Brussels, 19/06/2024



Mr Eric Thévenard Head of Unit E4 'Pesticides and Biocides' Directorate-General for Health and Food Safety European Commission

## Subject: PAN Europe's reply to your letter of 22 April 2024 and raises further concerns about PFAS pesticides & their persistent metabolite trifluoroacetic acid (TFA)

Dear Mr Thévenard,

With this letter, PAN Europe would like to follow up on your response dated 22 April 2024<sup>1</sup> to our previous correspondence of 28 February regarding PFAS pesticide residues in food sold in the European Union (EU). We appreciate your taking the time to respond, although we regret to read that there was a misunderstanding about the methodology we used in our report. We fear that this led to the undermining of our findings and their scientific robustness. We also regret that your letter fails to address any of our urgent demands for stricter regulation of PFAS pesticides, and consequently misses to reply to the critical importance and urgency of strengthening the implementation of the EU law provisions and halting PFAS pollution in the EU.

First, let us re-emphasise that phasing out PFAS is now a priority for the European Union (EU) to protect human health and reduce pollution from chemicals (Chemical Strategy for Sustainability, 2020). As a result, the REACH proposal aims to restrict PFAS as a group, based on the recognition that the persistent properties of all PFAS substances pose an unacceptable risk to human health and the environment. It is therefore expected that decisive action is undertaken to address all PFAS sources, and PFAS pesticides should be no exception. The use of PFAS pesticides leads to direct and deliberate PFAS pollution, which certainly cannot be considered essential for agriculture, taking into account the available chemical and non-chemical alternatives.

Our report reveals that the proportion of the most common fruit and vegetables containing residues of PFAS pesticides in the EU has nearly tripled between 2011 and 2021. The methodology used to calculate variations over the years is clearly explained in the corresponding section of our report. Our analysis has selected the most common conventional fruit and vegetables, for which the exposure is considered relevant for the general population, and we have excluded the targeted 'risk-based' samples<sup>2</sup>. These, as you also explain in your letter, are targeted

<sup>&</sup>lt;sup>1</sup> Ref. Ares(2024)2930194.

<sup>&</sup>lt;sup>2</sup> Cf page 6 of our report.

samples that are likely to exceed the MRLs and therefore were not considered representative for the assessment of consumers' exposure. Furthermore, in the report, we explain that the percentage of increase/decrease of the detected residues is based on the trend points, not on the data points. As clarified in the report *"trend lines provide (...) a more accurate representation of the long-term trend by smoothing out the anomalies or irregularities that can occur in individual years*"<sup>3</sup>.

At PAN Europe we disagree with your argument that since "the vast majority of results remains below the MRLs, which are safe for consumers, there is no basis for your claim that consumers would be at risk from those findings in food". As explained in our report, we do not consider the current MRLs to be sufficiently protective for consumers. First, MRLs are set without taking into account that the persistent and sometimes bioaccumulative properties of pesticide substances will result in exposure to higher levels (i.e. the fact that certain PFAS substances and their residues build up into bodies to levels that can cause adverse effects). Second, MRLs are based on the assessment of individual pesticide substances, without taking into consideration cumulative and synergistic effects with other pesticides as required by EU law (Regulation 396/2005 on MRLs) or even other pollutants present in the environment. We are aware of EFSA's work on cumulative assessment organ groups. We have already pointed out its clear limitations by design and the extended delay in the regulation of mixtures of pesticides multiple times. As shown in our report, consumers' exposure to pesticide cocktails is a reality that needs to be addressed urgently to ensure their protection. In this context, PAN Europe has consistently asked the European Commission to implement an additional Mixture Assessment Factor (MAF) of 10, which is aligned with the EU's commitment of the EU Chemical Strategy for Sustainability.

