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COMMENT

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Commentary on the EU Commission's proposal for amending the Water Framework Directive, the Groundwater Directive, and the Directive on Environmental Quality Standards

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Abstract

The EU Commission published on the 26th of October 2022 its proposal for amending three central water management Directives, the Water Framework Directive, the Groundwater Directive, and the Directive on Environmental Quality Standards. The proposal introduces a series of amendments and changes to remedy shortcomings that were identified in the previous fitness check of the European water legislation and to align the legal framework with the scientific and technical progress of the last decades. This commentary briefly summarizes and evaluates the new elements that are most relevant from a toxicological and ecotoxicological perspective.

The Commission proposal substantially extends the list of WFD priority substances and now includes 68 substances and substance groups. It also identifies five substances and substance groups as a priority for groundwater management. In several instances, generic sum-EQS values are suggested for selected substance groups, an approach that lacks scientific underpinning and might not always be sufficiently protective. EQS values for substances groups are certainly needed, but are better set using relative potency factors or other implementations of the Concentration Addition concept. The Commission proposal employs this approach for setting groupwise EQS values for PFAS chemicals and PAHs and it should be systematically applied also to other groups of priority substances.

Effect-based methods (EBMs) are now included in the legal text of the WFD, which is highly welcome. However, the Commission proposal limits EBMs to explorative studies and does not include the setting of EQS values based on EBM-methods.

Revising the major legislative frameworks offers opportunities to streamline water pollution management in the spirit of the "one substance, one assessment" idea. Further details on how substance evaluations performed in the context of water management can be harmonized with those performed by EFSA, ECHA and EMA during substance registration and authorization would have been welcome.

Keywords Chemicals Strategy for Sustainability, Chemical regulation, Priority substances, Chemical mixtures

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Introduction

On the 26th of October 2022, the EU Commission released its proposal for modifying three important water management Directives: the Water Framework Directive (WFD, Directive 2000/60 [1]), the Groundwater Directive (GWD, Directive 2006/118/EC [2]), and the Directive on Environmental Quality Standards (EQSD, Directive 2008/105/EC, [3]). The proposed amendments and changes address inadequacies identified in the previous fitness check of European water legislation [4]. The new Commission proposal brings the legal framework in line with advancements in science and technology over the past few decades and is therefore much welcome.

This commentary provides a concise overview and evaluation of the novel aspects that hold the most significance from a toxicological and ecotoxicological standpoint. Unfortunately, the Commission did not publish a background paper that provides the rationale of the proposed changes and the technical details. Not even all the final dossiers on the new environmental quality standards (EQS values) are publicly available at the time of writing (early March 2023). This commentary is therefore based on the text of the proposal itself [5] and its annexes [6].

Priority substances and priority hazardous substances

The aim of all three Directives is the management and mitigation of chemical pollution in European water bodies. The ultimate goal with respect to chemical pollution is to achieve a good chemical and ecological status of European aquatic ecosystems and protect citizen's health. Given the complexity of chemical use and emissions, the Directives focus to a good extend on so-called priority substances. Those are currently defined in Art 2(30) of the WFD, referring to repealed Regulations and Directives that governed the use of biocides, pesticides, and industrial chemicals in previous decades. The Commission proposal now provides a simpler and more generic definition of priority substances as chemicals that "*present a significant risk to or* via *the aquatic environment in a high proportion of Member States*", leaving it open how many water bodies and Member States would qualify as a "high proportion".

"Priority hazardous substances" are priority substances that are also "*marked as 'hazardous' on the basis that they are recognized in scientific reports, in relevant Union legislation, or in relevant international agreements, as being toxic, persistent and liable to bio-accumulate or as giving rise to an equivalent level of concern, where this concern is relevant to the aquatic environment*". The ultimate aim of the WFD is to eliminate priority hazardous substances.

Endocrine activity is not specifically mentioned in the definition of priority hazardous substances. As in the past, it will be possible to consider those characteristics under the heading "equivalent level of concern". However, it would facilitate future prioritization work and political discussions if the definition of priority hazardous substances (Art 1(2c) of the Commission's proposal) would specifically include endocrine disrupting (ED) and PMT/vPvM characteristics (substances that are Persistent, Mobile and Toxic and very Persistent, very Mobile, respectively [7, 8]). Explicitly including those criteria into the definition of priority hazardous substances would bring the text of the WFD in better alignment with the planned amendments of Regulation (EC) No 1272/2008 (Ares(2022)6485391), supporting the implementation of a "one substance, one assessment" strategy.

