Concawe Feedback to the JRC EQS PFAS Total Dossier

Concawe welcomes the opportunity to feedback on the Draft EQS Dossier on "PFAS total" and continues our engagement at the scientific discussions both in the relevant EC working groups* and also by actively been involved in research to shed light on the complex scientific questions around PFAS. Concawe research was aimed at improving the understanding of PFAS fate and transport[1], water and soil treatment options[2], and a currently ongoing research project with a university consortium focuses on improving the understanding of ecological risks from PFAS†.

Introduction

In 2022, the European Commission published a proposal for amending the Water Framework Directive (2000/60/EC), the Groundwater Directive (2006/118/EC) and the Environmental Quality Standards Directive (2008/105/EC). Overall, the proposal faces multifaceted challenges as further elaborated below. Addressing these challenges will require further scientific research and improved monitoring.

The proposal includes an environmental quality standard (EQS) for both surface water and biota and a groundwater quality standard (GWQS) for the sum of 24 per- and polyfluoroalkyl substances (PFAS)[3]. The surface water and groundwater thresholds are set at 4.4 ng/l of PFOA equivalents. In April 2023, the European Parliament requested that in addition to the EQS for the sum of 24 PFAS, an EQS be derived for the total of all PFAS components (PFAS-Total). Separate feedback on the 24 PFAS and its EQS dossier is additionally being prepared by Concawe. Herein feedback is restricted only to the new dossier on PFAS-total ('this dossier' from now on). Specific comments per section of this dossier are elaborated below in dedicated sections.

The concerns, there already for the original EC amendments including 24 PFAS, become more significant, since a 25th PFAS (TFA) is introduced under the same QS without an appraisal of impact. Concerns increase because a PFAS-total EQS is pursued with chemical analysis against the ECHA used definition in the Universal PFAS restriction (OECD 2021)[4]. This does not give a pertinent quantitative evaluation of PFAS. The use of total Fluorine tests that are suggested in the PFAS-total dossier are only described as Screening Techniques. When comparisons against known PFAS analysis are done, the bulk of the result is 'unidentifiable' – this tool is useful for determining when to do more detailed quantitative PFAS analysis, but currently available scientific evidence shows this tool should not be used as a quality standard[5].

*Concawe is stakeholder of PFAS EG and WDD CIS WG Chemicals and WG Groundwater.

† Work submitted to SETAC-Seville 2024 "Deriving Fluorochemical Membrane-Water and Protein-Water Partition Coefficients from in Vitro Experiments with Phospholipids and Albumin" and "Biomimetic Chromatography and Associated Models to Predict Biological Partitioning".

[1] Concawe Report 8/16. Environmental Fate and Effects of Poly and Perfluoroalkyl Substances (PFAS); Brussels, 2016. https://www.concawe.eu/wp-content/uploads/rpt_16-8.pdf.

[2] Concawe Reports: 1) Concawe report 14/20. Review of Water Treatment Systems for PFAS Removal; Brussels, 2020. https://www.concawe.eu/wp-content/uploads/Rpt_20-14.pdf; 2) Concawe Report 5/21. Performance of Water Treatment Systems for PFAS Removal; Brussels, 2022. https://www.concawe.eu/wp-content/uploads/Rpt_21-5.pdf. 3) Concawe Report to be published by Q1 2024. PFAS Soil Treatment Processes - Operating Ranges and Constraints; Brussels, 2024.

