

Scientific Committee on Health, Environmental and Emerging Risks

(SCHEER)

Request for a scientific opinion: on groundwater quality standards for proposed additional pollutants in the annexes to the Groundwater Directive (2006/118/EC).

European Commission Department requesting the Opinion: Directorate-General for Environment, Unit C1

1. Background

Groundwater as a resource

Groundwater (GW) constitutes the largest reservoir of freshwater in the world, is a valuable resource for drinking water, irrigation in agriculture and industry and has an increasing environmental value. It provides a base flow for surface water systems, feeds wetlands and river flows, and acts as a buffer through dry periods.

The combination of a wide range of pressures arising from human activity and the longer residence times of groundwater in the subsurface can result in long-term contamination and risks to environmental and human health. Pollution that occurred decades ago - whether from agriculture, industry or other human activities - may still threaten GW quality today and, in some cases, will continue to do so for decades to come. GW policy and legislation in the EU therefore emphasise the need to prevent contamination and deterioration of GW quality. In addition, new and emerging pollutants are detected in GW nearly everywhere, and pose a risk to this source.

Legislative framework and updates

As required by Water Framework Directive¹ (WFD) Article 17, the Groundwater Directive² (GWD), as a WFD ‘daughter directive’, has as its main focus the prevention and control of groundwater pollution, with a view to ensuring the protection of drinking water sources and dependent ecosystems³. The GWD clarifies the criteria for good chemical status of groundwater and provides **EU-wide GW quality standards for nitrates and pesticides** (individual and total, in **Annex I**). It also requires Member States (MS) to set their own **threshold values** and apply them for all other pollutants that put groundwater bodies at risk of failing to meet good chemical status, taking into account identified pressures and the minimum lists of pollutants in **Annex II**.

The GWD Annex II was revised in 2014⁴. The amendments included adding principles for the determination of natural background levels (an important factor behind the variation in threshold values between MS), and nitrites and phosphorus (total)/phosphates to the minimum list of pollutants for MS to consider when setting threshold values. This revision also acknowledged the need to establish a **voluntary watch list mechanism** to increase monitoring and knowledge of substances posing a potential risk to groundwater (including emerging pollutants).

¹ [Directive 2000/60/EC](#) of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1–73.

² [Directive 2006/118/EC](#) of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJ L 372, 27.12.2006, p. 19–31.

³ In this context, when risks from pollutants are difficult to deal with, where scientific information is not yet fully complete, conclusive, or certain, the precautionary principle should be considered. “*Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, but that scientific evaluation does not allow the risk to be determined with sufficient certainty.*” COM (2000) 1 final (<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF>).

⁴ By [Commission Directive 2014/80/EU](#) of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration.

Although the GW Watch List (GWWL) mechanism is voluntary, substances identified through it as posing a relevant risk should be considered for inclusion in Annex I or Annex II to the GWD; some might require additional monitoring before a decision is made.

As a result of recent work using data reported by MS on a voluntary basis, several substances have been identified for possible inclusion in Annex I or II of the GWD⁵ and the GWWL⁶, and prioritised on the basis of a methodology defined in a concept paper⁷ (acknowledged by EU Water Directors). The prioritisation process used to rank substances for the GWWL is based on (i) groundwater monitoring data (i.e. occurrence in EU MS GW), (ii) theoretical environmental exposure, mobility and persistence and (iii) toxicity, i.e. the relative risk they pose in the groundwater environment (Lapworth et al. 2019⁸).

As indicated in Article 10 of the GWD, the Commission is under the legal obligation to regularly review the lists of pollutants in Annexes I and II. The need to review them was confirmed by the results of the recent Fitness Check (evaluation) of the water legislation⁹. The Fitness Check concluded that the covered water directives were broadly fit for purpose, but it also concluded that there was some room for improvement to tackle chemical pollution, confirmed the need to reflect the latest scientific insights, and highlighted the need to consider additional pollutants of emerging concern, such as **pharmaceuticals** and **PFAS**¹⁰. In addition, the GWWL technical work has allowed gathering data on non-relevant metabolites (nrMs) of pesticides, which will be considered in the review of the GWD annexes.

The Commission is currently working on an **Impact Assessment**¹¹ to support legislative proposals regarding the lists of groundwater pollutants. The Commission has recently launched a study to quantify the costs and benefits (economic, social and environmental; direct and indirect) of the most relevant policy options. The Commission plans to publish the Impact Assessment study by the end of 2021, and table legislative proposals in 2022.

