Reflections on several technical issues related to the implementation of Environmental Quality Standards for PFAS

Summary

*In 2022, the European Commission (EC) 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). The proposal includes an environmental quality standard (EQS-Sum) for both surface water and biota and a groundwater quality standard (GWQS) for the sum of 24 per- and polyfluoroalkyl substances (**PFAS-sum**[1]). The surface water and groundwater thresholds are set at 4.4 ng/l of PFOA equivalents. More recently 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**)[i]. Whilst this document focuses on the EQS for 24 PFAS and briefly reflects on several issues of the PFAS-total EQS, it is important that at the current time (March 2024), the JRC group of experts are considering the methodology for analysis of Total PFAS, in those working documents a 25th PFAS - Trifluoracetic Acid (TFA) is being considered to be added under the same quality standard discussed herein - the JRC should acknowledge the scientific lack of assessment that has been done by the Commission in determining the impact of adding TFA - as this is not included in the Commissions current Impact Assessment[ii].*

Concawe recognizes that PFAS are a cause of several environmental issues in Europe and welcomes initiatives by the EC to address these issues. In order to better understand risks from PFAS, Concawe has carried out several PFAS focused research projects: In 2016, an overview was published of the fate and effects of PFAS[1] and two reports on PFAS water treatment[2,3]. A currently ongoing research project with a university consortium focuses on improving the understanding of ecological risks from PFAS[iii]. These R&D projects showed that the scientific field of PFAS is continuously evolving providing new insights into PFAS toxicity, analytical capabilities and water treatment.

This memorandum highlights some of the scientific challenges that surround the proposed PFAS criteria under these directives, more specifically i) the selection mechanism of 24 PFAS substances, ii) uncertainty in the EQS & GWQS thresholds, and iii) analytical challenges to measure the 24 substances.

In brief, the following reflections are made:

- *The EQS and GWQS are derived from tolerable weekly intake (TWI) derived by EFSA for 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. A validation of the assumption that RPFs derived for liver effects can be extended to immune effects is not possible[4,5] 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[4].*

[i] **PFAS-sum** is the sum of the 24 PFAS components expressed in PFOA equivalents (a list of the 24 substances is included in Appendix A).
PFAS-total is intended to represent the total of all PFAS components and is detected with methods which aim at determining total organically bound fluoride.
[ii] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022SC0540
[iii] 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".

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Work by Ehrlich et al.[6] on the other hand does suggest there is substantial evidence for immunotoxic effects from a variety of PFAS beyond PFOS and PFOA but they also state further work is needed. Ecotoxicological testing data described in the JRC dossier[4] for PFAS are sparse resulting in assessment (uncertainty) factors of 10-10,000. There is a clear need for additional testing as described by the SCHEER[7] and an independent panel of experts[8].

- *Achieving the required detection limits for all 24 PFAS substances poses a challenge, especially for longer-chained PFAS compounds. Demonstrating compliance with the EQS / GWQS will, given the currently achievable detection limits and certified analytical methods, be strongly dependent upon the methodology of how non-detects are treated. Currently available methods for total PFAS can only provide qualitative and semi-quantitative data of substances, and not quantitative data.*

1. Introduction

In 2022, the European Commission published a proposal for amending the Directive amending the Water Framework Directive (2000/60/EC), the Groundwater Directive (2006/118/EC) and the Environmental Quality Standards Directive (2008/105/EC). The proposal includes an environmental quality standard (EQS-Sum) for both surface water and biota and a groundwater quality standard (GWQS) for the sum of 24 per- and polyfluoroalkyl substances (PFAS). The proposed EQS and GWQS value were developed by the EU Joint Research Centre (JRC) and documented in the PFAS dossier[4]. More recently 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). The JRC has prepared a dossier that lays out various options for developing an EQS for PFAS-total[9].

PFAS are also components in certain firefighting foams used, at least historically, at industrial and municipal facilities (including Concawe member assets) for flammable liquid fire suppression and firefighting training. In order to better understand risks associated with PFAS at these sites, Concawe has carried out several PFAS focused research projects: In 2016, an overview was published of the fate and effects of PFAS[1] and two reports on PFAS water treatment[2,3]. A currently ongoing research project with a university consortium focuses on improving the understanding of ecological risks from PFAS. These R&D projects showed that the scientific field of PFAS is continuously evolving providing new insights into PFAS toxicity, analytical capabilities and water treatment. The continuing body of scientific literature leads to great variations in quality standards: A recent review paper showed that surface water criteria for PFAS for the same end-point can vary over five orders of magnitude[10]. This alone highlights the need of further scientific work to support robust water criteria.