[3] Previously, EQS were only established for one PFAS, namely PFOS. https://eur-lex.europa.eu/eli/dir/2008/105/2013-09-13

[4] https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf

[5] PFAS testing, Total Organic Fluorine (TOF), Total Fluorine (TF) (eurofins.com) Frequent Questions about PFAS Methods for NPDES Permits | US EPA https://www.sciencedirect.com/science/article/pii/S2214158823000041

Specific comments per section of PFAS-total dossier

COMMENTS ON - "SECTION 1 INTRODUCTION"

The EQS and GWQS in the proposed original EC amendments, and also valid for the PFAS-total dossier, are derived from tolerable weekly intake (TWI) derived by EFSA for only four PFAS, based on reported effects on the response of the immune system to vaccinations. A Relative Potency Factor (RPF) methodology, derived for liver effects was used to extend the TWI to a further 20 PFAS, expressed as PFOA equivalents. Data to support the assumption that RPFs derived for liver effects can be extended to immune effects is limited and for some of the reported PFAS it is not known whether they impact on the immune system, as stated in the dossier developed by JRC. Ecotoxicological testing data for PFAS are sparse resulting in assessment (uncertainty) factors of 10-10,000. This is highly significant when each PFAS comprising the 24 (or 25?) is to be measured at the nanogram limit, the absolute limit of capability, and not guaranteed to be reproducible. Thus, there is a clear need for additional testing as described by the SCHEER[6] and an independent panel of experts[7].

COMMENTS ON – "SECTION 2 – DEFINITION OF TOTAL PFAS"

We appreciate the need for regulation, and aspiration for a PFAS-total target, and thus the need for a definition of PFAS-total. As the Dossier Section 2 makes clear, the definition of PFAS is not globally aligned – many complex definition approaches are identified. Adopting the definition that ECHA have used in their restriction proposal at least creates EU level commonality. Although, whilst not explicitly stated, the PFAS-total dossier needs to make it obvious, that a chemical analysis for PFAS-total against the ECHA used definition in their universal PFAS restriction (OECD 2021)[8] is currently not technically possible.

The reference to "PFAS total" as something that explicitly excludes the 24 PFAS + TFA is inconsistent with the common meaning of "total." This seems reflected in the sentence provide on p. 17. "*The value of 'PFAS total' would refer to the 'other PFAS' in water*." This seems confusing, with great potential for misunderstanding. A new manner to describe these concepts seems required, e.g.:

- A descriptor of what is measured/analyzed (e.g., Adsorbed Organic Fluorine (AOF)), or "Adsorbed Organic Fluorine other than 24 PFAS +TFA" may be more appropriate. This might provide a more understandable description of the measure, but also indicates a challenge of introducing this as a measure of "PFAS total."
- A descriptor of AOF (or equivalent) would more transparently communicate that many substances may be incorporated in the measure, including those vastly different than the 24 PFAS + TFA.

There is an uncertainty in the calculation of a "Total PFAS" less the 24+1 from the existing dossier expressed as ng F / L water – with technical as well as procedural challenges, most notably:

- An approach which measures on a Fluorine basis is likely to pick up other fluorine-containing compounds which do not (or even should not, despite previous erroneous inclusion) fit the definition of PFAS. This includes, but is not limited to, pharmaceuticals and pesticide compounds. Fluorinated pharmaceuticals account for ~ 20% of commercialized medications

[6] Scientific Committee on Health, Environmental and Emerging Risks. Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" PFAS; 2022. https://health.ec.europa.eu/system/files/2023-08/scheer_o_037.pdf.

[7] Garvey, G. J.; Anderson, J. K.; Goodrum, P. E.; Tyndall, K. H.; Cox, L. A.; Khatami, M.; Morales-Montor, J.; Schoeny, R. S.; Seed, J. G.; Tyagi, R. K.; Kirman, C. R.; Hays, S. M. Weight of Evidence Evaluation for Chemical-Induced Immunotoxicity for PFOA and PFOS: Findings from an Independent Panel of Experts. Critical Reviews in Toxicology 2023, 53 (1), 34–51. https://doi.org/10.1080/10408444.2023.2194913.

[8] https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf

in recent years; including three widely used drugs fluoxetine (Prozac), atorvastatin (Lipitor), and the antibiotic ciprofloxacin (Ciprobay).

