Bernhard Url
Executive Director
European Food Safety Authority
Parma, Italy

Brussels, 08/05/2024

Subject: Concerns regarding risk assessment of PFAS active substances used in pesticides and their residues in food, and meeting request

Dear Mr. Bernhard Url,

PAN Europe and the undersigned member organisations would like to express our serious concerns about the risk posed by the increasing detection of PFAS-active substances in EU fruit and vegetables and about the current limitations in the assessment of these substances and their metabolite trifluoroacetic acid ('TFA'). The ongoing situation does not ensure the high level of protection of European citizens and the environment required by Regulation 1107/2009, particularly regarding the cumulative effects of these substances that remain unaddressed. Given the importance of the issue, we would like to kindly request a meeting to discuss it in depth.

A recent report[1] by PAN Europe and its member organisations examined the presence of PFAS pesticides in fruit and vegetables grown in the EU and those imported into the EU over the decade from 2011 to 2021. To our concern, this investigation[2] revealed an increasing detection of residues of PFAS active substances with a substantial proportion of samples containing multiple PFAS pesticide residues. The percentage of common fruit and vegetables with PFAS residues has tripled at EU level in the past decade, with the Netherlands (27%), Belgium (27%), Austria (25%), Spain (22%) and Portugal (21%) being on the top of the list. Moreover, residues of up to four different PFAS pesticides were detected in a single sample of EU-grown strawberries and table grapes. This shows that allowing PFAS pesticides to be deliberately sprayed on crops makes food consumption a direct and systematic route of exposure to cocktails of PFAS for EU consumers. It also points to a **constant increase in the background exposure of European consumers to mixtures of these persistent substances, which accumulate in the environment, waters and the food chain.** This raises serious environmental and human health concerns, indicating the failure to meet the objectives outlined in the General Food Law and Pesticide regulations for a high level of protection.

[1] European citizens face increasing exposure to PFAS pesticides through fruit and vegetables | PAN Europe (pan-europe.info)

[2]Based only on randomly sampled data from the EU Member State monitoring programmes for pesticide residues in food.

In 2020, the EU pledged to phase out PFAS in the framework of the EU Chemical Strategy for Sustainability, and in 2021 a 'universal' proposal for a restriction on PFAS was submitted to the European Chemicals Agency ('ECHA'). The proposal indicates the presence of PFAS among the active substances approved under the Pesticide Regulation and provides a list of these substances. Nevertheless, PFAS pesticides are left outside the scope of the PFAS restriction leaving it up to pesticide risk assessors and managers to address this issue in the context of the Pesticide Regulation. Under this framework, 37 active substances that are PFAS are currently approved for use in pesticides. While the renewal process is underway for most of them, some have been approved recently, raising concerns about ongoing shortcomings in their risk assessment[3]. An earlier report by PAN Europe and Générations Futures[4] demonstrated that, while the Pesticide Regulation aims to ensure that active substances (or products and their residues) placed on the market do not adversely affect human or animal health or the environment, **PFAS pesticide substances are 'slipping through the cracks" of the risk assessment procedure and are not adequately regulated**. By zooming into the top 10 sales of PFAS pesticides in France, for none of them did EFSA highlight their persistence or that of their metabolites, or their cumulative effects as a concerning issue.

The proposal for a universal PFAS restriction is founded on the grounds that the common persistence of chemicals belonging to this group poses an unacceptable risk to human health and the environment. PFAS active substances are part of a PFAS subgroup containing at least one -CF3 moiety, which are persistent themselves and/or break down into persistent metabolites including TFA. Moreover, pesticides are designed to be toxic to living organisms, and therefore present concerning toxicity profiles. Our examination of the dossiers of the top ten most detected PFAS substances in fruit and vegetables revealed **known or potential toxicity to human health and/or environment of these persistent substances**. Namely, scientific data points at acknowledged or unaddressed concerns about harm to unborn children, brain damage, disruption of the endocrine system and cancer risk. Furthermore, potential adverse effects such as impact on the immune system or the nervous system, particularly during early development, and the risks posed by mixtures or chronic cumulative exposure are either poorly investigated or not investigated at all. The latter is particularly concerning, as our report has shown, that single samples of common fruits (e.g. strawberries, grapes, peaches) contain 3 or 4 PFAS pesticides. It falls within EFSA's responsibility to communicate to risk managers that the available data fail to ensure the high level of protection that is required by the EU law, given the wide range of adverse effects these substances may cause, coupled with their high persistence or that of their metabolites and potential cumulative effects. We regret to see the lack of such a communication.

