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Discussion Paper

Managing PFAS contamination in soil and water – a risk based and sustainable approach

Core message: The case for a more sustainable and risk based approach

Poly- and per- Fluorinated Alkyl Substances (PFAS) are gaining increasing societal and regulatory attention due to evolving understanding of the potential risks they pose to people and ecological systems. The need for appropriate regulation is evident including, for example, the need to set suitable environmental quality standards (EQS).

However, the quantitative underpinning of the EFSA (2020) tolerable weekly intake (TWI) of 4 PFAS of 4.4 ng/kg bw/week does not provide a robust case to justify the extremely low EQS (of 4.4 ng/l for the weighted sum of 24 PFAS) proposed in the Annexes of the Water Framework Directive (EU Commission Proposal dd 26-10-2022)[1.] Respectable organizations as the World Health Organisation (WHO), the UK Committee on Toxicity (CoT) or the International Alliance for Risk Assessment (ARA) either call the EFSA opinion weak[2,3,4] or estimate that 15-20 times higher value[5] is considered protective to human health.

The precautionary approach of EFSA may seem a safe approach, but the Commission's proposed value of 4.4 ng/l PFOA equivalents (that is based on the EFSA TWI) for water lies significantly below background levels in many European ground- and surface waters (see Table 1 for references). This implies that the proposed targets either cannot be met or would cause significant and unsustainable impacts in attempting to meet them. As such, there is a need for a more proportionate and sustainable risk-based underpinning of the proposed target values.

How robust is the quantitative underpinning of EFSA ?

WHO[2,3] and the UK CoT[4] call the evidence for the EFSA TWI "weak" and the TWI "arguably low". Earlier in 2024 WHO initiated a review of the toxicological landscape to better understand the risks of PFAS. The main reason that the underpinning is weak is because it is based on the work of one single dataset (Abraham et al.

2019/2020)[6] which found higher PFOA blood levels were associated with fewer antibodies after maternal vaccination in breast fed one-year old babies, but:

- Only a vaccine response was observed, not a decrease of immune response. There was no increase observed of the diseases that the vaccine targeted. There were no reported actual health effects;
- Whereas EFSA concludes equipotency (toxicity) for PFOA, PFOS, PFNA and PFHxS, the study only revealed an association for PFOA. There was no association found for the other three PFAS;
- The statistics behind the benchmark dose modelling are very sensitive to minor changes in base data, whereas epidemiological data are scarce and susceptible to external factors. The blood samples used by Abraham were from the 1990s and had comparatively higher levels of PFOA than those currently found in blood.

The Dutch RIVM noted[7] that Abraham et al. 2020 showed too much uncertainty in the dose-response relationships to justify the robust benchmark dose modelling needed to derive the TWI value.

Additionally, the introduction of Relative Potency Factors (RPF) in the proposal for amendment of the Annexes of the WFD is invalid. It is acknowledged that this is the only available means of dealing with the different toxicity of multiple PFAS, and that the TWI and the RPF are based on different endpoints (Human immune toxicity versus liver toxicity in animals); however, the EFSA value is based upon equipotency (i.e. all 4 PFAS have equal toxicity) so if a different potency factor is applied for different PFAS (as proposed), then a different value to 4.4 ng/kg bw/wk should also be used. For example, a concentration of 4 ng/l PFNA accounts for 40 ng/l PFOA Equivalents (PEQ), which leads to an exceedance by almost one order of magnitude of the proposed EQS, but is not according to EFSA's equipotency starting point.

Is the proposed quality standard too low considering ambient values?

For many EU member states the ambient or anthropogenic background levels are currently not known. Levels of PFAS reported in various matrices in the Netherlands are given in Table 1. The table illustrates that a content of 4.4 ng/l is exceeded nearly everywhere. Only rainwater with a level of 1-2 ng/l sum PFAS lies below the proposed EQS. Roughly 35-40% of phreatic groundwater lies above the proposed value for the EFSA 4. Recently background levels became available for Flanders, Belgium, which show similar values in soil and groundwater (OVAM 2024)[11].