- Surface water concentrations of Prozac, for example, have been reported to range from 12 – 1400 ng/L globally (Weinberger & Klaper, 2014[9], Christensen et al., 2009[10]; Kolpin et al., 2002[11]; Webb 2001[12]). Using the calculation presented in the appendix of the EQS dossier this would correspond to a fluorine-based concentration of 2.2 – 257 ng/L F or 4% - 500% of the proposed QS value. It should be noted that this is a single pharmaceutical drug of many.

COMMENTS ON – "SECTION 3 EXISTING EVALUATIONS AND REGULATORY INFORMATION"

The dossier Section 2 adopted the same definition of PFAS as the PFAS Restriction Proposal (ECHA 2023), and as the restriction process is ongoing, they (and ECHAs own Forum for Exchange of Information on Enforcement Advice on PFAS) noted significant improvements would be needed in the availability of standardised analytical methods and in supplying additional guidance related to PFAS and the definitions of it[13]. This supports the reviews of several commentators that PFAS total cannot (yet) be effectively analysed.

COMMENTS ON – "SECTION 5 – PROPOSED ENVIRONMENTAL QUALITY STANDARD (EQS)"

The dossier Section 5 states: "*Finally, the sum of 25 PFAS as F content should be subtracted to [sic. from] the F content concentration of 'PFAS total*' in water". **The value of "PFAS total" would refer to the "other PFAS" in water.**

Actually, because of the limitations of the techniques, the 'F' result is not a PFAS result. It is a concentration reflecting all of the detectable fluorine in the sample. Fluorine is present in many organic complexes, not just PFAS – so the result cannot be said to be PFAS. If the sum of 25 PFAS as F content is subtracted (using the Dossier equation in section 11.3) from the F content concentration, then the value only represents Total F content minus 25 PFAS. The residual concentration cannot be considered "other PFAS" because the original total is not a PFAS concentration, therefore the result cannot be a proxy for "PFAS total".

The Kärrman et al. (2019)[14] paper used by the JRC in Section 6 of the Dossier to describe estimated environmental emissions, highlights that even when multiple individual PFAS and PFAS groups were subtracted, in surface water, the unidentifiable organofluorine material represented between 83-98% of the Extractable Organic Fluorine (EOF) in surface water. This is not the 'PFAS-Total' portion – it is simply not known what it is – except that it contains Fluorine (pls see Figure below).

Further, when devising the PFAS Total EQS requested by the Parliament, it is important to consider the previous data available:

- The most comprehensive water data on PFAS is available from the sampling done under the Groundwater Watchlist process (i.e., from the 'List Facilitating the Review' of Annex 1 and 2 of the GWD prepared by the WFD CIS Working Group Groundwater). Here, multiple PFAS (identified by actual PFAS compound by compound analysis) were monitored across groundwater in Europe[15]. Although different suites were tested, the process 'frequently

[9] https://pubmed.ncbi.nlm.nih.gov/24210950/
[10] https://pubmed.ncbi.nlm.nih.gov/19682723/
[11] https://pubmed.ncbi.nlm.nih.gov/11944670/
[12] Webb SF. A data based perspective on the environmental risk assessment of human pharmaceuticals II - aquatic risk characterization. In: Kümmerer K, editor. Pharmaceuticals in the environment : sources, fate, effects and risks. Springer; Berlin; New York: 2001. p. 265.
[13] Link -> ECHA's Forum for Exchange of Information on Enforcement Advice on enforceability of the Annex XV restriction proposal regarding PFAS
[14] Kärrman A., Wang T., and Kallenborn R. (2019): PFASs in the Nordic environment: Screening of Poly- and Perfluoroalkyl Substances (PFASs) and Extractable Organic Fluorine (EOF) in the Nordic Environment. TemaNord 2019:515. Nordic Council of Ministers. DOI: 10.6027/TN2019-515
[15] Link -> Voluntary Groundwater Watch List (Endorsed V3.1 - June 2019)

found' 10 PFAS, even though the analysis was done for up to 23 PFAS, other detections were not commonly recorded, with a recommendation to take forward 2.

