To: Guilhem de Seze
Head of Risk Assessment Production Department
European Food Safety Authority
Parma
Italy

Cc:
Bernhard Url
Executive Director

Brussels, 25/07/2024

Subject: written follow-up to our discussions on PFAS pesticides following the meeting on 11 July 2024

Dear Mr. Guilhem de Seze,

On behalf of Générations Futures, Global 2000, Nature & Progrès Belgique and PAN Europe, I would like to thank you and your staff for your response[1] to our letter raising concerns about PFAS pesticides and their residues in food from 7 May 2024. We appreciate your invitation and the constructive meeting on PFAS pesticides on 11 July 2024, aimed at contributing to a high level of protection of human health and the environment. We hope you find it fruitful as well.

With this letter, we would like to continue our discussion in writing. In the annex, you will find a series of unresolved questions from the meeting due to time constraints, along with some follow-up questions based on discussion.

[1] Ref. GdS/MT/jwc-OC-2024-30663246.

In your letter from 4 June 2024, you stated that *"given their direct dissemination into the ecosystem, they* [PFAS pesticides] *pose distinct concern"*. We welcome and agree with this statement. However, we consider that the urgency of this concern has so far not been sufficiently communicated by EFSA to pesticide risk managers, as discussed during our meeting. In particular, we are critical of EFSA's 'substance by substance' approach 'in silos', which fails to reflect the real exposure of citizens and the environment to mixtures of PFAS pesticide residues (active substances and metabolites) and other chemicals. By not considering mixture effects and cumulative background levels, this approach underestimates the actual risks. We acknowledge and understand that EFSA is partly bound by specific individual and lengthy procedures set out in the Pesticide Regulation when peer-reviewing pesticide risk assessments. Nevertheless, we would like to highlight that according to the General Food Law, EFSA's mission, as an independent scientific agency, is to contribute to a high level of protection of human life and health. To achieve its mission, EFSA is empowered to undertake any necessary action to identify and characterise emerging risks in the field of food safety, express its conclusions independently and even take its own initiative on matters within its mission (Articles 22, 23 & 29 of Regulation (EC) 178/2002). Therefore, we urge EFSA to use its power of taking its own initiative to highlight the true risks of PFAS pesticides to the risk managers in line with EFSA's mission for the protection of health and the environment.

A major concern regarding PFAS pesticides, in addition to the 'usual' residue issues of the active substances, is their almost irreversible accumulation and that of their highly persistent terminal degradation product trifluoroacetic acid (TFA) in the environment and the food chain (crops). This accumulation contributes to background levels of TFA from other sources, such as fluorinated gases, leading to unacceptably high exposure levels to TFA. Despite TFA's widespread distribution, there is limited toxicological data available. However, the existing data on general toxicity and reproductive toxicity suggests that TFA may have effects and target organ impacts similar to those known for many other PFAS, to which significant portions of the European population are already exposed above acceptable health levels. Exposure to TFA from multiple sources now adds to these existing exposures. EFSA did not properly characterise this risk in the course of individual PFAS pesticide risk assessments, lacking a global approach to account for the different sources of human and environmental exposure to TFA.

Such an overarching approach is critically needed today given the existing data on TFA's presence in our environment and the food chain and the growing evidence of its toxicity. In our joint report published in May 2024[2], the average detected concentration of TFA in European groundwaters was 1025 ng/L. Given that TFA now *"qualifies for a classification of their reproductive toxicity"* (GD Sanco/221/2000[3]), in this respect all tested samples in our study were found to largely exceed the legal threshold of 100 ng/L (0.1 µg/L) applicable to relevant pesticide metabolites according to Regulation 284/2013 (point 9.2.4.1 of Part A) and the

[2] TFA in Water: Dirty PFAS legacy under the radar (May 2024).
[3]According to the SANCO guidance document on the assessment of the relevance of metabolites in groundwater, any *"metabolites which qualify for a classification of their reproductive toxicity (any category) are considered to be "relevant"*.

Groundwater Directive 2006/118/EC (Annex I). Our report of July 2024[4] further revealed that this threshold is also exceeded by 86% of our tested tap water samples, contrary to what is required by the Drinking Water Directive 2020/2184 (Annex I, part b). The results of our research are consistent with TFA monitoring data existing for surface, ground and drinking waters. Therefore, PFAS pesticides do not meet the approval requirement of the Pesticide Regulation that residues *"shall not have any harmful effects on human health, including that of vulnerable groups, or on groundwater"* (Article 4(2)). We are aware that the TFA detected in the environment comes from different sources. However, PFAS pesticides were found to be the most important source in rural areas[5]. There is therefore enough information today for EFSA to take action and inform risk managers that PFAS pesticides, known or suspected to form TFA, do not meet the approval requirements of Regulation (EC) 1107/2009 aiming to ensure a high level of protection of human health and the environment from pesticides.

We look forward to continuing our exchange and for EFSA to undertake swift and decisive action to ensure the risks posed by PFAS pesticides and TFA are properly assessed and communicated to pesticide risk managers.

Sincerely yours.