For this process, it is essential to have a **scientific expert opinion on quality standards for the pollutants (or groups of pollutants) to be proposed for inclusion in Annex I to the GWD**, and on the possible alternative inclusion of those pollutants in Annex II.

⁵ First 'List facilitating' for the GWD annexes review (2 pharmaceuticals and 10 PFAS) (2019). [https://circabc.europa.eu/sd/a/b746af1-3169-4135-95ec-312a4359676f/First%20List%20facilitating%20Annex%20I%20and%20II%20review%20process%20of%20the%20Groundwater%20Directive%20\(Endorsed%20V2.1%20-June%202019\).pdf](https://circabc.europa.eu/sd/a/b746af1-3169-4135-95ec-312a4359676f/First%20List%20facilitating%20Annex%20I%20and%20II%20review%20process%20of%20the%20Groundwater%20Directive%20(Endorsed%20V2.1%20-June%202019).pdf)

⁶ First voluntary groundwater watch list (2 PFAS and 9 pharmaceuticals) (2019). [https://circabc.europa.eu/sd/a/e6882891-d4a2-4a64-9cf7-f04e13b0d17e/Voluntary%20Groundwater%20Watch%20List%20\(Endorsed%20V3.1%20-%20June%202019\).pdf](https://circabc.europa.eu/sd/a/e6882891-d4a2-4a64-9cf7-f04e13b0d17e/Voluntary%20Groundwater%20Watch%20List%20(Endorsed%20V3.1%20-%20June%202019).pdf)

⁷ Concept paper describing the methodology for the watch list and facilitating a list for the annexes review (2018). Voluntary Groundwater Watch List Concept and Methodology. Technical Report. https://circabc.europa.eu/sd/a/d3fa0178-0134-4316-a11c-dcfd71efca69/Watch-List_Concept_Final.pdf

⁸ Lapworth et al. Environ. Res. Lett. 14 (2019) 035004. *Developing a groundwater watch list for substances of emerging concern: a European perspective*. <https://doi.org/10.1088/1748-9326/aaf4d7>

⁹ [https://ec.europa.eu/environment/water/fitness-check-of-the-eu-water-legislation/documents/Water%20Fitness%20Check%20-%20SWD\(2019\)439%20-%20web.pdf](https://ec.europa.eu/environment/water/fitness-check-of-the-eu-water-legislation/documents/Water%20Fitness%20Check%20-%20SWD(2019)439%20-%20web.pdf)

¹⁰ PFAS have recently been included in the Drinking Water Directive Recast, <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1519210589057&uri=CELEX:52017PC0753>, PFOS is already subject to a quality standard in surface waters <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:3A02008L0105-20130913>, and this might soon be broadened to cover PFAS. Also, the new Chemicals Strategy <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf> includes an Action Plan on PFAS promising further action.

¹¹ Inception impact assessment, Revision of lists of pollutants affecting surface and groundwaters. Roadmap available at: <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12662-Revision-of-lists-of-pollutants-affecting-surface-and-groundwater>

2. Terms of reference

The SCHEER is requested to provide scientific advice on the quality standards for substances that could be proposed for inclusion in Annex I to the GWD. In particular, quality standards might be established for certain PFAS, pharmaceuticals and nrMs found in GW (as described in the Appendix to this mandate). More specifically, the SCHEER is asked to express its opinion on the following points:

- Would the quality standard proposed for **10 PFAS** provide adequate protection (to human health and dependent ecosystems) from those PFAS if applied to groundwater? (The value is linked to that for 20 PFAS in the Drinking Water Directive (DWD) Recast¹²). If not, what value would the SCHEER propose, taking into account the DWD Recast and the findings of the GWWL PFAS report, and the risk from individual PFAS¹³?
- Following WHO recommendations and to seek coherence with the approach in the DWD recast, which includes a limit of 0.5 µg/l for PFAS total, does the SCHEER consider enough scientific basis to propose the same quality standard at EU level for **total PFAS**¹⁴ in Groundwater for comparison with the relevant measured concentration total?
- Would the quality standards proposed for the two individual pharmaceuticals (Carbamazepine, Sulfamethoxazole) provide adequate protection (to human health and dependent ecosystems) if applied to groundwater? (values based on quality standards work for these substances in surface waters¹⁵). If not, what values would the SCHEER propose?
- In the opinion of the SCHEER, which scientific criteria could the Commission use to propose a quality standard at EU level for all pharmaceuticals (i.e. addressing pharmaceuticals as a group of substances) or for subgroups of pharmaceuticals (e.g. human and veterinary pharmaceuticals, pharmaceuticals with particular modes of action), for comparison with the relevant concentration total? In the light of the findings of the report from the GWWL experts on pharmaceuticals in GW and the risk from individual pharmaceuticals¹⁶, does the SCHEER consider enough scientific basis to propose a group total quality standard?
- Would the proposed uniform quality standard(s) for individual nrMs and for total nrMs provide adequate protection (to human health and dependent ecosystems) if applied to groundwater in relation to the 16 listed nrMs (and possibly others)?