- Currently some laboratories are able to offer the detection of up to 47 individual PFAS, and these 'Detectable PFAS Species' with an EQS of 0.5 ug/L could be used as a proxy for PFAS Total.
- In a PFAS-Total it may be more applicable to consider the total based on the widest suite of analysis that will actually find PFAS compounds, rather than all Fluorine, the list of PFAS comprising the Total can be updated regularly as techniques adapt.
- A comprehensive 'Total Fluorine' analysis could be added to both the Surface Water and Groundwater watch lists and the data obtained from the 'Detectable PFAS Species' EQS screened against the 'Total Fluorine' data to determine correlations and therefore the potential to better set a Total over time. Research can be concurrently conducted on PFAS, and proxies found for analysis of some kind of a total.

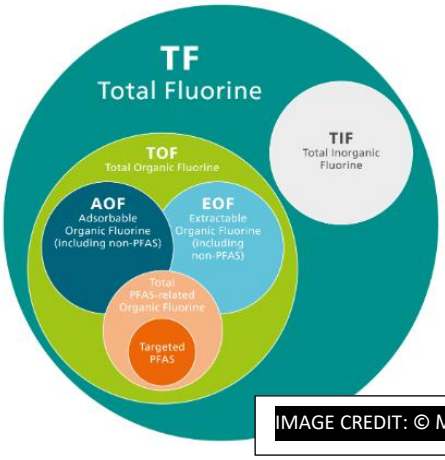

IMAGE CREDIT: © Metrohm USA 2010-2022

This image taken from the site of -> Home (metrohmusa.com) graphically depicts some of the challenges, limitations and benefits of the different types of analysis result that can be captured under 'Total Fluorine'

COMMENTS ON – "SECTION 6 – MAJOR USES AND ENVIRONMENTAL EMISSIONS"

The Dossier strongly references findings of the paper by Kärrman et al. (2019)[14] to attempt show the impact of PFAS, and summarise the data to give a result *"…of total PFASs in surface water measured in the study..."*. This paper does not give that result. The paper notes that in effluent, when accounting for all the PFAS tested by quantifiable methods, the unidentified organofluorine accounted for 56–98% of EOF, and between 83-98% in surface water. Note that this is not unidentifiable PFAS, this is unidentifiable organofluorine material – obviously because of the scope of the report the authors did not test this for other potential types of Fluorine compounds. The final conclusion of Kärrman et al. (2019) was "*The identity of the additional organofluorine substances contributing to the measured extractable fluorine in environmental samples needs to be elucidated to further assess future risks.*"

If the intent is to have a PFAS-Total result that meets the definition given by OECD and used by ECHA in the REACH restriction (~10,000 PFAS), then the analysis of Kärrman et al. (2019) actually reveals how this is not currently possible. The Paper describes how measurements were taken, and how great the uncertainties were from the testing. This suggests more research and understanding, or uses of quantifiable tests - rather than using a "screening test" that does not determine PFAS as a regulatory tool.

- Section 5 of the Kärrman et al. (2019) paper well explains the results showing that the EOF test (as described in Section 7.0 of the Dossier) reported a significant amount of unidentified organofluorine material – it is unknown if that material is PFAS or not.
- A range of quantifiable PFAS Compounds / Groups (Ultrashort PFAS, Novel PFAS, PFPiA, PFPA, PFSA precursors, PFCA precursors, PFSA and PFCA) were measured in water using a range of analytical techniques, and are reported.

COMMENTS ON – "SECTION 7 – ANALYTICAL METHODS AND LIMITATIONS

The dossier notes that currently available methods can only provide qualitative and semi-quantitative data of substances, and not quantitative data.