Some of the priority substances are classified in Annex V of the Commission proposal [6] as "Ubiquitous Persistent, Bioaccumulative and Toxic (uPBT)". However, no definition of the term is provided in the Commission proposal itself, nor seem any consequences foreseen for priority substances with that label.

The first list of 33 surface water priority substances and substance groups was published as Annex II of the EQSD, subsequently updated by Directive 2013/39/EU [9], which comprises 46 substances and substance groups. The Commission proposal now contains a new and updated list with EQS values for 68 substances and substance groups. Alachlor, chlorfenvinphos, and simazine were deselected from the list of EU-wide priority substances and moved to Part C of Annex II (riverbasin-specific pollutants). 23 new substances and two substances groups (pesticides(total) and PFAS) were added and the list of considered PAHs was extended with chrysene, benzo(a)anthracene, and dibenz(a,h)anthracene.

Overall, few EQS values have changed for those substances already included in the list of priority substances in 2013 (Additional file 1: Table S1). The Commission proposal introduces the most notable changes for chlorpyrifos, for which the EQS values are lowered by factors between 40 (EQS for acute exposure in freshwater, MAC-EQS) and 650 (EQS for chronic exposure in marine waters, AA-EQS). The Biota-EQS was substantially reduced for brominated diphenylethers (flame retardants, by a factor of 30) and hexabromocyclododecane (HBCDD, another flame retardant, by a factor of 50) and dioxins (by a factor of 186). For nonylphenol, the AA-EQS for marine ecosystems was reduced by a factor of 167. The EQS was increased most notably for long-term exposure to heptachlor and dicofol in marine ecosystems (AA-EQS), by factors of 17 and 6, respectively.

The initial list of priority compounds for groundwater was provided in Annex I of the GWD which includes only a quality standard (QS) for nitrates (50 mg/L) and a generic QS value for individual pesticides (0.1 µg/L) and the total sum of pesticides (0.5 µg/L). The Commission

proposal keeps those and includes in Annex III an additional 5 QS values for the following groundwater priority pollutants: per- and poly-fluorinated alkyl substances (PFAS, 0,0044 PFOS equivalents, see below), carbamazepine (0.25 µg/L), sulfamethoxazole (0.01 µg/L), a sum-EQS for pharmaceuticals (0.25 µg/L) and a sum-EQS for non-relevant pesticide metabolites (nrMs) (between 0.1 and 0.5 µg/L for the individual nrMs and between 0.5 and 12.5 µg/L for the sum of nrMs).

The generic QS of 0.1 µg/L for individual pesticides in groundwater was established in the 1980's in view of the chemical–analytical sensitivity at the time. However, the performance of analytical methodologies has markedly improved over the course of the past 40 years, thereby rendering a QS value of 0.1 µg/L unjustified. Furthermore, using such a generic QS value means treating the usually well-characterized pesticides as toxicologically and ecotoxicologically unknown chemicals, which violates a basic principle of chemical hazard and risk assessment, i.e., to make the best use of the available data while ensuring an adequate level of protection.

Most importantly, the case does not seem to have been made that a generic value of 0.1 µg/L is sufficiently protective. A more convincing alternative would be to compile acceptable daily intakes (ADIs) or similar health-relevant thresholds from the various EFSA and ECHA assessments in order to estimate the resulting threshold of toxicological concern (TTC). It would better support the notion that a generic threshold of 0.1 µg/L is sufficiently protective for human health if it would be demonstrated that the TTC is $\geq$ 0.1 µg/L. Such a systematic data evaluation would also be another step toward the implementation of the "one substance, one assessment" principle (see below).

The assumption that a generic value of 0.1 µg/L is sufficiently protective becomes even more questionable if one is also concerned about groundwater-living organisms. Currently, we have only a minimal understanding of groundwater ecotoxicology. Quality standards for groundwater bodies should therefore not exceed the corresponding maximum acceptable concentrations for surface freshwater (AA-EQS). However, only 7 of the 33 pesticides included in the list of priority substances have an AA-EQS greater or equal to 0.1 µg/L (Additional file 1: Tables S1 and S2). Of course, some AA-EQS values below 0.1 µg/L are driven by human health concerns (drinking water consumption, seafood consumption), but that simply supports the notion that a generic threshold of 0.1 µg/L needs to be carefully justified.