2. Selection of the PFAS-substances

The JRC PFAS-Sum dossier notes several aspects that were considered to select the 24 substances (e.g., availability of relative potency factors and toxicity data) but does not provide specific 'minimum criteria' to select the specific 24 PFAS substances to be regulated. The Impact Assessment[11] report contains a prioritization framework but this is applied to select the PFAS as a group and not specific substances.

The EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)[5] therefore noted that the selection of substances is not well documented and lacks a prioritization method. This implies that the selection of PFAS substances is not sufficiently transparent and it is not clear whether the selection of substances follows the principles from the CIS Guidance Document no. 27[12] which lays out how EQS-values should be developed. This guidance describes that substances to be selected pose a risk to receptors. A well-documented prioritization and selection framework is of importance, both for regulators as well as industry, to assure that the most critical substances are selected and for screening of risks of new components.

- An example of such a methodology is the prioritization framework used for the Groundwater Watch List used to select substances for monitoring[13]. The Watch List is used to determine whether substances actually pose a risk to receptors. The Impact Assessment notes that the outcomes from the Groundwater Watch List process resulted in 10 PFAS substances being selected (i.e., from the 'List Facilitating the Review' of Annex 1 and 2 of the GWD) but does not describe how the other 14 substances were selected. Furthermore, the JRC dossier notes monitoring data were available only for 17 of the 24 PFAS substances (no monitoring data was available for the other 7 substances).

- A Surface Water Watch List mechanism was first developed in 2013. The objective was to "improve the available information on identifying the substances of greatest concern". European MS are requested to monitor the watch list substances annually, for a period of four years. The first Surface Water Watch list was established in 2015, updated in 2018 and 2020 and again in 2022. PFAS have never appeared on the Surface Water Watch list of concern, and for many PFAS substances (not PFOS and PFOA) the Watch list mechanism, i.e. to collect the data first, would make more sense from a scientific perspective,

In order to derive an EQS for PFAS-total, it is crucial to clearly define which substances are considered PFASs. The PFAS-total dossier contains several definitions and the dossier describes that toxicity, bioaccumulation, toxicokinetics, and exposure profiles vary considerably among PFAS. The dossier cites work by Anderson et al.[14] who compiled the opinion of PFAS' expert panel on the grouping strategies of PFAS for human health risk assessment and concluded that PFAS should not be grouped together due to high diversity. Despite these considerations, a scope for the PFAS-total EQS is proposed that includes all fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (in line with the OECD 2021 definition of PFAS)[15].

3. Technical challenges and uncertainties related to the EQS-values

The JRC dossier that accompanies the proposal presents different QS associated with different receptors (human health and ecological) and water types (fresh water and marine). The most stringent QS are those for surface water used for drinking water and human consumption of biota (respectively, $QS_{dw,hh}$ and $QS_{biota,hh}$). These most stringent QS are subsequently selected as EQS and included in the proposal to amend the three directives.

This resulted in an EQS for both inland and other surface waters (e.g., coastal saline water) and groundwater QS of 4.4 ng $PFOA_{eq}$/l and an EQS for biota of 0.077 µg $PFOA_{eq}$/kg wet weight. The EQS is derived using PFOA as an 'index parameter'. The measured concentrations in the 23 other PFAS components are converted to 'PFOA-equivalent' ($PFOA_{eq}$) concentrations. The sum of the PFOA-concentration and the 23 PFOA-equivalent concentrations measured in water and biota are compared against the EQS values for water and biota. The conversion to $PFOA_{eq}$ is carried out using 'relative potency factors' (RPFs) available for 16 PFAS derived from a paper from Bil et al.[16] - the remaining RPFs are derived from a read-across (this is a method to fill data gaps). The RPFs are included in Appendix A and show potencies range several orders of magnitude.

From the JRC dossier several technical and scientific issues and uncertainties emerge that warrant further research:

- All of the above listed EQS values were based on the tolerable weekly intake (TWI) of 4.4 ng/kg body weight (bw) for the sum of four PFAS (PFOA, PFOS, PFHxS and PFNA) derived by the European Food Safety Authority (EFSA) - Panel on Contaminants in the Food Chain [17]. A key difference between EFSA and JRC approaches is that while EFSA assessed a total of 27 PFAS, they considered it appropriate to develop a TWI for only four of the assessed PFAS (based on effects reported in literature). JRC on the other hand, applies the TWI derived by EFSA to a group of 24 PFAS using the RPF derived by Bil et al.[16] to convert other PFAS concentrations to PFOA.

