Message

From: Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]
Sent: 9/6/2019 1:21:07 PM
To: DavidJ Miller [Miller.DavidJ@epa.gov]
Subject: FW: EFSA Epidemiology Conference: follow-up

From: Antonio Hernández Jerez <ajerez@ugr.es>
Sent: Monday, March 19, 2018 5:26 AM
To: Miller, David <Miller.DavidJ@epa.gov>; 'CRIVELLENTE Federica' <Federica.CRIVELLENTE@efsa.europa.eu>
Cc: 'Matteo Bottai' <matteo.bottai@ki.se>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear David,

It's good to hear from you. Yes, the Scientific Opinion is already out and now it's time for applicants to use the recommendations given on epi evidence for further renewal authorizations. Let's see whether it works properly.
I am happy that in the end you take the chance of drafting a paper together with Mateo on the effect size magnification. This initiative will provide a strong scientific support to the EFSA Opinion and will have an impact on pesticide risk assessment. As you mention in your email, the Opinion published in EFSA Journal will be quoted in that paper, and I would suggest you to also mention the Opinion in the Introduction, in addition to the separate note you enclosed in your email. In that sentence you can indicate that the paper is triggered by the Scientific Opinion and that a preliminary exercise on effect size magnification is dealt with in one of its appendices.
I also want to thank you very much for the emails exchanged with the Greek colleagues on the examples of active substances where US-EPA has used epi data for risk assessment.
I will appreciate very much to receive a PDF file of the paper once published.

Best regards,
Antonio

De: Miller, David [mailto:Miller.DavidJ@epa.gov]
Enviado el: viernes, 16 de marzo de 2018 17:47
Para: Antonio Hernández Jerez; CRIVELLENTE Federica
CC: Matteo Bottai
Asunto: FW: EFSA Epidemiology Conference: follow-up

Dear Federica and Antonio,

I hope you are both well. And I am sure you are both very happy that the EFSA PPR epi document out and the EFSA symposium is over. Congratulations to both of you.

I did want to communicate to you two things:

1. Recall that there was a question asked during the EFSA symposia from a representative from Greece re: examples of epi assessments that the US EPA has done. I indicated during the Q&A session that I would follow-up on that, and – after the Q&A session – we exchanged business cards and subsequently emails so as to close out that communication. More as an FYI, please see the email exchanges below,. if interested. You are likely aware of a number of these anyway.

2. On a somewhat separate topic, Antonio encouraged me on at least a couple of occasions during our interactions to follow-up some on the effect magnification work that was discussed briefly in the main EFSA Panel document in some detail in one of the Annexes. He indicated that he thought it might be be useful and be of general interest to publish on this topic as an article separate from the EFSA J. . I did briefly talk to Matteo B. on this during the November EFSA symposia and bring this article idea up with him as possibly something he and I could jointly write for the *Stata Journal* (see http://www.stata-journal.com/) if he was willing to write the code for this in Stata (James Nguyen in my branch had done this in SAS for the EFSA Panel Opinion and the calculations that are there were from these runs). Matteo and I agreed at that time to communicate again on this topic early in January 2018, after the holidays.

We did, and are now working on a manuscript that we are planning to submit to *the Stata Journal* for publication , but - before we do – I wanted to alert both of you and make sure there were no concerns or objections on either of your parts or on the part of EFSA. The manuscript has expanded beyond pesticides (we still give the diazinon AHS example, but now include one for lung cancer and exposure to resins in a transformer facility). We also expand some on the Ioannidis work, recreating his Table 2 in

Ioannidis, J. P. A. 2008. Why most discovered true associations are inflated. *Epidemiology* 19: 640-648. [accessed 24 February 2018 at http://www.dcscience.net/ioannidis-associations-2008.pdf]

TABLE 2. Simulations for Effect Sizes Passing the Threshold of Formal Statistical Significance ($P = 0.05$)

			Observed OR in Significant Associations	
True OR	Control Group Rate (%)	Sample n Per Group	Median (IQR)	Median Fold Inflation
1.10	30	1000	1.23 (1.23–1.29)	1.11
1.10	30	250	1.51 (1.49–1.55)	1.37
1.25	30	1000	1.29 (1.28–1.39)	1.03
1.25	30	250	1.60 (1.50–1.67)	1.28
1.25	30	50	2.73 (2.60–3.16)	2.18

IQR indicates interquartile range.