Secondly, such a generic mass-driven EQS value penalizes pesticides with low (eco)toxicity. Those substances often have a lower efficacy and are used at higher application rates, which might lead to a higher prevalence of concentrations > 0.1 µg/L, which might divert managerial attention away from more toxic pesticides with seemingly less worrisome exposure patterns.

The same arguments are to be made regarding the generic quality standard of 0.25 µg/L for individual pharmaceuticals.

The Commission proposal also assesses the occurrence of non-relevant pesticide metabolites (nrMs) using a generic QS of 0.1, 1, 2.5 or 5 µg/L, depending on the available toxicological and ecotoxicological data (the more data are available, the higher the generic QS). This seems to make only little sense for data-rich nrMs (which qualify for the highest generic QS), for which the data demonstrate high (eco)toxicity. In the end, it remains unclear why the QS for data-rich nrMs is not derived directly from the available empirical data, similar to any other well-characterized chemical.

Assessment of mixtures

The Commission proposal aims to "*improve the monitoring of chemical mixtures to better assess combination effects and take account of seasonal variations in pollutant concentrations;*" This is in line with previous recommendations (e.g., [10–12]). However, mixture assessment is implemented inconsistently for different substance groups.

Reports and reviews unanimously establish Concentration Addition (CA) as a reliable and widely applicable first-tier assessment of mixture (eco)toxicities and risks, as long as the components of the mixture are known, see e.g. [10–14]. CA builds on the notion that substances contribute to a mixture's (eco)toxicity in proportion to their individual concentration and potency. One option to implement CA is by using relative potency factors (RPFs) that scale the concentration of a chemical to the (eco)toxicological potency of a pre-defined index chemical. RPFs are roughly equivalent to toxicity equivalency factors (TEFs) used to assess dioxins and dioxin-like substances [15]).

An appropriate mixture-EQS can be established as the sum of the RPF-adjusted concentrations, an approach that was already applied in the EQSD for dioxins and dioxin-like compounds. The Commission proposal now also includes the RPF-approach for assessing PFAS substances, for which the sum-EQS shall be expressed as PFOA equivalents. A mixture-EQS using the RPF-approach is also set in the Commission proposal for mixtures of (some of) the PAHs. It remains unclear why the PAHs anthracene, fluoranthene and naphthalene are still included as separate entities in the list of priority substances, with separate EQS values.

It is surprising that similar RPF-based mixture-EQS values are not put forward also for the six (xeno-)

estrogens (17ß-estradiol, estrone, 17-ethinyl-estradiol, bisphenol A, octylphenol, nonylphenol), in particular because the EQS for estrone is already based on a simple RPF-based extrapolation from 17ß-estradiol. The same applies to the 5 photosynthesis-inhibiting herbicides (atrazine, diuron, isoproturon, cybutryne, terbutryn) and the 5 neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid, thiamethoxam).

The assessment of mixtures in the Commission proposal also includes generic sum thresholds for pesticides in surface waters and groundwater (0.5 µg/L for the sum of all pesticides), for pharmaceuticals in groundwater (0.25 µg/L for the sum of all pharmaceuticals) and nrMs in groundwater (0.5–12.5 µg/L for the sum of all nRMs, depending on the available (eco)toxicological knowledge). Similar generic sum-QS- or EQS-values are not foreseen for industrial chemicals.

The suggested sum values might be under-protective, depending on the potency of the substances that make up a particular mixture. This is shown in Additional file 1: Table S2, using the suggested generic sum-EQS of 0.5 µg/L for pesticides as an example. Suppose 27 of the 33 pesticides (those with the lowest individual EQS values) would be co-occurring at their individual EQS concentrations. In that case, the concentration of the mixture is 0.48 µg/L, i.e., approximately equal to the suggested sum-EQS of 0.5 µg/L. Under the assumption of a concentration-additive behavior, this concentration is 27 times higher than an appropriate RPF-based mixture-EQS, which is only 0.018 µg/L (at the concentration ratios outlined in Additional file 1: Table S2).

