EEB response to SCHEER Preliminary Opinion on Groundwater quality standards for proposed additional 11 pollutants in the annexes to the Groundwater Directive 12 (2006/118/EC)

Brussels 8 February

Relationship between quality standards for surface waters and groundwater

Groundwater ecosystems are more vulnerable to stressors than many other freshwater ecosystems due to slower biological and physical degradation processes (resulting from the lack of sunlight and slower metabolic rates of subterranean fauna) together with longer residence times for water.[1] This results in prolonged exposure times for groundwater flora and fauna due to longer persistence of chemicals.

Given the great difficulty to restore contaminated groundwater bodies, as well as indications that groundwater ecosystems are less resilient to stressors, they need to be treated with a corresponding level of care.

We agree with the SCHEER opinion that groundwater quality standards (QS) should not exceed the concentrations put forward as quality standards for surface waters. However, in lines 32-34 the position of SCHEER is stated to be that freshwater EQS can be applied to groundwater until new scientific data is available. We don't agree with this approach and recommend SCHEER to take a more precautionary approach.

The European Medical Agency (EMA) already applies such a precautionary approach in their guidance to assessing environmental and human health risk of veterinary medical products (VMP) in groundwater.[2] EMA points out that "groundwater ecosystem are fundamentally different and therefore may be more vulnerable than surface water ecosystems as they lack the ability to recover from perturbations." With regards to this vulnerability, EMA recommends a precautionary approach **and to use a factor of 10 (lower) when extrapolating PNEC for surface water to PNEC groundwater**, i.e. one order of magnitude lower thresholds for groundwater ecosystems than for surface waters.

SCHEER recognises that the Water Framework Directive (WFD) and the Groundwater Directive (GWD) have as a main aim to prevent groundwater pollution with the aim to ensure protection of drinking water sources and dependent ecosystems. SCHEER also mentions that "there might be good reasons to go below surface water QS values, in particular for PMT / vPvM compounds, antibiotics and chemicals with insecticidal properties". **We therefore recommend SCHEER to reconsider their**

[1] EMA 2018, Assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater EMA/CVMP/ERA/103555/2015

[2] EMA, 2018, Assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater EMA/CVMP/ERA/103555/2015

opinion and to recommend that groundwater quality standards are set more stringent than surface water EQS (per default).

Inclusion in Annex I or Annex II

We welcome the recommendation from SCHEER to set uniform EU-wide quality standards for groundwater bodies for chemicals with no natural background concentrations, such as PFAS, pharmaceuticals and nRM.

Mixtures

Setting individual standards, based on the effect of a specific substance working on its own, while important for the tracing and trends of specific substances, does not reflect the impacts of chemical mixtures.

We recommend considering the Mixture Assessment Factor (MAF) concept that has been developed for REACH[3] and see how it could be integrated in the setting of surface water EQS and groundwater quality standards. The MAF concept includes a factor of 10 to take into account mixture effects of different chemicals and another factor 10 to account for different exposure sources. In short, a factor 100 in the derivation of Derived No-Effect Level (DNEL)/PNEC under REACH.

PFAS

- SCHEER does not agree with group Quality Standards for PFAS (0.50 µg/L)
    - but recommends individual standards of 4.4 ng/L for PFOA equivalents.

On the proposed approach based on relative potency factors (RPF): The approach proposed by the SCHEER presents two difficulties:

- Establishing RPFs for all homologues;
- Assuming *similar toxicokinetic properties, accumulation and long half-lives in humans*.[4]

Therefore, it appears recommendable to assume similar potencies for all homologues by default, which can be fine-tuned to RPFs were specific data are available, and taking into account toxicity for the different endpoints.