- Another key difference between the JRC and EFSA approaches relates to the toxicological end-points considered. Different PFAS are associated with a variety of effects to humans[18,19] including (but not limited to) increased cholesterol, liver function, kidney and thyroid diseases and a reduced response to vaccination. The RPFs reported by Bil et al.[16] are derived for liver effects while the most critical effect considered by EFSA is a reduced response to vaccination. Although Bil et al.[16] reported that differences in potencies are also observed for other effects, it was not clear whether RPFs can equally effective be applied to a TWI for reduced vaccination response. A more recent study by Bil et al.[20] used additional data and demonstrated differences in immunotoxic potencies of different PFAS and an effect of the sum of PFOA, PFNA, PFHxS, and PFOS on antibody concentrations and available data in rodents and humans was used to derive RPFs for immune suppressive effects. Although the SCHEER endorses the use of RPFs for immune effects and conclude that RPFs 'might be applicable to immune effects'[7], recent papers by Antoniou et al.[21], Garvey et al.[8] and Cotruvo et al.[22] describe the data limitations for immune end-points. Work by Ehrlich et al.[6] on the other hand suggests that there is substantial evidence for immunotoxic effects from a variety of PFAS but they also state further work is needed, for example to investigate a broader suite of PFAS substances.

- As stated earlier the most critical QS is that for human health (via drinking water and consumption of biota). The JRC PFAS-Sum dossier[4] also presents an overview of ecotoxicological data and derived QS for both acute and chronic exposure in fresh and salt water environments. The QS derived for ecotoxicological effects are also in the sub-µg/l to ng/l range which is mainly the result of limitations in ecotoxicological data availability which requires the use of assessment (or uncertainty) factors ranging between 10 and 10,000. This implies that a no-effect concentration in the range of µg/l can result in a QS in the range of ng/l. Additional ecotoxicological data can reduce the value of the assessment factor required. In addition, a recent review of PFOS ecotoxicological data showed that more enhanced multigenerational ecotoxicological testing resulted in screening levels which are two orders of magnitude higher than the screening value currently used by the US-EPA[23]. This is an area where the currently ongoing Concawe research project can provide additional data to fill this gap.

- The draft dossier for PFAS-total describes several options for an EQS-value, which are based on the Drinking Water Directive (DWD) PFAS-total criterium of 500 ng/l (derived for the sum of 20 PFAS substances). Several options are described: to optionally apply an assessment factor of 10 to the DWD PFAS criterium and to optionally subtract the sum of 24(+TFA) PFAS substances defined under the PFAS-sum EQS. Based on these options, the JRC recommends to use an EQS-value for PFAS-total of 50 ng F/l (based on the criterium from the DWD and an assessment factor of 10) and to compare this against an analyses of PFAS-total minus the sum of 24 PFAS+TFA. It is noted that the draft dossier for PFAS-total[9] points out that the EQS for PFAS-total is not a toxicological effect value but rather 'a policy complement to risk-based values'.

In summary, there are still many issues that need further scientific research surrounding the derived EQS values. Most critical are the uncertainties related to vaccine response and immunotoxicity (i.e., which PFAS substances, with what potency and the implications of reduced vaccine-induced antibody concentrations) and the limited amount of ecotoxicological data points.

4. Analytical challenges of the 24 PFAS substances

The JRC dossier provides an overview of the achievable limits of detection (LOD) for most of the 24 PFAS substances (included in Appendix A of this memo based on Table 8.1 from the JRC dossier) based on standard (i.e., certified) methodologies. The achievable LOD ($LOD_{achievable}$) for most substances are in the ng/l range, with the LOD for PFBA and C6O4 being an order of magnitude higher (resp. 13 and 40 ng/l) and the LOD for frequently measured PFAS such as PFOA and PFOS being lower (resp. 0.5 and 0.2 ng/l). These levels correspond to LODs reported in two recent review papers[24,25].

The EQS is expressed in $PFOA_{eq}$/l for the sum of 24 substances. An estimate of the required LOD for individual PFAS substances to demonstrate compliance to the sum-EQS is not provided by JRC but can be estimated when assuming all 24 PFAS substances contribute equally to the $PFOA_{equivalent}$ concentration. In that case the required LOD for each substance is equal to:

$$LOD_{required,\ PFAS[i]} = 2 \times [EQS / 24] / RPF_{PFAS[i]}$$

where $LOD_{required,\ PFAS[i]}$ is the required LOD for the i^{th} PFAS substance and $RPF_{PFAS[i]}$ is the RPF for i^{th} PFAS substance. The factor 2 is included in this calculation because a value which is below the level of quantification can be replaced by 0.5 x LOQ (as described in the JRC dossier if the LOQ is a factor 2 higher than the EQS). For example, for PFBA -> LOD = 2 x 4.4 ng/l / 24 / 0.05 = 7.3 ng/l. This is a factor 2 lower than the achievable LOD of 13 ng/l reported in Table 8.1 of the JRC dossier. The estimated required LOD for each of the 24 PFAS substances is included in Appendix A. This overview shows that for >10 of the 24 PFAS substances the achievable LOD is still far above the required LOD, in particular for long chained PFAS substances including PFNA, PFDA, PFUnA and PFDoDa.

