPD notify Oxitec in writing, by certified mail, identifying such information that BPPD proposes to release. Upon providing such notification, BPPD shall not release any information from the relevant DERs for a period no less than thirty (30) days.

Given the sensitivity of this confidential information and the importance to Oxitec that the confidentiality of its business, commercial, and trade secret information regarding the unregistered pesticide OX5034, the unregistered active ingredient tTAV-OX5034, and the inert DsRed2-OX5034 be maintained, we are available to meet, if necessary, with individuals from OPP's FOIA Office and/or the Office of General Counsel to discuss.

Best regards,

Keith

wiley

Keith A. Matthews
Attorney at Law
kmatthews@wiley.law

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Note: The firm's domain has changed to wiley.law. To update my contact information, please download my vCard

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Monday, May 04, 2020 3:22 PM
To: Matthews, Keith <KMatthews@wiley.law>
Cc: Nathan Rose <nathan.rose@oxitec.com>; McNally, Robert <Mcnally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Subject: Detailed Confidentiality Claims Request as Follow Up to Our Call Today

Keith,

As a follow up to the verbal claims of confidentiality you made on our call today regarding the Oxitec EUP application and EPA's Risk Assessment, please provide detailed claims in writing by 12 noon this Wednesday 5/6/2020.

Mike Mendelsohn, Chief
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Biopesticides and Pollution Prevention Division (7511P)
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