Reflections on technical issues related to derivation of PFAS Environmental Quality Standards

Summary

*In 2022, the European Commission (EC) published a proposal to amend the Water Framework Directive (2000/60/EC), the Groundwater Directive (2006/118/EC) and the Environmental Quality Standards Directive (2008/105/EC) (hereinafter "the proposal"). 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**)[i]. 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**)[ii].*

Concawe recognises that PFAS are a cause of health and environmental concern in Europe and welcomes initiatives by the EC to address them. In order to better understand risks from PFAS, Concawe has carried out several PFAS related research projects: a review of the environmental fate and effects of PFAS[1] and three reports dealing with removal of PFAS by water/ soil treatment[2,3,4]. An ongoing research project with a university consortium focuses on improving the understanding of ecological risks from PFAS[iii]. These R&D projects all reflect that the scientific field of PFAS is rapidly evolving and providing new insights into PFAS toxicity and behaviour, analytical capabilities and water/ soil treatment.

This document highlights some of the scientific challenges that surround the proposed PFAS criteria in the proposal, more specifically: i) the selection of the 24 PFAS in PFAS-sum is not well documented and lacks a clear prioritisation method; ii) EQS- and GWQS-values are not clearly derived and lack underlying data; and iii) Many PFAS QS are below achievable limits of detection and/or quantification.

In brief, the following reflections are made:

- *The EQS and GWQS are derived from Tolerable Weekly Intake (TWI) derived by EFSA for 4 (four) PFAS based on reported effects on the immune system response to vaccinations. A Relative Potency Factor (RPF) methodology, derived for liver effects was used to extend the TWI to a further 20 (twenty) PFAS, expressed as PFOA equivalents. It is not possible to confirm the assumption that*

i **PFAS-sum** is the sum of the 24 PFAS expressed in PFOA equivalents (the list of the 24 substances is included in Appendix A).

ii **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.

iii Work presented at 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".

RPFs derived for liver effects can be extended to immune effects[5,6]. And for some of the 24 PFAS there is even no clear evidence presented in the PFAS dossier[5] that these impacts the immune system. Work by Ehrlich et al.[7], 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. To account for the sparseness of ecotoxicological testing data described in the PFAS dossier[5], high assessment (uncertainty) factors of 10 - 10,000 need to be applied. Thus, there is a clear need for additional testing as described by the SCHEER[8] and an independent panel of experts[9].

- *Achieving the required detection limits for each of all 24 PFAS substances poses a challenge, especially for longer-chained PFAS compounds. Demonstrating compliance with the EQS / GWQS will be strongly dependent upon the methodology of how non-detects are treated, given the currently achievable detection limits and certified analytical methods.*

Introduction

In 2022, the European Commission published a proposal to amend 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) (hereinafter "the proposal"). 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 values for these 24 PFAS were developed by the **PFAS Expert Group**[iv] led by the EC Joint Research Centre (JRC) and is documented in the PFAS dossier[5]. In April 2023, the European Parliament requested that in addition to the EQS for the sum of 24 PFAS, an EQS should be derived for the total of all PFAS components (PFAS-Total).

PFAS are components in many products, including certain firefighting foams at least historically used 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 more recently three reports on water/ soil treatment to remove PFAS[2,3,4]. An ongoing research project with a university consortium focuses on improving the understanding of ecological risks from PFAS. These R&D projects show that the scientific field of PFAS is rapidly evolving providing new insights into PFAS toxicity, analytical capabilities and water/ soil treatment. The fluid state of PFAS understanding leads to great variations in quality standards: a recent review paper looking at criteria in Australia, Canada, the EU, four US states (Florida, Michigan, Minnesota, and

[iv] **The PFAS Expert Group** is a group led by the JRC which consists of EU MS and stakeholder representatives. The PFAS Expert Group reports to the Working Group Chemicals under the Water Framework Directive Common Implementation Strategy (WFD CIS). The PFAS Expert Group was formed in 2020 to prepare for upcoming amendments to the WFD, Groundwater Directive (GWD) and Environmental Quality Standards Directive (EQSD). A key deliverable of the PFAS Expert Group was the PFAS Dossier which is a 236 page document intended to provide the background for the EQS values in the EQSD and GWD proposals.

Wisconsin), and the San Francisco Bay Regional Water Quality Control Board (California, US) showed that surface water criteria for PFOA 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.