Table 1: Background levels in soil, groundwater and surface water, and average values in rain, vegetables, blood serum and consumer goods for PFAS compounds in the Netherlands

Material/ substrate	PFAS Compound	Typical concentration
Soil background NL/BE[8,9]	PFOS or PFOA	~ 1,500 ng/kg dw
Ground water Phreatic (NL)[10,11]	Sum PFAS	~ 30 ng/l
Surface water Rhine/Meuse[12]	EFSA 4	~ 10 ng/l
Rain[13]	EFSA 4	~ 1-2 ng/l
Vegetables[14]	Sum PFAS	~ 10 ng/kg dw
Dust households and offices[15]	Sum PFAS	~ 1,000,000 ng/kg
Blood serum EU[16,17]	Sum PFAS	~ 20,000 ng/l
Consumer goods[15]	Sum PFAS	~ 100,000 ng/l

Proposed EQS values that are more stringent than ambient or anthropogenic background levels should be avoided unless achieving the EQS is practicably achievable or necessary. Given the scale of exceedances anticipated considering the concentrations in the table above, achieving the proposed EQS is, in our opinion, not considered viable nor sustainable. Additionally, the need to achieve the proposed EQS is not clear and too uncertain to justify action to try and achieve this, given the considerable impacts this in turn would likely create and already creates. Examples of such impacts are for instance: water treatment facilities, groundwater extraction systems for construction purposes and other discharges that are burdened with target values below background values; industries are required to treat water that they have not contaminated, just because the groundwater with background values that they are using has higher concentrations than the limit values; reuse of excavated soil that is not allowed resulting in additional waste and need for new resources.

Discrepancies between different regulatory and legal regimes, one substance – one assessment?

For one group of substances, regulatory limits for different media or legal contexts should ideally be based on similar risk endpoints or similar levels. A recent study by Reinikainen et al. 2024[18] (study supported by the EU Horizon Europe research and innovation programme) provides a more detailed review highlighting the inconsistencies in the current EU regulatory frameworks and the need for adjustment to address this including detailed commentary on the proposed EQS. Some of the inconsistencies that we have noticed:

- The EU Drinking Water Directive (2021) has much higher target levels (100 ng/l 20 PFAS) compared with the proposed EQS value. The underpinning of this drinking water guidance value is unclear,

however, the Water Framework Directive (WFD) and Groundwater Directive (GWD) proposal (4.4 ng/l), based on the 2020 EFSA TWI, is 23 times lower.

- More strikingly, whereas the EFSA opinion is meant for food safety, the EU regulation setting maximum levels for certain contaminants in foodstuffs (Regulation (EU) 2022/238821) is not based on EFSA, but on a P95 percentile approach of the ALARA principle. It is possible that a food category is safe according to the Foodstuff regulation, and can be put on the market, but exposure from its consumption could exceed the EFSA TWI by 10-100x. Especially fish scores high in this respect. Both Norwegian and Finnish studies however indicate that for the average PFAS levels measured in fish, the positive health effects of eating fish exceed the negative health effects of PFAS intake[19,20].
- Although product regulation under REACH[21] does not cover human intake, the allowed level of PFAS in a product does influence the level found in the environment or, for example, in household dust. Proposed maximum levels for PFAS in products under REACH[21] are very high (25,000 ng/kg), considering that these PFAS might end up in the environment one way or another. Cleaned fire-fighting equipment is a good example of this.

Impacts and proportionality

Whereas both the Foodstuff Regulation and REACH look into the impacts or cost-benefits of setting regulatory limits, this is not the case for the EQS proposed by the WFD/GWD. As far as NICOLE is aware, no studies have been undertaken to specifically assess the potential impacts of the proposed EQS values For reasons highlighted in the previously mentioned paper of Reinikainen[18] and here, the potential impacts likely to be incurred in trying to return to ambient background levels are obvious, already noticeable and serious. These impacts go beyond technical or financial feasibilities of chemical analyses and treatment technologies, but are also visible, for example, with regard to discharges needed for both infrastructural works or industrial emissions; stagnation arises when demands for purification are more strict than the ambient levels in surface waters. Preparation, permitting and studies into the feasibility of (redevelopment) projects take considerably more time, and projects are abandoned and avoided.