These estimations show that, at the very least, a more detailed mixture toxicity evaluation is needed, before setting generic sum-EQS values for mixtures. It might be worth mentioning in this context that the Commission's Research Centre (JRC) has already published empirical data that show that individual EQS values do not always provide sufficient protection against mixture toxicities [16].

The use of generic sum-values also unfairly penalizes compounds with a low (eco)toxicity that might occur in higher environmental concentrations if they are, for example, used as pesticides with likely higher application rates. The overall concentration of a mixture is irrelevant. It is the overall (eco)toxicity and risk that matters. And concentrations are simply no suitable surrogate, in view of the vast differences in toxicity and ecotoxicity of the involved substances.

The suggested generic sum-QS values for pesticides and nrMs in groundwater are also higher than the generic QS values for the individual substances, for which no rationale is provided. For example, even under the assumption that 0.1 µg/L is a generally adequate QS for an individual pesticide in groundwater (but see discussion above), a sum-QS of 0.5 µg/L would be inadequate if a largely additive behavior of the mixture is assumed. Under this condition, the mixture-QS must correspond to an average of the individual QS values, assuming that an equal level of protection is to be achieved for individual substances and mixtures.

As mentioned earlier, there is widespread agreement that the use of relative potency factors, which is an operationalization of the broader concept of Concentration Addition, is an appropriate approach for assessing mixture toxicities in general, which can be accompanied, if needed and feasible, by specific mixture considerations [10, 12–14]. This allows for a mixture assessment that encompasses all priority substances. Given that EQS values are available for all individual priority substances, it would be straightforward to include a provision to calculate the EQS of the mixture of all priority substances, based on relative potencies as:

$$EQS_{Mixture} = \left(\sum_{i=1}^{n} \frac{p_i}{EQS_i} \right)^{-1} = EQS_{index} \times \left(\sum_{i=1}^{n} (p_i \times RPF_i) \right)^{-1},$$

where EQS_{index} is the EQS of the index chemical, EQS_i denotes the individual EQS values of substances *1,…,i*, RPF_i denotes the relative potency factor for substance *i* (with higher RPF values indicating a higher (eco)toxicological potential, i.e., a lower individual EQS) and p_i denotes the corresponding fraction in the mixture, i.e., $\sum_{i=1}^{n} p_i = 1$.

The chemical status assessment of a water body would then be based on an assessment on whether the mixture concentration exceeds EQS_{mixture}, for every compartment/protection goal (pelagic, benthic, biota, human health via the consumption of drinking water, human health via the consumption of seafood) and exposure condition (annual average, maximum acceptable concentration). Achieving mixture concentrations below EQS_{mixture} would constitute a successful implementation of the toxic-free ambition in the Zero Pollution Action Plan ("Air, water and soil pollution is reduced to levels no longer considered harmful to health and natural ecosystems"). Mixture concentrations exceeding EQS_{mixture} would warrant either more in-depth mixture risk assessments or risk mitigation efforts.

Riverbasin-specific pollutants

Riverbasin-specific pollutants (RBSPs) do not factor into the chemical status assessment of a water body

under the current WFD. Instead, RBSPs are part of the ecological status assessment. The Commission proposal now includes RBSPs as an element of the chemical status assessment. This eliminates a logical inconsistency of the previous version of the WFD and is therefore much welcome.

Watchlist mechanism

Art 8 of the EQSD provides for the so-called "watch list" of substances for which EU-wide monitoring data are to be gathered to provide adequate data for possible future inclusion in the list of priority substances. The watch list was updated in a sequence of implementing decisions by the Commission, first in 2015 [17], then in 2018 [18], 2020 [19], and again in 2022 [20]. These monitoring activities identified several new priority substances, but not all substances initially included in a watchlist gave reasons for EU-wide concern. The watchlist mechanism indeed seems to function as a filter for identifying new priority substances.

This mechanism is now extended to groundwater and a new article 6a is inserted into the GWD, implementing a watchlist also for chemicals in groundwater. The Commission proposal suggests limiting the number of chemicals on the watchlist to a maximum 10 and 5 for surface water and groundwater, respectively. This implies a considerable reduction of the current surface water watchlist, which currently lists 26 substances [20]. No details are provided on how this reduction will be implemented.