Technical issue 1: The selection of the 24 PFAS is not well documented and lacks a prioritisation method

The PFAS dossier[5] establishes that several aspects 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 proposal Impact Assessment[11] report contains a prioritisation framework but this is applied to select the PFAS as a group and not specific substances within the family of PFAS. The EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)[6] therefore noted that the selection of substances is not well documented and lacks a prioritisation 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 states that substances to be selected should be shown to pose a potential risk to receptors. A well-documented prioritisation 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 selection methodology is the prioritisation framework used for the Groundwater Watch List used to select substances for monitoring[13]. The Watch List methodology is used to determine whether substances actually pose a risk to receptors. The proposal Impact Assessment[11] notes that the outcomes from the Groundwater Watch List process resulted in 10 PFAS substances being identified as having potential risk to European groundwater (i.e., were included in 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 PFAS dossier notes monitoring data were available only for 17 of the 24 PFAS substances (no monitoring data was available for the other 7 substances).

Furthermore, 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". EU 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, 2020 and again in 2022. PFAS have never appeared on the Surface Water Watch, and for many PFAS substances (excluding PFOS and PFOA) the Watch list mechanism, i.e., to collect the monitoring data first, would be the established procedure to follow.

Technical issue 2: EQS- and GWQS-values are not clearly derived and lack underlying data

The PFAS dossier[5] that accompanies the proposal presents different Quality Standards (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 ($QS_{dw,hh}$ and $QS_{biota,hh}$, respectively). These most stringent QS are subsequently selected as EQS and GWQS and included in the proposal to amend the Water Framework Directive (2000/60/EC), the Groundwater Directive (2006/118/EC) and the Environmental Quality Standards Directive (2008/105/EC), respectively. This resulted in an EQS for both inland and other surface waters (e.g., coastal saline water) of 4.4 ng $PFOA_{eq}$/l, a GWQS of 4.4 ng $PFOA_{eq}$/l and an EQS for biota of 0.077 µg $PFOA_{eq}$/kg wet weight. All of the above mentioned QS 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[15].

The EQS is derived using PFOA as an 'index parameter'. The measured concentrations of the 23 other PFAS components are to be 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 to be 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.[14]. The remaining RPFs are derived from a read-across (i.e., a method to fill data gaps), how this read-across is done is not well explained in the PFAS dossier other than it is stated that it is based on “the perfluoroalkyl carboxylic or sulfonic acids with a shorter or a longer alkyl chain”. The RPFs are included in Appendix A and range several orders of magnitude.

From the PFAS dossier several technical and scientific issues and uncertainties warrant further research:

- A key difference between the PFAS Expert Group and EFSA approaches relates to the toxicological end-points considered. Different PFAS are associated with a variety of effects to humans[16,17] including (but not limited to) increased cholesterol, decreased liver function, kidney and thyroid diseases and a reduced response to vaccination. The RPFs reported by Bil et al.[14] are derived for liver effects while the most critical effect considered by EFSA is a reduced response to vaccination. Although Bil et al.[14] reported that differences in potencies are also observed for other effects, it was not clear whether RPFs can equally effective when applied to a TWI for reduced vaccination response. A more recent study by Bil et al.[18] 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 endorsed the use of RPFs for immune effects and conclude that RPFs 'might be applicable to immune effects'[8], recent papers by Antoniou et al.[19], Garvey et al.[9] and Cotruvo et al.[20] describe the data limitations for immune end-points. Work by Ehrlich et al.[7] 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.

- Another key difference between EFSA and the PFAS Expert Group 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 (PFOA, PFOS, PFHxS and PFNA). The PFAS Expert Group on the other hand, applied the TWI derived by EFSA to a group of 24 PFAS using the RPF derived by Bil et al.[14] to convert other PFAS concentrations to PFOA. The PFAS Expert group's conclusion of including an additional 20 PFAS raises several questions which are not clearly explained in the PFAS dossier. For example: how can one take the EFSA TWI value for four PFAS, apply it to another 20 PFAS (which lacks a clear prioritisation method; see Technical Issue 1 above) using a method based on another toxicological end-point and subsequently end up with QS values for 24 PFAS? In the PFAS dossier it is not well explained how this is possible nor is it backed up by conclusive evidence that this approach is scientifically robust based on the state of current science.

- As stated earlier, the most critical QS is that for human health (via drinking water and consumption of biota). The PFAS dossier 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 magnitude of the assessment factor required. In addition, a recent review by Pandelides et al.[21] 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. This is an area where the ongoing Concawe research project can provide additional data to fill this gap.

In summary, there are still many issues that need further scientific research surrounding the derived EQS and GWQS 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.

<u>Technical issue 3:</u> Many PFAS QS are below achievable limits of detection and/or quantification

The PFAS dossier[5] provides an overview of the achievable limits of detection (LOD) for most of the 24 PFAS substances (included in Appendix A of this document based on Table 8.1 from the PFAS 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[22,23].