On the proposed set of PFAS to be monitored:

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[3] For more details see NGO comments on CA/MS/47/2020 Synthesis paper for CARACAL provided by KEMI and the Netherlands "Comments on a pragmatic procedure to regulate the risks of exposure to coincidental combinations of chemicals, in the EU"

[4] This is the wording used in the JRC report (Niegowska et al. 2021) to justify the RPF approach across PFOS, PFHxS, PFOA and PFNA. This is a valid assumption for this group of four substances of rather similar chain lengths, but it may not be extended to extreme chain lengths, nor across endpoints. A striking example of unexpected potency behaviour in a less-studied endpoint can be found in Rosenmai *et al.* (2017), https://doi.org/10.1002/jat.3515.

It is not clear to us which the 24 PFAS that SCHEER is referring to but assumes that SCHEER means the 22 PFAS candidates for surface water EQS. If this is the case, we think the list should be completed with C6O4, 6:2 FTS.

SCHEER correctly points out (p. 14, line 7) that analytical standard methods exist and are broadly deployed, although capacity building in member states will be beneficial. Strangely, in line 15, SCHEER then recommends that "further development of analytical methodologies" be initiated – although the methods are already available. Analytical standards (i.e. the certified high purity samples allowing for precise quantification of the analytes) for potential other PFAS are also generally available, or can be made available relatively quickly.

We recommend reviewing the proposed list as following:

- Exclude longest homologues (such as ≥ C11 for PFCAs and ≥ C10 for PFSAs), because of
    - Lower environmental relevance (partitioning into sediment)
    - Lower potential to take action (mostly legacy pollution, if any)
    - Poor solubility, resulting in adsorption to experimental apparatus, and hence poor quantification
    - Poor solubility of the standards, leading to the use of solvents, which in turn lowers analytical resolution of the shortest homologues
- Include relevant PFAS that are not PFCAs nor PFSAs, and that are used industrially, such as C6O4 (EC 682-239-6), 6:2 FTS (EC 248-580-6), on top of GenX and ADONA.

Pharmaceuticals including Carbamazepine and Sulfamethoxazole

- SCHEER does not agree with group Quality Standards for pharmaceuticals (0.5 µg/L)
    - but recommends individual standards for carbamazepine (0.5 µg/L) and sulfamethoxazole (0.1 µg/L)

Granted that hundreds of pharmaceuticals have been detected in groundwater, we find it much too restrictive to only set EU quality standards for two pharmaceuticals and it would not provide adequate protection (to human health and dependent ecosystems). SCHEER in its response also lists a number of pharmaceuticals of concern that can be present in groundwater including cancer chemotherapy drugs (**antineoplastics)** for where there is no safe level of exposure for pregnant women, and the **antibiotics** azithromycin, clarithromycin and erythromycin as well as chloramphenicol and fidaxomycin, that are a concern for groundwater wildlife as well as for antimicrobial resistance.

SCHEER wants to avoid a scenario where a good quality groundwater becomes bad quality surface water just because it leaves the ground. By setting quality standards for only two pharmaceuticals we are moving into precisely such a scenario as the European Commission is considering setting an EQS for three antibiotics for surface water (azithromycin, clarithromycin and erythromycin), either as a group or as individual substances.

We therefore support the option proposed by SCHEER to generate limits for sub-classes of similar pharmaceutical groups, such as **anti-neoplastics**, **endocrine disrupters** and **antibiotics**.

Non relevant metabolites of pesticides

- SCHEER does not agree with group Quality Standards for non-relevant metabolites (nRM) (10 µg/L)
    - but recommends individual standards of 0.1 µg/L for nRM

We support the suggestion from SCHEER to expand the existing individual value for active substances in pesticides, including their relevant metabolites, degradation and reaction products to include also nRM. Therefore, we also welcome the opinion from SCHEER that the nRM should not be limited to the 16 nRM identified by the CIS WG GW but should be flexible to apply to also other nRM identified.

However, the 0.1 µg/L threshold for individual substances was introduced in the GWD as a general threshold value for contaminants. It reflected at the time the detection limit for substances and was therefore regarded as a measure of no emissions into groundwater. Since then, analytical techniques have developed and it is now possible to detect lower concentrations. The ongoing revision of quality standards should therefore include a revision of this value.