As for the origin of this growth in PFAS pesticide residues, your proposal that it may partially result from an increase of authorisations of PFAS pesticides over time only strengthens our concerns. It confirms that the EU Pesticide Regulation 1107/2009 -as currently implemented- fails to phase out PFAS pesticide substances, which meet the OECD definition. This was already the conclusion of an analysis by PAN Europe and Générations Futures shared with your unit in November 2023<sup>4</sup>. While the Pesticide Regulation aims to ensure that pesticides and their residues have no harmful effects on human health, animal health and groundwater and no unacceptable effects on the environment (Article 4), persistence alone of synthetic active substances is not considered sufficient to refuse or withdraw their authorisation. Although some PFAS substances might be banned in the EU if they meet the criteria of Annex II to be considered mutagenic, carcinogenic, toxic for reproduction (CMRs) and endocrine disruptors (ED)<sup>5</sup>, substances that are persistent are banned if they are found to be Persistent Organic Pollutants (POP), Persistent Bioaccumulative and Toxic (PBT), very Persistent very Bioaccumulative (vPvB). However, these criteria may fail to capture all PFAS substances. This is mainly because PFAS do not necessarily bioaccumulate and their toxicity is not sufficiently assessed. We welcome the new hazard classes for persistent

<sup>&</sup>lt;sup>3</sup> Cf page 7 of our report.

<sup>&</sup>lt;sup>4</sup> <u>Europe's Toxic Harvest: Unmasking PFAS Pesticides Authorised in Europe | PAN Europe (paneurope.info)</u>

<sup>&</sup>lt;sup>5</sup> Recent non-renewal of approval of the PFAS substance tritosulfuron-methyl based on its endocrinedisrupting properties for humans and wild mammals.

Toxic and Mobile (PMT) and very Persistent and very Mobile (vPvM) substances introduced by the revised CLP Regulation 1272/2008 and look forward to seeing them applied to the Pesticide Regulation. However, having PMT and vPvM cut-off criteria will still not lead to a comprehensive phase-out of PFAS substances. To ensure such a phase-out, the persistence of PFAS synthetic substances or of their metabolites must be considered as an unacceptable effect on the environment in light of the intrinsic toxic properties of synthetic pesticides and the cumulative nature of the PFAS pollution. This will align the Pesticide Regulation with the proposal of a universal restriction of PFAS under the REACH Regulation.

Another reason to ban PFAS pesticides is their breakdown into trifluoroacetic acid (TFA). The stability, mobility, and solubility of TFA make it an exceptionally problematic contaminant, which accumulates in water bodies and remains for many years. A new report by the Pesticide Action Network and its members highlights alarming levels of TFA in both surface and groundwater samples from ten EU countries<sup>6</sup>. Detected TFA levels ranged from 370 ng/l to 3,300 ng/l, with an average of 1,180 ng/l. Worryingly, this contamination is not confined to industrial hotspots but is widespread. In rural areas, PFAS pesticides appear to be the primary source of TFA contamination<sup>7</sup>. Thus, this extensive environmental pollution can, at least in part, be attributed to the lack of regulation of TFA and PFAS pesticides under the Pesticide Regulation.

The Commission and Member States have been aware of TFA as a pesticide breakdown product of PFAS pesticides for a while but have not stopped the authorisation of PFAS pesticides. In 2014, EFSA published a list of active substances degrading into TFA according to their molecular structure<sup>8</sup>. With a few exceptions<sup>9</sup>, this list corresponds to the one included in the PFAS restriction proposal from February 2023. Despite this long-decade knowledge of the probability of C-CF3 pesticide conversion into TFA, to our understanding neither EFSA nor the Commission have asked for applicants to provide metabolism and degradation studies confirming or invalidating this TFA-conversion assumption. Furthermore, the toxicological profile of TFA has been underinvestigated by the producers, EFSA and Rapporteur Member States notwithstanding its completely stable property. In the very few cases<sup>10</sup> where the toxicity of TFA was assessed, it has repeatedly been considered of no concern despite significant data gaps. The only exception to this is the active substance flurtamone. In 2017, in the course of flurtamone's risk assessment, EFSA identified TFA as a relevant metabolite<sup>11</sup> and the potential of groundwater contamination above 100 ng/L as a critical area of concern. This played a key role in the non-approval of the substance. Logically, this should have triggered the review and consequently the withdrawal of approval of all PFAS pesticides that have the potential to contaminate groundwater with TFA