Moreover, it is advised that studies should be undertaken into the effects of a restriction of PFAS (REACH) compared to the effects of active measures needed to operate within the proposed EQSs. Levels in environmental media of PFAS that are restricted (PFOS and PFOA) are already declining and are at much

lower levels than in the nineties. It may turn out that a restriction is far more effective than EQSs below backgrounds.

Regulatory limits should be proportionate and contribute to sustainable development and operational activity in managing and regulating environment impacts.

Conclusions

Given the fact that:

- The quantitative underpinning of the EFSA tolerable weekly intake (TWI) is reported to be weak by other authoritative bodies;
- This TWI often is used stringently in setting environmental target levels whilst it is developed for food, but not used in the directive on foodstuff. In the directive on foodstuff the ALARA-principle was considered and a proportionate approach is chosen;
- Regulatory limits differ by orders of magnitude between different media (food, water and soil);
- There is no assessment available of the impacts of these stringent environmental standards.

We strongly stress the need for:

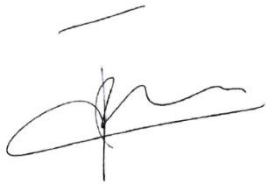
- A better understanding of critical toxicological effects and associated dose-response relationships;
- More assessment of background levels in multiple media with greater availability of such data;
- An evaluation of proportionality or sustainability. A societal cost-benefit analysis could also be an option, in order to compare uncertain health benefits against financial, social and environmental impacts; and,
- Clear legislation and specific guidance on how different degrees of exceedance of any limit value should be interpreted.

Maintaining the 4,4 ng/kg bw/wk (4 PFAS) or the 4,4 ng/l for water (24 PFAS), could be counterproductive towards moving to a sustainable society. Until we have a better understanding of the actual health effects and the impacts involved, we strongly suggest to not operationalize the proposed EQS. Further assessment could also consider the use of values based on robust animal studies, which already comprise an uncertainty factor. The TDIs based on animal studies are noted to be a factor of 20 times higher and are considered to be

"protective for human health" by many (Burgoon et al, 2023[5]), and would lead to EQS at levels above ambient levels.

There is an urgent need for robust and proportionate screening levels: robust regarding science and ambient levels (as well as increased availability and transparency of these data); and proportionate regarding the balance between the positive and negative effects that result from measures that are needed to reach these levels, in order to be more consistent with a sustainable risk-based management approach. Otherwise, our strong concern is that the negative effects might outweigh the potentially positive uncertain health effects.

Discussion paper prepared by NICOLE Working Group PFAS.



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Chair of NICOLE

CONTENT DISCLAIMER

This paper does not necessarily reflect the opinion of individual members of NICOLE.

NICOLE is a network bringing together industry, service providers and academics. It was formed in 1996 with an aim to bring together professionals involved in sustainable risk-based management of land and water in Europe – www.nicole.org. NICOLE has drafted this paper to reflect its science and long-term experience in the field of industrial land management based opinion and provide input for discussion on managing PFAS contamination in soil and water in a risk based and sustainable approach

Since its inception NICOLE and its members have been focused on sustainable land management of industrial sites. Over the years, our focus and insight have evolved, culminating in several publications on Land Stewardship (booklet) and associated initiatives, which explain how to create value by connecting industrial land management to societal, ecological and economic challenges. Another recent example is a joint statement with Common Forum on how to include sustainability in contaminated land management (statement).

The NICOLE Working Group PFAS was started mid 2022, and gathers members from different backgrounds (industry, service providers and academics) to exchange experience, knowledge and insights around PFAS topics in (mainly) soil and groundwater. The work is organised in 4 sub teams on the following topics: remediation technologies, analytical techniques, regulations-policy and characteristics-assessment.