Angeliki Lysimachou
Head of Policy & Science
Pesticide Action Network Europe

On behalf of:
Générations Futures
Global 2000
Nature & Progrès Belgique
Pesticide Action Network Europe

[4]Please refer to TFA: The forever chemical in the water we drink (July 2024)
[5] Trifluoroacetate (TFA): Laying the foundations for effective mitigation | Umweltbundesamt

Annex: written questions to EFSA about PFAS pesticides

1. It has been known since the late 1990s at the latest that PFAS pesticides can degrade into TFA and that TFA accumulates almost irreversibly in the environment, particularly in water bodies, due to its chemical properties. Consequently, it was foreseeable that human exposure through drinking water, as well as through plant and animal foods produced simply by using TFA-contaminated water, would increase. Therefore, it was to be expected that any approval of a PFAS pesticide would further increase the existing TFA contamination of groundwater from emissions of already approved PFAS pesticides and other TFA sources (e.g., F-gases), thus contributing significantly to an "emerging risk in the field of food safety." Has EFSA ever characterised this emerging risk according to its mandate? If so, in what way?

2. According to our research, TFA was for the first time identified as a soil metabolite likely to contaminate groundwater in 1998/2001 (flurtamone*) and in crops in 2007/2008 (fluazinam**). Yet, in both cases, the toxicological relevance of TFA for groundwater and consumer risk assessment was discarded despite lacking data on its toxicological properties, including its genotoxic potential. These data gaps have persisted in subsequent risk assessments where TFA was identified in metabolism and/or soil/lysimeter studies (haloxyfop-R in 2009, fluometuron in 2010, oxyfluorfen in 2010). According to the SANCO guidance document on the assessment of the relevance of metabolites in groundwater and EFSA's guidance on the establishment of the residue definition for dietary risk assessment, the genotoxicity and general toxicity of detected metabolites such as TFA must be investigated to conclude on their toxicological relevance. Why did EFSA not request studies assessing the three genotoxic endpoints of TFA (gene mutation, clastogenicity and aneugenicity) despite a clear data gap at that moment (2009-2010)?

*Flurtamone (1998/2001): TFA was found in a lysimeter study at average concentrations over a three-year period of 1.4 and 3.1 µg/l, i.e. above the trigger value of 0.1µg/L for further assessment in groundwater. At that time, reproduction, developmental and long-term toxicity and carcinogenicity studies were missing to assess the mammalian toxicity of TFA.
**Fluazinam (2007/2008): TFA was found in primary and rotational crops but there was no risk for consumers identified provided that information on the toxicological relevance of TFA and the actual consumer exposure are provided by the applicant.

3. Point 5.8.1 in the Annex to Regulation (EU) No 283/2013 regarding toxicity studies of metabolites states that *"supplementary studies, where they relate additional tests relating to substances other than the active substance, are not routinely required"*, but are decided on a *"case-by-case basis"*. In this respect, we would like to receive information indicating which additional toxicity studies, when, and as part of which test procedure EFSA requested so far for the metabolite TFA.

4. In 2014, in the course of the assessment to set MRLs for saflufenacil, EFSA derived toxicological reference values (TRVs) for TFA, namely an ADI of 0.05 mg/kg per day using an uncertainty factor of 200. In deriving TRVs, according to the WHO recommendations[6], additional uncertainty factors beyond the standard uncertainty factor of 100 for inter- and intraspecies variability are also provided to account for potential deficiencies in the general toxicity database, such as lack of a key (pivotal) chronic toxicity study, as well as for the severity and irreversibility of an effect. What guidelines does EFSA follow when applying uncertainty factors? Could you explain how EFSA applied these rules in deriving an ADI of 0.05 µg/kg/d for TFA?

5. In 2014, in the course of the assessment to set MRLs for saflufenacil, EFSA identified 39 approved substances and five pending substances that could lead to TFA emissions into the environment. However, when examining the assessment of a number of these pesticides after 2014, we were surprised to see that for most of them, TFA is not identified as a metabolite (and the relevant tests had not been performed). Did EFSA ask for TFA analysis within the requested soil degradation and residue studies from the applicants, and if not, what is the reason? Is it because EFSA considers it plausible that some CF3 active substances do not degrade to TFA? What would then be a plausible degradation pathway that would not lead to the formation of a highly persistent final degradation product from the PFAS group according to EFSA?

6. During our meeting, in your presentation, you informed us that EFSA has identified 11 PFAS pesticides producing TFA in residues, soil and/or groundwater. Could you please provide the names of the 11 substances? Following our own review of EFSA's peer reviews and Renewal Assessment Reports (RARs), we came to the following list of 11 substances: flurtamone (crops, soil, groundwater); fluazinam (crops), haloxyfop-P (soil), fluometuron (crops); oxyfluorfen (crops); saflufenacil (crops); flumetralin; trifloxystrobin (crop); tritosulfuron (crops, soil, groundwater); flutolanil (crops); flufenacet (crops, soil, groundwater). We also noticed in the renewal application dossier of fluopyram of TFA formation and risk for groundwater contamination.