<sup>&</sup>lt;sup>6</sup> <u>TFA in Water: Dirty PFAS Legacy Under the Radar | PAN Europe (pan-europe.info)</u> - published on 27 May 2024.

<sup>&</sup>lt;sup>7</sup> Trifluoroacetate (TFA): Laying the foundations for effective minimization - Spatial analysis of the entry pathways into the water cycle | Federal Environment Agency (umweltbundesamt.de)

<sup>&</sup>lt;sup>8</sup> <u>Reasoned opinion on the setting of MRLs for saflufenacil in various crops, considering the risk related to</u> the metabolite trifluoroacetic acid (TFA) (wiley.com) - Appendix C.

<sup>&</sup>lt;sup>9</sup> Mefentrifluconazole, Tetraconazole, Triflumuron (no longer approved, 2020).

<sup>&</sup>lt;sup>10</sup> Fluazinam (EFSA, 2008), saflufenacil (EFSA, 2014), flurtamone (2017, EFSA).

<sup>&</sup>lt;sup>11</sup>TFA was considered a relevant metabolite due to the proposed classification of its parent compound (flurtamone) as carcinogenic category 2.

above the accepted threshold value. In fact, not only did this not happen, but also, still in 2023, EFSA could not conclude on the TFA aneugenicity (genotoxicity) potential or the risks for birds, mammals, bees and aquatic organisms as a result of missing data<sup>12</sup>. This situation is now even more concerning as TFA has been proposed to be classified as 'toxic for reproduction' category' 1B<sup>13</sup>, which makes the substance a relevant metabolite and the groundwater threshold of 100 ng/L applicable. The levels of TFA we found in all groundwater samples exceed this safety threshold limit. Therefore, all the authorisations of PFAS pesticides that break down to TFA do not comply anymore with the EU law.

We hope this letter has convinced you of the urgent need to **ban all PFAS active substances**, **as defined by OECD**, that are persistent or degrade into persistent metabolites, such as TFA.

We urge you to make the first steps in that sense by implementing the following actions during the SCoPAFF meeting of July:

- 1) Present a draft proposal to ban flutolanil and pydiflumetofen in light of the persistent properties of these two synthetic substances and their intrinsic toxic properties as well as the cumulative nature of the PFAS pollution;
- 2) Present a draft proposal reducing to the shortest delay the current (prolonged) approval period of tritosulfuron and flumetralin. This follows the applicants' decision to withdraw their applications for renewal of the two substances, whose approval periods were respectively to expire in November 2018 and December 2022;
- 3) With reference to the rabbit study used for the classification of TFA as toxic for reproduction category 1B, review and withdraw all authorisations or PFAS pesticides that break down to TFA under Article 21 of the Pesticide Regulation.
- Present a proposal to amend Annex II of the Pesticide Regulation to include cut-off criteria for Persistent, Mobile and Toxic (PMT), very Persistent and very Mobile (vPvM), Persistent (P) and very Persistent (vP) synthetic substances.

From beforehand, thank you for your serious consideration of our letter.

Sincerely yours,

On behalf of PAN Europe

Angeliki Lysimachou Head of Science and Policy Pesticide Action Network Europe

 <sup>&</sup>lt;sup>12</sup> Peer review of the pesticide risk assessment of the active substance tritosulfuron - - 2023 - EFSA Journal
<u>- Wiley Online Library</u>

<sup>&</sup>lt;sup>13</sup> Registry of CLH intentions until outcome - ECHA (europa.eu)