It is noted that a comprehensive overview of concentrations of all of the 24 PFAS substances Europe-wide is not available. JRC reports that groundwater monitoring data were found only for 17 of the totally considered 24 PFAS. The seven substances missing measurements are ADONA, 6:2 FTOH, 8:2 FTOH, C6O4, PFHxDA, PFTrDA. The dossier also does not report emissions data for these substances which makes it difficult to assess whether these substances create an EU-wide risk for receptors.

With regards to PFAS-total, the dossier notes that currently available methods can only provide qualitative and semi-quantitative data of substances, and not quantitative data. Most proposed techniques cover analyses of Fluorine - in various forms - but not in a total method for all PFAS. Currently available scientific evidence shows this tool should not be used as a quality standard but rather as a screening tool[24].

Concawe recognizes there is a need to address the environmental issues around PFAS and welcomes the initiative of the EC to develop Europe wide risk-based water quality criteria. Concawe will continue to support these efforts through research in the fields of PFAS remediation, water treatment and risk assessment.

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Appendix A: List of 24 PFAS Substances with RPF and LODs (from JRC) - compared to required LOD

Acronym	Relative potency factors from JRC (Bil et al., 2021) or read across (indicated with *)	RPF (with range replaced with middle value)	Lowest LOD achievable in water according to JRC dossier (ng/l)	LOD required based on $PFOA_{eq}/24$ (ng/l)[1]	Ratio $LOD_{achievable}$ / $LOD_{required}$ (>1 means $LOD_{achievable}$ is insuffcient)
PFBA	0.05	0.05	13	7.3	1.8
PFPeA	0.01 ≤ RPF ≤ 0.05 *	0.03	0.2	12.2	0.02
PFHxA	0.01	0.01	1	36.7	0.03
PFHpA	0.01 ≤ RPF ≤ 1 *	0.505	0.71	0.7	0.98
PFOA	1	1	0.53	0.4	1.4
PFNA	10	10	1.4	0.0	38.2
PFDA	4 ≤ RPF ≤ 10 *	7	1.6	0.1	30.5
PFUnA or PFUnDA	4	4	1.6	0.1	17.5
PFDoDA or PFDoA	3	3	1.2	0.1	9.8
PFTrDA	0.3 ≤ RPF ≤ 3 *	1.65	0.72	0.2	3.2
PFTeDA	0.3	0.3	1.1	1.2	0.9
PFHxDA	0.02	0.02	0.2	18.3	0.011
PFODA	0.02	0.02	0.2	18.3	0.011
PFBS	0.001	0.001	1.8	366.7	0.005
PFPeS	0.001 ≤ RPF ≤ 0.6 *	0.3005	Not available in JRC Dossier		
PFHxS	0.6	0.6	1.4	0.6	2.3
PFHpS	0.6 ≤ RPF ≤ 2 *	1.3	0.53	0.3	1.9
PFOS	2	2	0.2	0.2	1.1
PFDS	2 *	2	0.2	0.2	1.1
6:2 FTOH	0.02	0.02	6.6	18.3	0.4
8:2 FTOH	0.04	0.04	5.5	9.2	0.6
HFPO-DA (Gen X)	0.06	0.06	1.9	6.1	0.3
ADONA	0.03	0.03	0.88	12.2	0.1
C6O4	0.06 *	0.06	40	6.1	6.5

Note 1: Required LOD is calculated by assuming all 24 PFAS substances contribute equally to the $PFOA_{equivalent}$ concentration. In that case the required LOD is equal to: $LOD_{required, PFAS[i]}$ = [EQS / 24] / $RPF_{PFAS[i]}$ where $LOD_{required, PFAS[i]}$ is the required LOD for the i^{th} PFAS substance and $RPF_{PFAS[i]}$ is the RPF for i^{th} PFAS substance. For example, for PFBA --> LOD = 4.4 ng/l / 24 / 0.05 = 3.7 ng/l. This is a factor 3.5 lower than the achievable LOD reported in Table 8.1 of the JRC dossier.

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