And, of course -- most importantly of all -- the new Stata command `-emagnification-` authored by Matteo is introduced and described. This is able to re-create the work in the EFSA J. using a very much more convenient custom-made command. Some of the material originally authored by me that appeared in the EFSA opinion is also used as introductory background material in the manuscript. To lay this fact out clearly, the manuscript states:

> **Note:** Some material presented here was originally generated by the two of the authors who served in various capacities on a European Food Safety Agency (EFSA) Panel on Plant Protection Products and their Residues (PPR), which followed up on findings of the External Scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' (University of Ioannina Medical School, 2013) (EFSA-Q-2014-00481). As part of their work on the PPR, the authors contributed to the review and writing of "Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report 'Literature review of epidemiological studies linking exposure to pesticides and health effects' "and its Annex D where much of this material originally appeared. The PPR Panel report is published in the EFSA Journal, an official publication of EFSA. This *Stata Journal* article introduces the new Stata command `-emagnification-` and is the result of an expansion and extension of the original EFSA PPR Panel work as part of a post-PPR Panel collaboration by the authors.

Note that we reference in the manuscript where the EFSA J. can be located.

Anyway, I wanted to let you know this and verify you had no concerns or objections with the above or with Matteo and I submitting this for publication to the *Stata Journal*. . Note that we are not making any representations for EFSA in the manuscript in terms of policies, practices, or opinions and the article is not meant to focus on pesticides at all. . So I suspect that there will not be any problem. I think there is enough new material – especially with the new Stata command by Matteo – and it covers more than just pesticides to warrant a publication separate from the EFSA J., particularly given what I think a number of us feel is an important topic in and of itself.

If you would like us to send you the draft manuscript, feel free to let me know and I would be happy to forward it to you. It's not final at this point, but it is pretty close and we are getting ready to submit it.

Regards,

David.

David J. Miller CAPT | USPHS Commissioned Corps
Branch Chief

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From: Νικολοπούλου Δήμητρα [mailto:d.nikolopoulou@bpi.gr]
Sent: Wednesday, December 20, 2017 6:02 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Μαχαίρα Κυριακή <k.machera@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Thank you David!

Glyphosate! That is interesting. I will have a look.

May I also take this opportunity to wish you Merry Christmas & a Happy New Year !!!

Best,
Dimitra

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, December 21, 2017 12:58 AM
To: Νικολοπούλου Δήμητρα <d.nikolopoulou@bpi.gr>
Cc: Μαχαίρα Κυριακή <k.machera@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

You're welcome.

As an example of a Tier III-type review which blends animal toxicology, MOA, and epidemiology , see the link below:

https://www.epa.gov/sites/production/files/2017-12/documents/revised_glyphosate_issue_paper_evaluation_of_carcinogenic_potential.pdf

This was released by the Agency to the web earlier this week.

Regards,

David

From: Νικολοπούλου Δήμητρα [mailto:d.nikolopoulou@bpi.gr]
Sent: Monday, December 18, 2017 2:48 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Μαχαίρα Κυριακή <k.machera@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear David,

Thank you for the links!!! This is much appreciated.

Greece has acted as rapporteur Member State for the evaluation of 2,4-D, so it will be interesting to see what is there available regarding epidemiology.

Best regards,
Dimitra

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Mob: +30 6942988760 – e-mail: d.nikolopoulou@bpi.gr www.bpi.gr

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Monday, December 18, 2017 1:18 AM
To: Νικολοπούλου Δήμητρα <d.nikolopoulou@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear Ms. Nikilopolou,

They are finally out now, as of late last week : our 2,4-D epi documents (two: one dealing with carcinogenic effects and the other non-carcinogenic effects) have finally been released to the docket. The docket can be found here:

2,4-D docket.
https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0330

and direct links to the two epi reviews in that docket are here:

> https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0084 for carcinogenic effects (dated September 20, 2017)
>
> https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0087 for non-carcinogenic effects (dated September 27, 2017).

We typically would do one epi document, but 2,4-D was of sufficient size that we decided to split it into two. In addition, we would typically also include our incident (poisoning) reviews in the same document as our epi reviews, but we released our incident/poisoning review for 2,4-D much earlier. You didn't ask about these reviews, but if you have interested, it was posted earlier and can be retrieved from here:

https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0330-0046

Again, apologies for how long this has taken to have these appear in the docket. But I hope that the examples I provided earlier (below) and the above helps in in better understanding what we do.

Regards,

David.

David J. Miller CAPT | USPHS Commissioned Corps
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From: Miller, David
Sent: Thursday, December 14, 2017 7:43 PM
To: Νικολοπούλου Δήμητρα <d.nikolopoulou@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear Ms. Nikiloplou,

Apologies for having this information drift out to you so slowly. The 2,4-D Tier II epi memo completed in late September is not yet out in the public docket.

In the meantime, here is another example of a recently-completed Tier II for **permethrin**:

Tier II

Permethrin Tier II :

https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0039-0084

and another example of an earlier Tier I for aldicarb:

link to published **aldicarb** Tier I incident/epi memo:

https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0024

When the 2,4-D Tier II epi memo, we will provide you the link to that one.

Regards,

David

From: Miller, David
Sent: Wednesday, November 29, 2017 3:47 PM
To: 'Νικολοπούλου Δήμητρα' <d.nikolopoulou@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear Ms Nikolopoulou,

I am finding that we will need to send you the links to our Tier I, Tier II, and Tier III documents in separate emails so as not to delay a response to you.

