



## LEGAL AND ASSURANCE SERVICES

Parma, 25 June 2021  
Ref. LV/CP/mm (2021) – out-24969451

Dr. Peter Clausing

e-mail: ask+request-9458-  
4c2745df@asktheeu.org

### **Re: Your application for public access to documents of 9 May 2021**

*Our ref: - PAD 2021/061*

Dear Dr Clausing,

I refer to your application for access to documents submitted on 9 May 2021 by means of which you asked for:

- the information *"how many combined exposure assessments of pesticides based on the EFSA Guidance on risk assessment of combined exposure to multiple chemicals (cf. EFSA Journal 2019;17(3)5634) have actually been performed?"* and
- *"documents containing these assessments or provide a link where I can download these"*.

Your application is being assessed in accordance with [Regulation \(EC\) No 1049/2001](#) on public access to documents (hereinafter *"the PAD Regulation"*).

We proposed to handle your PAD application in successive stages allowing for a detailed assessment on the accessibility of each of the documents falling within the scope of your application. By means of this letter, we are pleased to provide you with a first batch of documents as detailed below.

#### **1. Disclosure**

In reply to your request for information on the number of scientific outputs having conducted a combined exposure assessments of pesticides based on the EFSA Scientific Committee Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (hereinafter the "MIXTOX 1 Guidance of 2019")<sup>1</sup>, please note that so far EFSA has not conducted any assessment based on the MIXTOX 1 Guidance of 2019. Indeed, MIXTOX 1 Guidance of 2019 sets up a general framework, which still requires additional developments to take into account specific sectorial needs. In the meantime, additional activities are ongoing as outlined in the following paragraphs.

In this regards we are pleased to provide you with some additional information and access to documents which may be of your interest and which relate to the ongoing work on mixtures as follows:

- Please be informed that EFSA is currently working on the combined risk assessments of pesticides based on the MIXTOX 1 Guidance of 2019 and preparing a MIXTOX 2 Guidance

<sup>1</sup> EFSA Scientific Committee, More SJ, Bampidis V, Benford D, Bennekou SH, Bragard C, Halldorsson TI, Hernandez-Jerez AF, Koutsoumanis K, Naegeli H, Schlatter JR, Silano V, Nielsen SS, Schrenk D, Turck D, Younes M, Benfenati E, Castle L, Cedergreen N, Hardy A, Laskowski R, Leblanc JC, Kortenkamp A, Ragas A, Posthuma L, Svendsen C, Solecki R, Testai E, Dujardin B, Kass GEN, Manini P, Jeddi MZ, Dorne J-LCM and Hogstrand C, 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal 2019;17(3):5634, 77 pp, <https://doi.org/10.2903/j.efsa.2019.5634>.

document. This updated version of the MIXTOX 1 Guidance of 2019 was presented in point 3 of 27<sup>th</sup> meeting of the Network on Pesticides Steering which minutes are available on EFSA's website:

<https://www.efsa.europa.eu/sites/default/files/2021-04/27th-meeting-efsa-pesticide-steering-network-minutes.pdf>.

- Regarding the cumulative risk assessment methodologies, please be informed that EFSA has issued three scientific outputs as follows:
  - Cumulative dietary risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides: <https://www.efsa.europa.eu/fr/efsajournal/pub/6392>,
  - Cumulative dietary risk characterisation of pesticides that have acute effects on the nervous system: <https://www.efsa.europa.eu/fr/efsajournal/pub/6087>,
  - Comparison of cumulative dietary exposure to pesticide residues for the reference periods 2014–2016 and 2016–2018: <https://www.efsa.europa.eu/fr/efsajournal/pub/6394>.

As you can see these three outputs cannot be seen as examples for using the MIXTOX 1 Guidance of 2019.

In addition to the above, we would like to share with you the **"EFSA-SANTE Action Plan on Cumulative Risk Assessment for pesticides residues"** which is publicly available at the following link: [https://ec.europa.eu/food/system/files/2021-03/pesticides\\_mrl\\_cum-risk-ass\\_action-plan.pdf](https://ec.europa.eu/food/system/files/2021-03/pesticides_mrl_cum-risk-ass_action-plan.pdf).

Finally, please be aware that there is more information:

- In the dedicated page on the European Commission website: [https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels/cumulative-risk-assessment\\_en](https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels/cumulative-risk-assessment_en),
- On EFSA's website on chemical mixtures at the following page: <https://www.efsa.europa.eu/en/topics/topic/chemical-mixtures>

With regards to your question received on 3 June 2021 regarding the reasons for asking you an alternative e-mail address, please note that the third party running the AsktheEU.org website is responsible and accountable for the processing of your personal data via that website, and not EFSA. For further information on your rights, please refer to the third party's privacy policy. We understand that the third party running the AsktheEU.org website usually publishes the content of applicants' correspondence with the EU institutions, including EFSA on that website. This includes the personal data that you may have communicated to EFSA (e.g. your private address).

Similarly, the third party publishes on that website any reply that EFSA will send to the email address of the applicants generated by the AsktheEU.org website.

If you do not wish that your correspondence with EFSA is published on a third-party website such as AsktheEU.org, you can provide us with an alternative private e-mail address for further correspondence. In that case, EFSA will send all future electronic correspondence addressed to you only to that private address, and it will use only that private address to reply to your request. You should still remain responsible to inform the third-party website about this change of how you wish to communicate with and receive a reply from EFSA.

For information on how we process your personal data consult the specific privacy statement – access to documents in Connect.EFSA: <https://connect.efsa.europa.eu/RM/s/termofuse>.

We hope you find the documents disclosed to you useful. I must remind you that in line with Article 16 of the PAD Regulation all persons reproducing, redistributing, exploiting or making commercial use of this information are expected to adhere to the terms and conditions asserted by the copyright holder.

EFSA is still in the process of assessing the accessibility to the remaining documents within the scope of your application. We will come back to you regarding the accessibility to these documents as soon as possible and by **16 July 2021 at the latest**.

## **2. Confirmatory application**

To exercise your right to appeal against this decision of partial disclosure by a confirmatory application, you may write to EFSA at the address below. You have fifteen working days from receipt of this letter to appeal. Please note that you can also exercise your right to appeal against this decision after your request for public access to documents has been fully addressed, i.e. after the final reply on your pending request has been sent to you. In case you submit a confirmatory application, EFSA will inform you of the outcome of this re-examination of your request within fifteen working days of receipt, either by granting you access to the documents or by confirming the refusal. In the latter case, you will also be informed of any further appeal routes available.

Confirmatory applications must be sent to:  
EFSA  
Dirk Detken  
Head of the Legal and Assurance Services  
Via Carlo Magno 1/A  
IT – 43126 Parma  
Italy

E-mail: [Dirk.Detken@efsa.europa.eu](mailto:Dirk.Detken@efsa.europa.eu)

Yours sincerely,

Luisa Venier  
EFSA Public Access to Documents

Cc: M. Tiramani, T. Robinson (EFSA)