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WK 13864/2023 INIT

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INFORMATION

From:	General Secretariat of the Council
To:	Working Party on the Environment
N° prev. doc.:	WK 13498 2023 INIT
N° Cion doc.:	14265/22 + ADD 1
Subject:	Priority Substances in Water: Follow-up to the VTC of the members of the WPE on 25 October 2023 – Presentation from the Commission and Call for Comments

Delegations will find attached the presentation from the Commission displayed at the VTC of the members of the WPE on 25 October 2023.

Delegations are kindly requested to send any additional drafting suggestions, in track changes, on the compromise text proposals in relation to the Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (WK 13498 2023) to the Presidency [REDACTED];

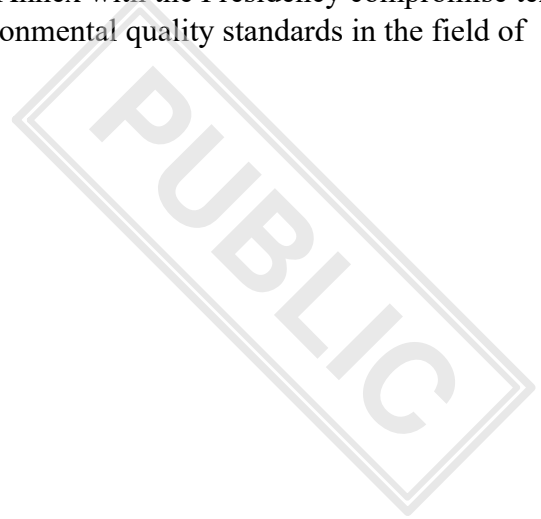
[REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED] and the Commission ([REDACTED]), with copy to the Council's Secretariat [REDACTED] and [REDACTED] by Thursday, 9 November, cob.

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The Presidency would also like to inform delegations that the next VTC of the members of the WPE on the Priority Substances in Water Directive will take place on 22 November 2023. Ahead of this meeting, the Presidency will distribute a steering note containing an Annex with the Presidency compromise text proposals in relation to the Directive 2008/105/EC on environmental quality standards in the field of water policy.





Integrated water management

WPE (VTC): Proposal of a Directive amending WFD, GWD and EQSD

Art. 2, Annexes III and IV amending Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (GWD)



25 October 2023



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Questions on the GWD

- 60 questions
- 6 clusters

Frequently asked questions



Commission observations



Deadlines

- The deadline for compliance is Dec 2033. Where compliance cannot be reached it is possible for MS to apply Art 4(5).



Reporting

- Monitoring data obtained for the WL should be reported in accordance with the proposed provision on annual reporting of monitoring and status data under Art 8(4) WFD;
- For certain aspects of WL monitoring, more frequent reporting might be useful, e.g. for pesticides;
- For WL monitoring, the EEA can at any moment 'receive' monitoring data from the MS.
- Reporting details are to be set out in an implementing act (under Art 8(4) and/or under WL provisions).



Watch List

- ECHA will play a major role in identifying WL substances and assessing monitoring results and developing scientific reports,
- Scientific reports will be discussed with stakeholders and the EC, in the context of the Common Implementation Strategy (CIS);
- Discussions would take place in the WG Groundwater, the WG Chemicals and related sub-groups throughout the three-year period,
- Groundwater watchlist is foreseen to use the same mechanisms with same stakeholder involvement as the surface water watch lists.

Commission observations

PFAS

- QS for the sum of 24 PFAS included in the proposal is based on the latest scientific information and most recent EFSA opinion from 2021 ([Risk to human health related to the presence of perfluoroalkyl substances in food | EFSA \(europa.eu\)](https://www.efsa.europa.eu/en/press/news/21-05-2021)). It is calculated from the maximum Tolerable Weekly Intake (TWI) of PFAS for human health through drinking water and food.
- For surface water the SCHEER endorsed the proposed EQS_{dw, hh} of 4.4 ng/L (PFOA equivalents) for the sum of 24 PFAS and recommended to use the same value for protecting groundwater.
- The EFSA 2021 opinion, also endorsed by the SCHEER in its opinions, was not available at the time of the adoption of the recast Drinking Water Directive (DWD).
- The DWD recast is thus **not** in line with the latest scientific evidence.
- The COM proposal for the recast DWD, originally included 16 PFAS. During the negotiations, 4 other PFAS were added (PFNS, PFUnS, PFDoS and PFTrS), though without a clear understanding of the scientific basis for doing so.
- Those 4 PFAS are not included in the group of 24 specific PFAS proposed for the EQSD and GWD for that reason, but the 16 that were originally proposed for inclusion in the DWD are.
- The listed 24-PFAS are those that are so far most found in surface waters.
- The SCHEER endorsed consideration of combined exposure to PFAS (e.g., in drinking water, food, air, consumer products, and waste) as a basis to set regulatory limits.



Commission observations



Pharmaceuticals

- **QS for Carbamazepine (anticonvulsant):** The SCHEER concluded a QS of 0.5 µg/l (for human toxicity) was not sufficiently protective. In line with EMA's approach for pharmaceuticals an AF of 10 was applied to the 2.5 µg/l EQS (for ecotoxicity) resulting in a QS of 0.25 µg/l.
- **QS for Sulfamethoxazole (antibiotic):** The SCHEER also concluded a QS of 0.1 µg/l was not sufficiently protective and to avoid the spread of antibiotic resistance, as for Carbamazepine, an AF of 10 was applied resulting in a QS of 0.01 µg/l.
- **QS Pharmaceutical active substances total:** The SCHEER concluded that a total standard of 0.5 µg/l for all pharmaceuticals is not sufficiently protective. But, applying an AF of 10 would go below the 0.25 µg/l proposed for carbamazepine, therefore the same value of 0.25 µg/l was set.
- **Specified list of pharmaceuticals for the sum of all pharmaceuticals:**
 - Thousands of active pharmaceutical ingredients are registered worldwide, and new ones are constantly being developed.
 - The most found Active Pharmaceutical Ingredients (APIs) and their occurrence levels vary per country
 - Listing all APIs would take a lot of time and the list would have to be updated constantly.
- **Primidone:** Included in Annex II (substances for which Member States shall consider setting national threshold values) as data collected by WG GW were insufficient to indicate an EU-wide threat but supported the inclusion of primidone in Annex II.
Note: Primidone must still be included in the assessment of compliance with the total pharmaceuticals QS of 0.25 µg/l in Annex I.

Commission observations



nrMs

- The SCHEER recommended using a quality standard of 0.1 µg/L as a benchmark to which an additional AF, as a precautionary requirement, should be applied to protect groundwater ecosystems
- The European Parliament proposed to set a standard of 0.1 µg/L for individual nrMs and 0.5 µg/L for total nrMs.
- There is no legally binding definition of nrMs at present, only of relevant metabolites.
- nrMs should be identified based on the technical Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Regulation (EC) No 1107/2009 (https://food.ec.europa.eu/document/download/918bd971-a1c1-4eeb-9885-eb5df074b31d_en).
- There are currently no plans to create an EU list of nrMs, but the possibility could be explored.

Thank you

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