The proposed approach is analogous to the current approach in the GWD and DWD to “pesticides”, and takes into account the range of values established by MS and the magnitude of certain values mentioned in the guidance on establishing relevance of metabolites in groundwater

¹² There is a very high correlation between PFAS listed in the DWD Recast and data collected on PFAS in GW. The voluntary GWWL mechanism collected information on 16 out of the 20 PFAS listed in the DWD Recast. (Out of these 16, 2 are currently on the GWWL and 10 on the list facilitating the review of the GWD annexes). The 4 substances from the DWD Recast for which data were not collected in the GWWL are sulfonic components of PFAS. In general, the percentage of detection for sulfonic acids is (significantly) lower than for the acid component.

¹³ Pilot exercise on PFAS -Per- and Polyfluoroalkyl substances. Specific report (2020) describing the exercise- with replies from 18 countries, 11 of which are monitoring PFAS. <https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/3f6900fe-107c-4551-bb13-393c9d9f600d/details>

¹⁴ ‘Total PFAS’ meaning the totality of per- and polyfluoroalkyl substances detected with available analytical methods and monitoring guidelines. The Commission should establish by 2024 technical guidelines regarding methods of analysis for monitoring PFAS total in drinking water, including detection limits, parametric values and frequency of sampling. These guidelines could be considered for groundwater.

¹⁵ JRC Technical report. Selection of substances for the 3rd Watch List under the Water Framework Directive, 2020. <https://ec.europa.eu/jrc/en/publication/selection-substances-3rd-watch-list-under-water-framework-directive>

¹⁶ Pilot exercise on pharmaceuticals with results from 12 participating countries (2016). <https://circabc.europa.eu/d/a/workspace/SpacesStore/a1e23792-6ecd-4b34-b86c-dcb6f1c7ad1c/1600204%20Pharm%20Pilot%20Study.docx>

(Sanco, 2003¹⁷), although that guidance recommends a case-by-case approach. The SCHEER is asked to take into account: relevant data from the assessment of individual substances performed in the context of Regulation (EC) No 1107/2009, the reasons underpinning the limit values already established by MS, relevant literature on the nrMs listed, and on others, as well as any relevant surface water quality standards and the Technical Guidance Document on Deriving EQS for pollutants in surface waters¹⁸.

- The SCHEER is also asked to provide a scientific view on whether the “uniform standard” approach is appropriate, and on whether the appropriateness of a uniform group standard would depend upon whether the group is limited to the 16 listed nrMs. It might wish to consider involving the European Food Safety Authority (EFSA)¹⁹ where necessary to ensure coherence and harmonisation in the spirit of the ‘one substance, one assessment’ approach as outlined in the EU Chemicals Strategy²⁰, bearing in mind that the approach supports a gradual move away from assessing and regulating chemicals substance-by-substance to regulating them as groups.
- In the opinion of the SCHEER, and given the existing data and reports as well as geographical and geological differences in MS, would it be more scientifically justified to include any of the proposed PFAS, pharmaceuticals or nrMs in Annex II instead of Annex I? i.e. would it be more appropriate for MS to set threshold values at national, river-basin-district (RBD) or water-body level to take account of variability in their presence/relevance, or differences in hydrological settings and aquifer types? In answering this question, it would be helpful if the Committee could consider the intention of the legislator to achieve where possible a level playing field regarding quality standards, the inter-comparability of results, and uniform implementation across the EU.

3. Deadline:

Preliminary opinion: by the end of summer 2021

Final opinion: end of 2021

¹⁷ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/221/2000 –rev.10- final. 25 February 2003.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr.pdf

¹⁸ CIS Guidance No27, Deriving environmental quality standards <https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/ba6810cd-e611-4f72-9902-f0d8867a2a6b/details>

¹⁹ The EFSA pesticides site: <https://www.efsa.europa.eu/en/topics/topic/pesticides>; European Commission pesticides database:

²⁰ Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>