Last, our concern about the risk assessment of **PFAS pesticides also relates to their emission of TFA** into the environment, including in water, and the food chain[5]. Based on their molecular structure, almost all PFAS-active substances are likely to degrade into TFA. As it is highly mobile

[3] Flutianil (approved in 2019).
[4] PAN Europe, Générations Futures, Europe's Toxic Harvest: unmasking PFAS Pesticides authorised in Europe, November 2023.
[5] Residues of DFA and TFA in Samples of Plant Origin; EURL-SRM – Residue Findings Report

and very persistent, TFA is found at significant levels in surface waters and in drinking water around Europe. Worryingly, it is still considered a 'non-relevant' metabolite of pesticides (with no toxicological concern), which means a generally high threshold value of 10 µg/L (100 times higher than the one for relevant metabolites) or even higher applies to groundwater and drinking water according to the relevant guidance document[6]. To our understanding, EFSA has been aware for years that TFA is one of the main metabolites of a number of pesticides but has not raised any concerns about its potential toxicity or cumulative effects[7]. However, recent information indicates that TFA is not that "irrelevant" after all, and the current high background exposure of citizens and the environment to this chemical is irreversible and therefore of great concern[8]. This is backed by the proposal of the German competent authority to classify TFA as toxic for reproduction (category 1B) based on its REACH registration dossier[9]. The German initiative is mainly driven by indications of developmental toxicity from studies reporting malformations in offspring, reduced pup weight gain during the lactation period and reduced weight of reproductive organs[10,11]. Particularly, a high incidence of major eye abnormalities was observed in a study in rabbits (Bayer, 2021) along with multiple cervical / thoracic / lumbar / caudal vertebral and rib abnormalities. It came to our attention that the 'TFA task force' (consisting of BASF, Bayer, Corteva and Syngenta) now attempts to disqualify these eye malformations as 'rabbit-specific' and therefore, not relevant for humans. However, similar eye effects have been observed in rats following exposure to Perfluorooctanoic acid (PFOA)[12] and in children in an epidemiological survey[13]. While these effects are now being investigated, people and the environment continue to be exposed to increasing levels of this substance.

Following Bayer's notification to inform risk managers about the TFA rabbit developmental toxicity study (under Article 56 from regulation (EC) 1107/2009), we noted that EFSA in 2023 highlighted in its peer review conclusion of the risk assessment of tritosulfuron- which also degrades to TFA- about the missing data in relation to TFA. EFSA stated that without such data it was not possible to assess the TFA aneugenicity (genotoxicity) potential and conduct the risk assessment for birds, mammals, bees and aquatic organisms[14]. Considering the widespread detection of TFA in food

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[6] Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009
https://food.ec.europa.eu/document/download/918bd971-a1c1-4eeb-9885-eb5df074b31d_en

[7] EFSA, 2014. Reasoned opinion on the setting of MRLs for saflufenacil in various crops, considering the risk related to the metabolite trifluoroacetic acid (TFA).
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3585

[8] https://www.theguardian.com/environment/2024/may/01/rapidly-rising-levels-of-tfa-forever-chemical-alarm-experts

[9] Substance Information - ECHA (europa.eu)

[10] Extended one generation reproductive toxicity study https://echa.europa.eu/lt/registration-dossier/-/registered-dossier/5203/7/9/2

[11] rabbit developmental toxicity study https://echa.europa.eu/lt/registration-dossier/-/registered-dossier/5203/7/9/3/?documentUUID=bbe1c0df-91db-4cef-a965-89ded98a88c8

[12] nnpw0228 - Ammonium Perfluorooctanoate - C8 - Rangefinder ... - Industry Documents Library (ucsf.edu)

[13] Industry Documents Library (ucsf.edu)

[14] EFSA, 2023. Peer review of the pesticide risk assessment of the active substance tritosulfuron.
https://doi.org/10.2903/j.efsa.2023.8142

and water, it is surprising that this data was not provided by the industry, and to our understanding was not requested by EFSA in all these years. In addition, already in 2017, during the peer review of the risk assessment of the substance flurtamone, EFSA had identified TFA as a relevant metabolite and consequently the contamination of groundwater with TFA (above 0.1 µg/L) as a critical area of concern, which played a key role in the non-renewal of this substance. To our surprise EFSA has not raised the same concerns for other substances that also produce TFA. This is a great and worrying inconsistency in the assessment of pesticides and their metabolites and it is incomprehensive why a full toxicity assessment was never requested by EFSA for such a common and very persistent metabolite.

Considering the increasing detection of TFA and PFAS in our environment, water resources and our food, urgent action is needed from EFSA to improve its current risk assessment and elevate the scientific rigour of its evaluations. Establishing a clear red line for the increasing levels of mixtures of active substances and their metabolites is crucial. It is central to EFSA's mission to deliver objective, high-quality scientific advice that contributes to the provisions of the EU law for a high level of protection of human life and health, and our ecosystems.

We trust you will respond favourably to our request for a meeting to discuss these pressing issues in detail.

We thank you in advance for your attention to this matter.

Sincerely yours,

Angeliki Lysimachou
Head of Science and Policy
PAN Europe

On the behalf of:
PAN Europe
PAN Germany
PAN Netherlands
Générations Futures
GLOBAL 2000
Ecologistas en Acción
ISDE (International Society of Doctors for Environment)
Nature & Progrès