Achieving the required detection limits for PFAS substances poses a challenge already for the 24 PFAS in the original EC amendments, especially for longer-chained PFAS compounds. Demonstrating compliance with the EQS / GWQS will, given the currently achievable detection limits and certified analyses methods, be strongly dependent upon the methodology of how non-detects are treated. While methods may be sufficiently sensitive, their precision may challenge situations where subtractions, as required in Options 3 and 4 of the dossier, may lead to ambiguity. Additional clarity is likely needed to help resolve situations where absolute uncertainties exceed proposed regulatory levels.

Those unfamiliar with the challenge of PFAS analysis in multiple media, including water, can be directed to work by the Nordic Council of Ministers whose independent scientific appraisal of the status of PFAS analytical tools[16] give a comprehensive overview.

Comment on subsection "Sum parameter analysis"

- Tools are only Screening Tools:
  - The text notes that Quantification of Fluorine content can be performed. However, what is critical for the objectives and final conclusion of this Dossier – which is that this Dossier reflects the scientific data also reflected in the same ECHA reference – that all PFAS (PFAS-total) themselves cannot currently be quantitively measured, nor can PFAS be discerned quantitatively from that Fluorine content. The US EPA references both note that these types of Sum parameter analyses only can be used as 'Screening Tools'. The US EPA specifically calls this analysis "Draft Method 1621 - Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC)"[17] – i.e., a screening tool does not give sufficient resolution of fluorine, let alone PFAS to perform a regulatory function sought. Moreover, the removal of inorganic Fluorine may not be complete using this method.
- Drinking Water Directive cannot provide a scientifically robust PFAS-total either:
  - The authors must acknowledge that, as noted in comments on SECTION 3 above, the reason that the EC has not (as experts we understand this remains undelivered) been able to develop a PFAS-Total and only a 'Sum of PFAS' for Drinking Water analysis is that such an analysis for a true PFAS Total is not possible. Only proxies can be approximated. Before closing this Dossier – given that EC should have reported out by 12th January 2024 – that opinion should be considered / integrated and not considered standalone.

The JRC should review the multiple responses given to ECHA by Laboratories - these can be filtered from ECHAs index[18] – and should be expanded properly in this summary. This part of SECTION 7 should reflect scientific fact that a Quantitative -PFAS Total analysis is not currently possible.

Comment on Table 7.1

The table somewhat contradicts itself and could give the impression that a PFAS Total, or even some kind of 'Quantitative PFAS analysis', can be given which it cannot.

[16] LINK > "Analytical Methods for PFAS in Products and the Environment" (norden.org)

[17] US EPA Draft Method 1621 - Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC). https://www.epa.gov/system/files/documents/2022-04/draft-method-1621-for-screening-aof-in-aqueous-matrices-by-cic_0.pdf

[18] Link to Comments submitted to date on restriction report on PFAS - ECHA (europa.eu)

The proposed total fluorine methods provided in Table 7.1 currently have detection limits in the order of 1 µg/L to 0.3 µg/L (= 1000 ng/L to 300 ng/L)[19] (), with likely uncertainties exceeding 10%. This may challenge accurate interpretation of results being close to the proposed EQS values. Additionally, while "organic" is included in the method titles, this is achieved through method operations not through the detection method, which is non-specific and typically quantifies inorganic fluoride species. As such, inorganic fluorine will provide a positive interference in these "total organic fluorine" methods that may bias results, particularly as concentrations are pushed lower.

