

FUELSEUROPE PRELIMINARY COMMENTS ON THE “Integrated water management – revised lists of surface and groundwater pollutants”

OUTLINE

1. General comment on the process driving the publication of the proposal from the European Commission

2. FuelsEurope areas of concerns

- Deletion of Art. 16;
- PFAS environmental quality standards (EQS) and ground water quality standards (GW QS).

1. General comment on the process driving the publication of the proposal from the European Commission

FuelsEurope supports the process aiming at regularly reviewing the lists of priority substances and groundwater pollutants and appreciates the possibility to share its preliminary views on the proposal recently adopted by the Commission in that context. From an industrial perspective, the importance of harmonised EU-level regulations is well recognised and the harmonisation foreseen in the Commission proposal well acknowledged. FuelsEurope particularly welcomes the general objective of increasing the effectiveness and reduce the administrative burden of the legislation. Setting standards at a non-science derived standard may require the need for technically unavailable or economically not viable ‘compliance’ control/remediation actions than where a more science-based and sustainability driven framework is in place.

Concawe provided for the following science-based inputs:

1. Inputs to Wood and Trinomics, Commission contractors, on Workshop on the potential revision of the lists of pollutants affecting surface and groundwaters and the corresponding regulatory standards in the Environmental Quality Standards Directive (EQSD), Groundwater Directive (GWD) and Water Framework Directive (WFD).
2. Inputs to the draft EQS dossier for the risk assessment of twenty-four per- and polyfluoroalkyl substances (PFAS).
3. Contribution to FuelsEurope response to the Open Public Consultation on the Integrated water management – revised lists of surface and groundwater pollutants.
4. Feedback to the targeted survey integrated water on the Integrated water management – revised lists of surface and groundwater pollutants.
5. Inputs to Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) scientific opinions on Groundwater Quality Standards (QS) for proposed additional pollutants in the annexes to the Groundwater & PFAS Draft EQS for Priority Substances under the WFD.

The procedural and scientific deficiencies in the derivation of Surface water EQS and Groundwater QS for 24 PFAS substances identified by members of the JRC Expert Group and discussed within the Expert Group and communicated to the SCHEER for their opinion have not been adequately considered. Rather than simply highlight deficiencies we do seek to identify a method to support the derivation of appropriate EQS criteria. Despite the fact that we very much appreciate the opportunity that we have been given to provide science-based inputs to the Commission, the JRC and SCHEER, we deplore that those have not sufficiently been taken into consideration in the development of the proposal adopted by the Commission.

2. FuelsEurope areas of concerns

Deletion of articles 16 and 17

The EC proposal includes a significant change in the way listing and identifying EQS for surface and groundwater bodies is done: replacing the requirement for the Commission to establish legislative proposals, by the provisions enabling the Commission to establish those lists via delegated acts instead.

Possible consequences:

- Smaller role of the European Parliament and the Council: the two co-legislators would not be allowed to actively participate in the decision-making process.
- Less time and/or less opportunities for stakeholders to provide input to the substance prioritisation process in the future.

Moreover, the current WFD makes explicit reference (in articles 16 and 17 of the WFD) to using risk as the basis to identify the appropriate cost-effective and proportionate level of control, which is not included in proposed revisions of WFD (amending 2000/60/EC), GWD (amending 2006/118/EC) or EQSD (amending 2008/105/EC). Particularly, the Commission proposal does not contain any reference to 'basis of risk', 'appropriate cost-effective level' and/or 'proportionate level', which was previously in Art 16(2), Art 16(6) & indirectly in Art 17(3).

The respect of these principles is fundamental in order to avoid any arbitrary way of identification or prioritisation of substances. To classify and identify them, a risk assessment developed based on clear science-based methodologies is key.

Our recommendation:

- To object to the proposed way to regulate and keep the current co-legislative approach.
- In the case the secondary legislation is nevertheless agreed (not our preferred option), it is critical that the above principles are explicitly mentioned in the articles enabling the Commission to adopt delegated acts.

PFAS environmental quality standards (EQS) and ground water quality standards (GW QS)

In the proposal for GWD Annex I (amending 2006/118/EC) and EQSD (amending 2008/105/EC) new EQS and GW QS for 24 PFAS are included. We understand and recognise the global causes for concern on PFAS compounds and we are not opposed in principle to their inclusion. The issue is, to date, that a thorough review of the literature and an assessment of the gaps in knowledge have not been adequately considered.

Version 1: when talking to a water expert

In particular, the proposal sets a unique limit for 24 PFAS (in practice: PFAS limits are set at 4.4 ng/L of PFOA-equivalents, on a sum of 24 PFAS) seem to be arbitrarily low with standards based on improper derivation because of:

- The assumption of an "equivalent mechanism of action" for 24 PFAS substances based on limited and conflicting evidence of correlation for a small subset of PFAS (PFOA, PFNA, PFOS, PFHxS).