References:

1. EU (European Union). 2022. Regulation (EU) 2022/2388 of 7 December 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs. Official Journal of the European Union L 316:38-41
2. WHO (2022) PFOS and PFOA in Drinking-water, Draft Background document for development of WHO Guidelines for Drinking-water Quality 29 September 2022, Version for public review
3. WHO (2023) Comments on the Draft background document https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances
4. CoT (2022) Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food. The Committee on Toxicity of Chemicals in Food, Consumer products and the Environment. Available online: https://cot.food.gov.uk/Introduction%20-%20Statement%20on%20the%20EFSA%20Opinion%20on%20the%20risks%20of%20perfluoroalkyl%20substances%20in%20food
5. Burgoon et al. (2023) Range of the perfluorooctanoate (PFOA) safe dose for human health: An international collaboration, Regulatory Toxicology and Pharmacology 145 (2023) 105502
6. Abraham et al. (2019) Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1- year- old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response. Archives of Toxicology, 94: 2131–2147. https://doi.org/10.1007/s00204-020-02715-4
7. Abraham et al (2020) Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response, Archives of Toxicology (2020) 94:2131–2147
8. RIVM (2020) Notitie: definitieve EFSA-opinie PFAS – wetenschappelijke overwegingen voor RIVM besluitvorming over EFSA-TWI, Finaal - 15 december 2020
9. RIVM (2020) Wintersen A., Spijker J., Van Breemen P., Van Wijnen H. (2020b). Achtergrondwaarden perfluoralkylstoffen (PFAS) in de Nederlandse landbodem. National Institute for Public Health and the Environment. Available online: https://www.rivm.nl/publicaties/achtergrondwaarden-perfluoralkylstoffen-pfas-in-nederlandse-landbodem
10. OVAM (2021) Toetsingswaarden voor PFOS en PFOA in bodem en grondwater
11. RIVM (2021) Wintersen A., C. J. (2021). Landsdekkend beeld van PFAS in Nederlands grondwater. National Institute for Public Health and the Environment. Available online: https://www.rivm.nl/publicaties/landsdekkend-beeld-van-pfas-in-nederlands-grondwater
12. OVAM (2024) Bepalen van streefwaarden voor PFAS in grond en grondwater, Bepalen van streefwaarden voor PFAS in grond en grondwater | Vlaanderen.be
13. Expertisecentre on PFAS (2021) "Vervolgvragen inzake EFSA opinie: bronnen van PFAS voor oppervlaktewater" VEWIN 2021
14. Cousins T., Johansson H., Salter M. B., Sha M., Scheringer M. (2022). Outside the safe operating space of a new planetary boundary for per- and polyfluoralkyl substances (PFAS). Environmental Science and Technology, 56 (16), pp. 11172-11179.
15. RIVM (2022) Risicobeoordeling van PFAS in moestuingewassen uit moestuinen in de gemeenten Dordrecht, Papendrecht, Sliedrecht en Molenlanden, RIVM- briefrapport 2022-0010P.E. Boon | J.D. te Biesebeek

16. Arcadis (2021) PFAS in products and waste streams in the Netherlands. Available online: https://www.rijksoverheid.nl/documenten/rapporten/2021/05/28/pfas-in-products-and-waste-streams-in-the-netherlands
17. Vito (2020) Colles et al. Perfluorinated substances in the Flemish population (Belgium): Levels and determinants of variability in exposure, Chemosphere 242 (2020) 125250
18. Yeung et al. (2016). Are humans exposed to increasing amounts of unidentified organofluorine? Environ. Chem. 2016, 13, 102–110, http://dx.doi.org/10.1071/EN15041
19. Reinikainen et al (2024) Inconsistencies in the EU regulatory risk assessment of PFAS call for readjustment, Environment International 186 (2024) 108614, Inconsistencies in the EU regulatory risk assessment of PFAS call for readjustment - ScienceDirect
20. Norwegian Scientific Committee for Food and Environment. 2022. Benefit and risk assessment of fish in the Norwegian diet. Scientific Opinion of the Scientific Steering Committee of the Norwegian Scientific, Committee for Food and Environment. VKM Report 2022:17, ISBN: 978-82-8259-392-2, ISSN: 2535-4019.
21. Koponen J, Airaksinen R, Hallikainen A, Vuorinen P, Mannio J, Kiviranta H. 2015. Perfluoroalkyl acids invarious edible Baltic, freshwater, and farmed fish in Finland. Chemosphere 129: 186-191. https://doi.org/10.1016/j.chemosphere.2014.08.077
22. REACH (2022) https://echa.europa.eu/sv/-/echa-publishes-pfas-restriction-proposal