The proposal does not yet provide suggestions for specific substances to be included in future watchlists, which will be put forward in future Implementing Decisions by the Commission. What is specifically mentioned in the Commission proposal is that antimicrobial resistance genes and micro/nanoplastic are to be included as soon as adequate monitoring methods are at hand.

It has been repeatedly pointed out that, in order to understand co-occurrence patterns, chemical monitoring studies must become more "mixture aware" [12, 21]. The current requirement to monitor the 10 fungicides on the 2022 watchlist as group can be considered a first step towards this goal. A similar requirement should be rolled out for all priority substances and the chemicals on the watch list, as far as technically feasible and practically useful.

Effect-based methods

Currently, EQS values are expressed as concentration values, which implies that the monitoring of European water bodies for chemical pollution and status assessment is performed exclusively by chemical–analytical methods. Given the limitations of this approach (the necessary focus on few selected chemicals, high costs, and resource requirements, the struggle to achieve sufficiently low detection and quantification limits for some of the priority substances), it has been repeatedly suggested to complement or even replace these techniques with effect-based methods (EBMs), e.g. [22, 23]. EBMs use a suite of biological assays that are applied in order to get a more realistic picture of chemical pollution. If EBMs apply specific endpoints, such as the binding to and/or activation of the estrogen receptor, their specificity is similar to chemical–analytical techniques. If EBMs apply more apical endpoints such as the inhibition of respiration or growth, a more holistic view of the toxicant load in a water body is obtained.

The Commission proposal now reacts to the published recommendations. As a first step, the proposal suggests amending Art 8a of the WFD to "*require Member States to carry out effect-based monitoring to assess the presence of estrogenic hormones in water bodies, in view of possible future setting of effect-based trigger values*". The use of EBMs for characterizing the estrogenicity in various water types has been successfully demonstrated in published studies, e.g. [24, 25], and it is not clear what the Commission hopes to gain from yet another data collection exercise. The inclusion of EBMs in the monitoring work under the WFD would certainly improve our understanding of the pollution situation in European water bodies and would provide tools for an improved water management—but only if EBMS are actually used for setting EQS values.

It should be pointed out in this context, that the use of RPFs (see above) is not limited to the use of substance concentrations, but can equally well be applied to the results from EBM data or to a combination of substance concentration values and EBM data.

It should not go unnoticed that also other groups of priority substances, such as the photosynthesis-inhibiting herbicides, could be well assessed using EBMs.

One substance one assessment

The link between EQS values and the chemical safety assessments conducted in the Regulations for industrial chemicals (REACH, CLP), pesticides (PPP Regulation) biocides (BPR) and pharmaceuticals (Regulation on Human Pharmaceuticals, Regulation on Veterinary Pharmaceuticals) needs to be strengthened. In view of the professed aim to harmonize substance assessments, the use of generic EQS values (see above) for well-characterized substances, such as pesticides, is particularly puzzling.

It is also interesting to note that the fourth major water-related Directive, i.e., the Drinking Water Directive 2020/2184 (DWD [26]), is not taken into account in the Commission's proposal, although the EQS values

developed under the WFD and EQSD specifically consider impacts on human health via the consumption of drinking water. The principal approaches and methods for the setting of QS values for drinking water should be harmonized with the approaches used in the WFD, EQSD and GWD, in order to further move towards "one substance, one assessment".

Updating the list of priority substances and the compounds on the watchlist by using delegated acts could accelerate the process and make it less cumbersome. This argument is employed, together with the "one substance one assessment" argument, as a rationale to move future work on priority substances and the setting of EQS values to the European Chemicals Agency (ECHA). It is beyond this paper to comment on the specific pros and cons of different institutional arrangements. But it should be emphasized that it will remain crucial to keep an element of independent scientific expertise in the process of assessing substances that are a priority for EU-wide pollution management, as currently provided by the opinions and reviews of the Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

Supplementary Information

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Additional file 1: **Table S1**. Comparison of EQS values for the priority substances listed in the EQS-Directive 2013/39/EU and in the Commission proposal for the revision of the WFD, GWD and EQSD. **Table 2**. Mixture risk calculation.

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