- The application of relative potency factors (RPFs) derived from a single study using a biologically unrelated endpoint (liver toxicity) for 24 PFAS using the selected endpoint (vaccine response).
- The direct application of tissue-based RPF (and concentration addition of PFOA-equivalents) to water-based values for exposure via drinking water without consideration of relative biological partitioning affinity of PFAS compounds.

In **Figure 1** below it is graphically depicted how the EQS and GW QS ‘targets’ seem to have been derived, where: 1) scientific data was available; 2) where assumptions with some scientific background / understanding have been used; and 3) where we cannot see any reliable data was used in EQS derivation. **We believe that moderately robust EQS can only be set for the top two tiers of the pyramid in Figure 1.**

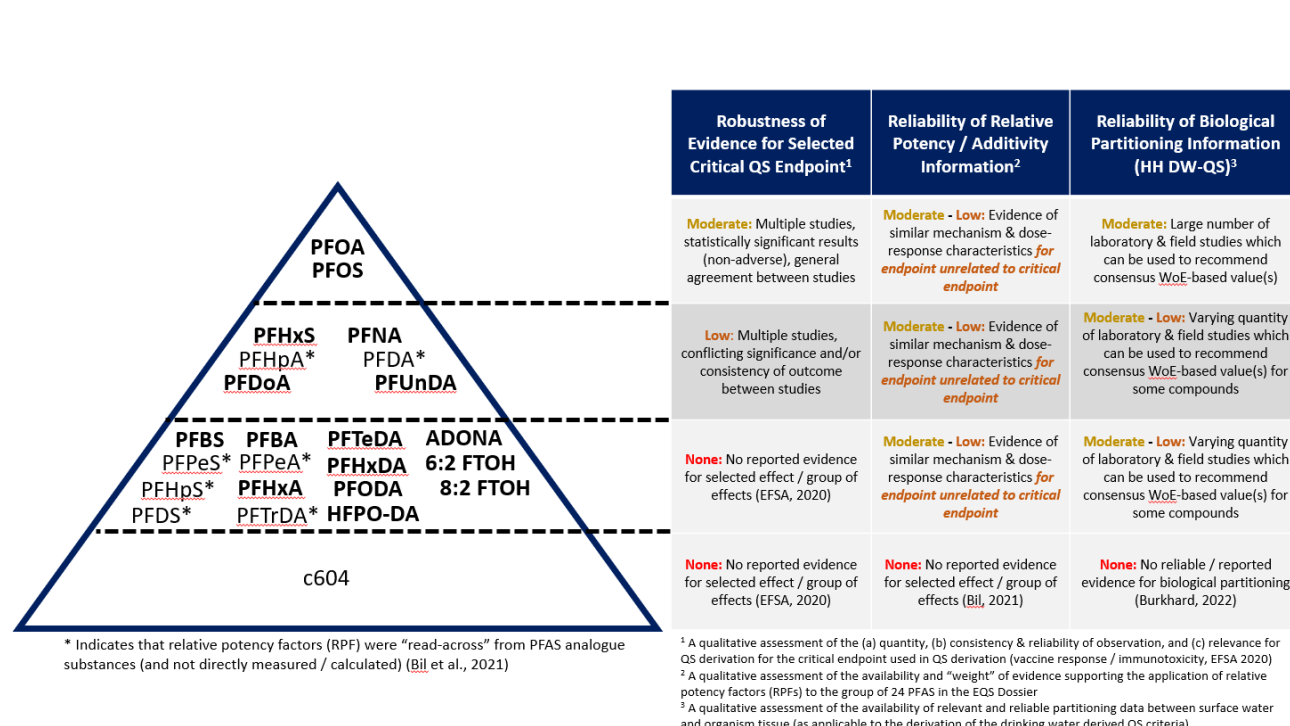


Figure 1: How EQS ‘targets’ seem to have been derived for the 24 PFAS in the

Version 2: talking to a decision maker

In particular, the proposal sets a unique limit for 24 PFAS (in practice: PFAS limits are set at 4.4 ng/L of PFOA-equivalents, on a sum of 24 PFAS) seem to be arbitrarily low with standards based on improper derivation because of:

- The absence of a robust methodology (uncertainties leading to a sum-parameter for 24 PFAS)
- The compounding of consistency of effects, using a single study and simplification are leading to significant uncertainty

We believe PFAS need to be regulated urgently but based on a robust approach. The tools are there to use more reliable data to support the majority of PFAS but not at the level in the current proposal.

Our recommendation:

- We agree PFAS need to be regulated urgently but :
 - Use the reliable data that support the establishment of EQS for a majority of PFAS (abstain simplifying / extrapolating for the 24 PFAS)
 - Include a provision requiring the Commission to come forward with a proposal to regulate the 24 PFAS as a whole at later stage after more robust data are made available, enabling the derivation of science-based standards.