Comments on Line 1 on Total Organic Fluorine (TOF):

- Column Principles = This technique analyses total Fluorine substances and does not give an 'indicator of PFAS contamination', as mentioned before that section of text is incorrect.
- Column Advantages = Although the EPA (in 2021) was considering standardising this approach, the result does not give a PFAS Total. Thus, the advantage is not clear. Rather the EPA (same documentation quoted in the JRC December 2023 PFAS - Draft EQS Dossier on "PFAS total"reference 21) note that TOF is only a screening technique – and actually in their 2023 version, the EPA have elected not[20] to continue developing TOF for National Pollutant Discharge Elimination System (NPDES) permitting.
- Column Drawbacks = TOF is not measuring 'other potential organic Fluorine substances that are not PFAS' – in fact as a drawback this technique measures all organic Fluorine substances that are both PFAS and non-PFAS and this method cannot differentiate between them.
- In summary, please see the suggestion below:

Method	Principles	Advantages	Drawbacks
Total Organic Fluorine (TOF)	Quantitative assessment of any organic Fluorine substances in samples. Screening for all fluorine-containing chemicals using Combustion Ion Chromatography (C-IC) ~~as an indicator of PFAS contamination~~.	No specialized or costly instrumental required.	Measurement of ~~other potential organic fluorine substances that are not PFAS.~~ **REPLACE WITH =** All organic Fluorine substances that are both PFAS, and not PFAS, this method cannot differentiate between them. **ADD (FROM THE EPA DOCUMENT) =** The detection limits for this technique are orders of magnitude higher than those for the AOF or EOF techniques.

Comments on Line 2 on Extractable Organic Fluorine (EOF):

- Column Principles = This technique does not use SPE to capture the PFAS compound. In the same EPA documents (and other referenceable material) this technique uses SPE to capture a specific range of organofluorine compounds, that cannot be restricted to just capturing a 'PFAS compound' – in fact as per the advantages column – it is known that although different SPE cartridges can be used, many 'miss' certain PFAS.
- Column Advantages = the fact that this technique results in poor selection of several PFAS, and many below C_6 is actually a significant disadvantage to the technique – so this comment should be moved to Column drawbacks.
- In Drawbacks – again like TOF, EOF is not measuring '*other potential organic Fluorine substances that are not PFAS*' – in fact as a drawback – this technique merely measures all organic Fluorine substances that are both PFAS and non-PFAS and this method cannot differentiate between them.

[19] Forster et al., 2023 (Water Research, doi: https://doi.org/10.1016/j.watres.2023.119859

[20] Point 14. Why Did EPA develop an AOF method and not a "total" organic Fluorine (TOF) method? LINK -> Frequent Questions about PFAS Methods for NPDES Permits | US EPA

- In summary, please see the suggestion below:

Method	Principles	Advantages	Drawbacks
Extractable Organic Fluorine (EOF)	Uses solid phase extraction (SPE) to capture ~~the PFAS compound~~ a range of organoflourine compounds and the liquid extract is then combusted and analyzed for total fluorine. Fluorine content of the extracts can be determined by e.g. C-IC.	EOF analysis captures all organofluorine substances extracted from a sample. The method is selective for only those organofluorines that can be extracted from the sample.	Measurement of ~~other potential organic fluorine substances that are not PFAS.~~ **REPLACE WITH =** all organic Fluorine substances that are both PFAS, and not PFAS, this method cannot differentiate between them. Organofluorine concentrations are dependent on the sorbent selectivity, which may result in poor recoveries for PFAS compounds with chain-lengths less than C_6 or neutral PFAS ([21]).

Comments on Line 3 on Adsorbable Organic Fluorine (AOF):

- Column Principles = This technique does not use granulated activated carbon (GAC) to adsorb the PFAS compounds – but uses GAC to capture organofluorine compounds. It therefore cannot be restricted to just capturing '*the PFAS compounds*' – as with the other techniques this is referenced in the same EPA documents (and other referenceable material) that the Dossier mentions.
- Column Advantages = the fact that this technique results in poor selection of several PFAS, and many below C_6 is actually a significant disadvantage to the technique – so this comment should be moved to Column drawbacks.
- In Drawbacks – again like TOF and EOF, AOF is not measuring '*other potential organic Fluorine substances that are not PFAS*' – in fact as a drawback – this technique merely measures all organic Fluorine substances that are both PFAS and non-PFAS and this method cannot differentiate between them.
- In summary, please see the suggestion below:

Method	Principles	Advantages	Drawbacks
Adsorbable Organic Fluorine (AOF)	Uses granulated activated carbon (GAC) to adsorb ~~the PFAS compounds~~ a range of organoflourine compounds which is then combusted and analyzed for total fluorine. The overall content of fluorine can be determined by e.g. C-IC. ([22])	US EPA is working on the standardisation of the method ([23]) (draft Method 1621 ([24])) as a screening tool.	Measurement of ~~other potential organic fluorine substances that are not PFAS.~~ **REPLACE WITH =** All organic Fluorine substances that are both PFAS, and not PFAS, this method CANNOT differentiate between them. More labour intensive and takes more time than EOF due to the extra steps. **ADD (FROM THE EPA DOCUMENT) =** The method is labelled as a screening method because it does not quantify all organofluorines with the same accuracy and has some known interferences.

COMMENTS ON SECTION "8.1 TRIFLUOROACETIC ACID (TFA)"

We note here that *"The JRC would recommend to include the TFA in the group of 24 PFAS of the EQS "sum of PFAS" with the RPF of 0.002 derived by RIVM (2023)."* We strongly disagree as the origins, fate and transport of TFA are under significant discussion and debate with TFA being abundant. TFA is

[21] US EPA website, Selection of techniques to measure aggregate PFAS concentrations https://www.epa.gov/cwa-methods/frequent-questions-about-pfas-methods-npdes-permits

[22] DIN 38409-59 describes how to use the combination of pyrohydrolytic combustion and ion chromatography (CIC) for AOF analysis.

[23] The U.S. EPA is in the process of validating a test method for AOF as Draft Method 1621. Multi-laboratory exercise completed and the data will be available in 2024. https://www.epa.gov/cwa-methods/cwa-analytical-methods-and-polyfluorinated-alkyl-substances-pfas

[24] Draft Method 1621: Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC), April 2022, U.S. Environmental Protection Agency, Washington, DC, EPA Document No. EPA/821/D/22/0202

prevalent for a variety of reasons, with concentrations in a "very pristine" area of Germany exceeding 200 ng/L (p.25 of dossier). If 200 ng/L is present as a background in a non-urban setting, then nominally 10% of the 24+1 EQS is made up of TFA (200 *0.002 = 0.4 of the 4.4 ng/L EQS. It is noted that TFA has been increasing in the monitored environment over time at concentrations well above a 'nanogram' limit, with recent work by a European laboratory[25] giving an overview of drinking water data. Adding TFA as a 25th PFAS needs serious consideration given its background prevalence.

We would welcome the opportunity to discuss the scientific validity of the selection of the 24 PFAS, in case TFA is also under consideration for addition. 'Increasing the 24 to 25 PFAS with the same EQS/ GWQS, without a scientific review and revision of the Impact Assessment would be inappropriate.

Misalignment of QS between PFAS Total and Sum of 24 (+TFA) dossier(s)

- There is a fundamental misalignment between the proposed PFAS Total EQS, which is a water-based EQS (fresh & marine) vs. the previous EQS derived for the sum of 24 PFAS (expressed as PFOA equivalents, which is a human EQS, based on dietary consumption. Further, there has not been a QS derived for TFA, either environmental or human, and its inclusion was not based on toxicological values collected and evaluated by the JRC or the PFAS Expert Group, previously. There are several technical and procedural issues with this misalignment. These are summarized subsequently:
    1. the toxicological basis for PFAS total has not been adequately established by the PFAS Expert Group. Previously Concawe have provided comments on the lack of fundamental basis for the development of a single QS for the group of 24 PFAS based on incongruent and missing data on mechanism of action and dissimilarity of observed endpoints. This concern is magnified significantly in the extrapolation to PFAS total. The uncertainty surrounding similarity of action and additivity of toxic effects is significant.
    2. the choice to develop a freshwater and marine QS, rather than a human health criterion and then subtract a water-equivalent value computed from a tissue-based human QS is fundamentally incorrect. These QS are intended to represent different receptors. Specifically, a water-based QS was not derived for the sum of 24, with most substances showing little to no acute or chronic ecotoxicity at concentrations which might indicate concern (in this case below existing threshold values from current EU and member state legislations).