For now- below -- please find some examples of our Tier I assessments. Very briefly, these include as a matter of course both epidemiology and poisoning (incident) information: since you are interested in only the epidemiology, you can ignore the incident information that is there: it is our practice to include these together in one memorandum.

Here are 4 examples, to start.

Links to Tier I Epi/incident reviews available in the chemical dockets:

1. Carbaryl https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0230-0035

2. EPTC https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0720-0017

3. Metribuzin https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0487-0021

4. Aldicarb https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0024

I had specifically mentioned dicamba and DDVP to you during the EFSA symposia as examples of Tier I assessments. These I will send later.

Two good **Tier II** assessments as examples are permethrin and 2,4-D (as I said during the EFSA symposium). While we have completed and signed our 2,4-D epidemiological Tier II assessment at the end of September, it is apparently not yet in the regulatory docket. However, we expect it to appear there in the next several days, and I will forward you the links to permethrin and 2,4-D epidemiology Tier II documents when the 2,4-D one becomes available to the public in the docket. Again, I expect this to be available in the next few days -- or next week at the latest.

The **Tier III** examples that integrate epidemiology, animal toxicology, and MOA I will sent later too. Those will be links to our Scientific Advisory Panel website where these were presented.

Sorry for the delay, but – hopefully -- the links provided above for our Tier I assessments will get you started.

Finally, please note that we are refining our approaches and (hopefully) getting better as we gain experience in conducting these epidemiological reviews. So you may find that the format, detail, content, and approach in earlier assessments we have done may differ someone from more recent assessments. But the recent assessments should be considered where we are headed.

Regards,

David

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From: Νικολοπούλου Δήμητρα [mailto:d.nikolopoulou@bpi.gr]
Sent: Monday, November 27, 2017 1:41 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear David,

I have already made notes of the examples you gave during the conference, but the links will be much appreciated.

Best regards,
Dimitra

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From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Sunday, November 26, 2017 11:02 PM
To: Νικολοπούλου Δήμητρα <d.nikolopoulou@bpi.gr>
Subject: RE: EFSA Epidemiology Conference: follow-up

Dear Ms. Nikolopoulou,

Thank you very much for your inquiry. I am glad you enjoyed the presentation I named several examples of Tier I, Tier II, and Tier II assessments during the afternoon Q&A , but – as promised – I will get the links to you to you can see some concrete examples.

I will try to get back to you by the end of the week.

Regards,

David

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From: Νικολοπούλου Δήμητρα [mailto:d.nikolopoulou@bpi.gr]
Sent: Wednesday, November 22, 2017 4:27 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: EFSA Epidemiology Conference: follow-up

Dear Dr Miller,

Hope you had a safe journey back home. Thanks for the very interesting presentation you gave on the US EPA approach regarding the use of epidemiology studies in pesticide risk assessment. As discussed during the Conference, I was interested in looking at real examples where you have applied the OPP framework. I would appreciate it if you could provide me with the web-addresses to access these evaluations.

Thank you in advance and best regards,
Dimitra

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ΔΗΛΩΣΗ ΑΠΟΠΟΙΗΣΗΣ ΕΥΘΥΝΗΣ

Το παρόν μήνυμα ηλεκτρονικού ταχυδρομείου και τα τυχόν συνημμένα σε αυτό αρχεία είναι εμπιστευτικό και προορίζεται αποκλειστικά για χρήση του φυσικού ή νομικού προσώπου στο οποίο απευθύνεται. Εάν δεν είστε ο ενδεδειγμένος παραλήπτης, οφείλετε να μην το αντιγράψετε, αναμεταδώσετε, χρησιμοποιήσετε ή αποκαλύψετε το περιεχόμενό του. Οφείλετε να ενημερώσετε τον αποστολέα του μηνύματος για την εσφαλμένη λήψη του και αμέσως να διαγράψετε το αντίγραφο από το σύστημά σας. Παρακαλώ σημειώσατε ότι οποιεσδήποτε θέσεις ή απόψεις που παρατίθενται στο παρόν μήνυμα ηλεκτρονικού ταχυδρομείου εκφράζουν αποκλειστικά το συντάκτη του και δεν αντιπροσωπεύουν, άνευ ετέρου, το Μπενάκειο Φυτοπαθολογικό Ινστιτούτο. Τέλος, ο παραλήπτης οφείλει να ελέγξει για τυχόν ύπαρξη ιού στο παρόν μήνυμα ηλεκτρονικού ταχυδρομείου και στα συνημμένα σε αυτό αρχεία. Το Μπενάκειο Φυτοπαθολογικό Ινστιτούτο αρνείται κάθε ευθύνη για οποιαδήποτε ζημία ήθελε προκληθεί από ιό που ενδεχομένως διαδοθεί από το παρόν μήνυμα ηλεκτρονικού ταχυδρομείου.

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