7. In your presentation, you mentioned that "TFA is naturally occurring in the environment", confirming a narrative that the fluoridation industry and scientists, often funded by this industry, have been supporting for decades. This narrative has been questioned by several independent scientists, and therefore we are surprised with the position of EFSA. Do you have any evidence for the naturally occurring TFA that is not available to the independent scientists who are sceptical about this?

8. According to point 6.9 of Regulation 283/2013 regarding estimation of the potential and actual exposure through diet and other sources, "Where relevant, the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances (for example use of active substances resulting in common

[6] WHO, 1997. Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits.

metabolites, use as biocide or veterinary drug), and their aggregate exposure shall be taken into account. In addition, the cumulative exposure to more than one active substance shall, where relevant, be considered." Has this fact been taken into account by EFSA in the risk assessment of PFAS pesticides, especially those that have been shown to emit TFA?

9. In 2017, TFA was considered a relevant metabolite in groundwater due to the proposed classification of its parent compound as carcinogenic category 2 (flurtamone). Yet, in subsequent risk assessments of PFAS active substances, TFA became again "non-relevant" for consumer risk assessment (trifloxystrobin) or an open issue for groundwater assessment (tritosulfuron). This happened despite a pending data gap on its aneugenicity potential (2023), which is one of the three key genotoxic endpoints to be investigated according to guidelines[7], and regardless of the notification under Article 56 of developmental effects in a rabbit study. Why did EFSA not consider TFA as a toxicologically relevant metabolite, for all PFAS pesticides that give rise to it, and therefore identifying their potential to contaminate the groundwater as a critical area of concern?

10. According to the German Federal Environmental Agency (UBA), flufenacet, diflufenican and fluopyram are the three greatest TFA emitters of all PFAS pesticides in Germany, considering their sales. Diflufenican and flufenacet are also the top-sold PFAS pesticides in France these last years[8]. While the Renewal Assessment Report of flufenacet and the Renewal application dossier of fluopyram both demonstrate that the substances degrade into TFA in soil leading to the exceedance of the PEC GW of 0.75 µg/L, the Renewal Assessment Report of diflufenican does not contain any information on TFA formation. Will EFSA require new analysis for monitoring of TFA in soil degradation studies for all PFAS pesticides for which this information is missing, including diflufenican? How will EFSA ensure that this information is provided early enough by applicants to avoid any delay in the risk assessment linked to the submission of these studies on TFA formation? Given that TFA "qualify for a classification as toxic for reproduction" (DG SANCO), will EFSA identify the risk of groundwater contamination with TFA at concentrations exceeding 0.1µg/ L as a critical area of concern in its peer review conclusions on flufenacet and fluopyram? When can we expect EFSA to deliver its conclusions on these three substances?

11. Will EFSA consider the very high persistence and mobility of TFA as a critical issue that could justify considering TFA as a relevant metabolite (whatever its toxicological properties)?

[7]SANCO's guidance document on the assessment of the relevance of metabolites in groundwater and EFSA's guidance on the establishment of the residue definition for dietary risk assessment.
[8] https://ventes-produits-phytopharmaceutiques.eaufrance.fr/search

12. In your presentation, you also mentioned that the approval of one PFAS active substance is pending. Is this substance pydiflumetofen? If yes, how did you communicate the risk posed by this highly persistent substance to risk managers? If this is not pydiflumetofen, could you please give us the name of the substance?

13. Moreover, you mentioned an update from the TFA task force on the Article 56 notification of May 2024. Could you please share this with us, since it is environmental information that is of public interest and relevant for decisions related to the authorisation of food-relevant matters?

14. During the meeting, you informed us that TFA is not monitored under the EU Multiannual Control Programme (MACP) and Multi-Annual National Control Programme (MANCP) as residue definitions for enforcement purposes can be different from those for risk assessment purposes. You nevertheless mentioned that TFA is part of a priorisation exercise which led to some monitoring data. Could you please share with us the main findings of this monitoring exercise as well as the link to access raw data?

15. We take note of the ongoing discussion with the Commission to mandate EFSA to conduct a systematic literature review on the toxicological hazard properties of TFA, coupled with a data call to establish TRVs. When setting these TRVs, will EFSA implement extra uncertainty factors to take into account the higher vulnerability of children, the background levels and cumulative exposure, as well as different sources of exposure (including food[9] and water)?

16. According to Zheng, et al, (2023)[10], TFA was found as one of the predominant PFAAs detected in blood and urine samples collected from residents in Indiana (United States). A clear positive correlation was found between TFA concentrations in serum samples and those detected in dust and water samples collected in their residential homes. Will EFSA consider epidemiological data on TFA exposure?

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9 https://www.google.com/url?q=https://www.eurl-pesticides.eu/userfiles/file/eurlsrm/eurlsrm_residue-observation_tfa-dfa.pdf&sa=D&source=docs&ust=1721731269155853&usg=AOvVaw2Q_-D8gv9K4gIef4bbIuLt

10 Zheng, Guomao *et al, Elevated Levels of Ultrashort- and Short-Chain Perfluoroalkyl Acids in US Homes and People,* 2023/10/24, doi: 10.1021/acs.est.2c06715, Environmental Science & Technology, URL link.