It would seem that scope of what the JRC have been asked to do by European Parliament extends to the consideration of generation of a PFAS-Total EQS/ GWQS – and not revision of the 24, although better understanding of the impact of the 24 PFAS has been a topic of stakeholder requests.

Recalling the European Parliaments provision to reduce the groundwater targets by a factor of 10, this would effectively set the 25 PFAS at 0.44 ng/L for groundwater.

COMMENT ON SECTION "9.6 FINAL PROPOSED EQS FOR "PFAS TOTAL" IN THE PROPOSAL FOR WFD"

COMMENT ON SECTIONS 9.1 & 9.2 (OPTIONS 1 & 2)

If 24 PFAS + TFA are included in measure of "PFAS total", then one confronts concerns that TOF does not account for differences in potency based on molecular structure, which is otherwise acknowledged by the use of RPF values in another context. This will likely result in ambiguity or other lack of clarity. For example, the non-specific method (e.g., TOF) might be dominated by compounds

[25] LINK to > Eurofins_ultrashort_PFAS_drink_water_23

with low potency, such as TFA, and it is not clear what useful information would be provided by such a measure.

COMMENT ON SECTIONS 9.2 & 9.3 (OPTIONS 3 & 4)

Options 3 and 4 seem to warrant a little further consideration before potentially being shortlisted for adoption. It appears that the suggested standards are based on, or otherwise developed, using information related to the 24+1 PFAS (or subset thereof) that are explicitly excluded from consideration through external subtraction.

- The dossier shares that experts believe the "*value is not based on any toxicological effect value*." It appears poorly supported and problematic to develop a standard based on substances that are explicitly excluded, while somehow not also including consideration of substances that would be included with a "PFAS total" measurement.
- Section 8 of the dossier provides several examples of other fluorine containing compounds (e.g., Prozac, Celebrex), several of which also appear to meet the dossier's definition of PFAS.

This appears likely to lead to confusion, ambiguity, and miscommunication.

Comments on text below Table 9.1

As described in our comments to Section 7, the preferred Option 4 selected by the JRC, does not give the result of "Sum of PFAS", by subtracting the 24(25) PFAS from the total Fluorine result, all that is obtained is a total Fluorine result minus the 24(25) PFAS. The total Fluorine result comprises all Fluorine from the technique and cannot differentiate PFAS from other organofluorine substances which are known to be present – these include (as discussed by the US EPA) non-PFAS fluorinated compounds, such as pesticides and pharmaceuticals and others. To quote the US EPA on their AOF technique: "*The method tells the user that the organofluorines are present, but does not identify which organofluorines are present.*" This selected option has insufficient or no scientific validity to be used as a regulatory criterion, and can provide a role as a screening technique only.

CONCLUDING REMARKS

Concawe appreciates the opportunity to feedback to the draft PFAS total Dossier and acknowledges that managing PFAS risks is complex, raising challenges for both industry and society and meeting the proposed thresholds will be equally challenging. In summary, we have raised herein scientific concerns over the terminology of PFAS total in view of the analytical capabilities, over the selection criteria and the basis for the inclusion of several of the suggested PFAS in the PFAS total, over the lack of a global alignment on PFAS definition, and over the need for an alignment of the on-going PFAS Restriction Proposal (ECHA 2023) with current regulatory initiatives. Overall, Concawe supports the need to regulate PFAS on a strong scientific evidence basis, and for this reason, we would be amenable to share scientific insights based on our expertise and on-going research.