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 in the PFAS dossier 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 of two 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 PFAS dossier if the LOQ is a factor of two higher than the EQS). For example, for PFHxS -> LOD = 2 x 4.4 ng/l / 24 / 0.6 = 0.6 ng/l. This is a factor of 2.3 lower than the achievable LOD of 1.4 ng/l reported in Table 8.1 of the PFAS 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 higher than the proposed EQS, in particular for long chained PFAS substances including PFNA, PFDA, PFUnA and PFDoDa.

Recently, on August 7 2024 – roughly 24 months after the PFAS dossier was made publicly available – the EC published Commission Notice C/2024/4910[24] which contains Limits of Quantification (LOQ) for the PFAS included in the Drinking Water Directive (the so called 'PFAS sum' parameter). This makes it possible to amend, to a great extent but not completely, the table comparing LOD and EQSs with another parameter, namely with LOQ. In Appendix A it is shown that the result of comparing with the LOQ instead of LOD is not changing the picture and still for >10 of the 24 PFAS substances the achievable LOQ is far higher than the proposed EQS.

It is noted that a comprehensive overview of concentrations of all of the 24 PFAS substances EU-wide is not available. The PFAS dossier reports that groundwater monitoring data were found only for 17 of the totally considered 24 PFAS. The six substances missing measurements are ADONA, 6:2 FTOH, 8:2 FTOH, c6O4, PFHxDA, and PFTrDA. The PFAS 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.

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Appendix A: List of 24 PFAS Substances with RPF and LODs (from PFAS dossier) – compared to required LOD and lowest LOQ for PFAS water analysis according to EC Notice C/2024/4910. NB: The PFAS dossier presents Limit(s) of Detection (LOD) while EC Notice C/2024/4910 presents Limit of Quantification (LOQ).

Acronym	Relative potency factors from PFAS dossier (Bil et al., 2021) or read across (indicated with *)	RPF (with range replaced with middle value)	Lowest LOD achievable in water according to PFAS dossier (ng/l)	LOD required based on $PFOA_{eq}$/24 (ng/l)[1]	Ratio $LOD_{achievable}$ / $LOD_{required}$ (>1 means $LOD_{achievable}$ is insuffcient)	Lowest LOQ for PFAS water analysis according to EC Notice C/2024/4910 (ng/L)[2] and short comment on Ratio $LOQ_{achievable}$ / $LOQ_{required}$
PFBA	0.05	0.05	13	3.7	3.5	1.3 – Ratio ≤1
PFPeA	0.01 ≤ RPF ≤ 0.05 *	0.03	0.2	6.1	0.03	Not available
PFHxA	0.01	0.01	1	18.3	0.05	1.3 – Ratio ≤1
PFHpA	0.01 ≤ RPF ≤ 1 *	0.505	0.71	0.4	2.0	1.3 – Ratio >1
PFOA	1	1	0.53	0.2	2.9	1.3 – Ratio >1
PFNA	10	10	1.4	0.02	76	1.3 – Ratio >1
PFDA	4 ≤ RPF ≤ 10 *	7	1.6	0.03	61	1.3 – Ratio >1
PFUnA or PFUnDA	4	4	1.6	0.05	35	1.3 – Ratio >1
PFDoDA or PFDoA	3	3	1.2	0.1	20	1.3 – Ratio >1
PFTrDA	0.3 ≤ RPF ≤ 3 *	1.65	0.72	0.1	6.5	1.3 – Ratio >1
PFTeDA	0.3	0.3	1.1	0.6	1.8	Not available
PFHxDA	0.02	0.02	0.2	9.2	0.02	Not available
PFODA	0.02	0.02	0.2	9.2	0.02	1.3 – Ratio ≤1
PFBS	0.001	0.001	1.8	183.3	0.01	1.3 – Ratio ≤1
PFPeS	0.001 ≤ RPF ≤ 0.6 *	0.3005	Not available in PFAS Dossier			Not available
PFHxS	0.6	0.6	1.4	0.3	4.6	1.3 – Ratio >1
PFHpS	0.6 ≤ RPF ≤ 2 *	1.3	0.53	0.1	3.8	1.3 – Ratio >1
PFOS	2	2	0.2	0.1	2.2	1.3 – Ratio >1
PFDS	2 *	2	0.2	0.1	2.2	1.3 – Ratio >1
6:2 FTOH	0.02	0.02	6.6	9.2	0.7	Not available
8:2 FTOH	0.04	0.04	5.5	4.6	1.2	Not available
HFPO-DA (Gen X)	0.06	0.06	1.9	3.1	0.6	Not available
ADONA	0.03	0.03	0.88	6.1	0.1	Not available
C6O4	0.06 *	0.06	40	3.1	13	Not available

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 PFAS dossier.

Note 2: See Section 3.3.1 of European Commission Notice C/2024/4910 where an LOQ of 1.3 ng/L for each of the 20 PFAS compounds of the Drinking Water Directive ('PFAS sum') is reported.