EPMF Position Paper

13 April 2023

Comments on the prioritisation of silver under the Water Framework Directive and derivation of freshwater EQS

In accordance with the relevant legislation, only "substances found to pose a significant risk" should be considered for inclusion on the Priority Substances list. **There is clear scientific evidence that silver poses low or no risk to or via the aquatic environment**:

- The STE score is the agreed methodology developed by JRC and various stakeholders for the monitoring-based prioritization, which exploits the inherent variability of measurements in the monitoring dataset, and evaluates the Spatial, Temporal and Extent of PNEC exceedances (STE) in order to rank and classify the substances for the risk they pose to European surface waters (see Carvalho et al. 2016). In the EQS dossier for silver (available at https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/fae4948d-3600-42cc-889c-0b58a4a94269/details), JRC has concluded that based on the available monitoring data the revised STE score for silver is 0.9 (rather than 2.2 as originally proposed in Carvalho et al. 2016). In accordance with JRC's own guidance on selecting candidate substances for scrutiny for final prioritisation, the criterion for shortlisting candidate priority substances based on risk classification is an STE score ≥ 1.8 and substances with an STE score < 1.2 - as is the case for silver - are to be considered "low risk".
- It should be noted that the above revised STE score was still calculated on the basis of an overly conservative approach, both in terms of the PNEC/EQS used (see also further below and Arijs et al. 2021 for a scientifically based derivation of a threshold value for silver) as in terms of the assessment of the available monitoring data (see Merrington et al. 2022 and Arijs et al. 2022).
- The study by Arijs et al. 2022 concludes that:
    - the available silver freshwater monitoring data sets need careful assessment to account for the values that are below the limit of quantification (LOQ);
    - silver does not pose a risk to the freshwater environment in those countries where a meaningful data assessment is possible because of sufficiently low LOQs: France, Germany, Norway, Poland, and the Netherlands;
    - reliable evidence is lacking to demonstrate a European-wide risk for silver in the aquatic environment;
    - speciation modeling of silver at conservative as well as environmentally relevant concentrations of sulfide and dissolved organic carbon conditions shows that silver in freshwater is mainly present in precipitated form, with dissolved silver concentrations being low (<0.5%).

In conclusion, robust scientific and technical data prove that there are insufficient grounds for silver to be added as Priority Substance. Selecting priority substances for which risk has not been demonstrated means that Member States will waste valuable time and resources on their routine measurement while bringing no benefit to the aquatic environment.

In their Position Paper on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive", the SCHEER also took the view that "*a rationale underlying the selection of the various substances as priority hazardous substances or the deselection of others would have been beneficial*".

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The selection of silver has not been based purely on risk (as mentioned in the WFD and as agreed during the prioritisation exercise) but also on a **concern related to anti-microbial resistance (AMR)** which was only discussed very briefly in the silver EQS dossier. This concern has been insufficiently investigated for silver and there is no evidence that silver can actually induce AMR at the extremely low concentrations found in the environment. Further research on AMR will be launched with ETAP (Environment Toxicity Advisory Panel) in 2023 during a 1.5 year project. The aim of the project conducted by the KULeuven and the University of Copenhagen, is to see if metals (including silver) can contribute to, or in itself lead to, the development of AMR. If so, it will be investigated under which conditions this will appear, and at what concentrations. Based on the current reasoning for prioritisation of substances, this information will be paramount for future change in the EQS/prioritisation. It is worth to note that this work will only consider published literature, and a recommendation will be given for further testing (if needed).

While there are some inconsistencies in the Impact Assessment report related to silver, it is mentioned that the environmental benefits of adding silver as a Priority Substance are small, while costs are high, meaning the **costs outweigh the benefits of addition**. However, AMR has subsequently been used as a criterion to justify the addition of silver.

The proposed EQS of 10 ng/l is overly conservative and not scientifically justified. The available chronic freshwater dataset for silver contains data on 16 test species in 12 taxonomic groups, which is more than the requirements set out in the ECHA / WFD guidance to apply a probabilistic approach using the lower 5th percentile (HC05) of a Species Sensitivity Distribution (SSD) to which an assessment factor is applied. Therefore, use of the deterministic approach (leading to an EQS of 10 ng/L) should not be further considered for silver. Moreover, the dataset includes data for cyanobacteria, which were considered to be particularly sensitive to silver (due to the anti-microbial properties of silver ions).

A peer-reviewed publication on the chronic freshwater dataset for silver and the scientifically correct threshold is available (Arijs et al., 2021). It should be noted that EPMF has recently further updated its chronic freshwater dataset for silver by adding ecotoxicity data from a recent study, resulting in a freshwater PNEC of 46 ng/L.

In their Position Paper, the SCHEER also pointed out that "*The TGD stipulates the most reliable extrapolation method be used from:*

- *the deterministic approach in which a specific assessment factor is applied to the lowest credible EC50 or NOEC value; or*
- *the probabilistic approach using the lower 5% percentile of a species sensitivity distribution (SSD) to which an assessment factor is applied; or*
- *the results from model ecosystem (e.g., mesocosms) and field studies.*"

In addition, for the estimation of probabilistic EQS values (HC05 estimation), the SCHEER also recommends applying more modern approaches for the SSD calculation than just the log-normal function, where at least several models should be comparatively fit to the data at hand and the best-fitting (based on Akaike Information Criteria) should then be selected for the final HC05-estimation. This approach has been applied in Arijs et al., 2021.

From the available silver monitoring data, it is clear that freshwater silver concentrations are very low and typically below (or very close to) limits of quantification (LOQ). Methods of analytical determination should be compliant with the technical specification for chemical analysis set out by the European Commission for water quality monitoring (EC 2009), which requires a method to have an LOQ of equal to or below a value of 30% of the relevant EQS. Given the very low EQS currently proposed for silver,

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it is anticipated that several countries will encounter practical problems to monitor silver at these low (analytically challenging) concentrations.

In the measured environmental concentrations (MEC) section in the EQS dossier for silver, the range of LOQs for non-quantified samples is reported (see Figure 6.3.1). This shows that the majority of the reported silver monitoring data are measured with analytical methods that do not have a sufficiently low LOQ (i.e. are not sufficiently sensitive) to allow a proper comparison with the proposed EQS: less than 20% of the non-quantified samples were reported with an LOQ below the (overconservative) proposed EQS of 10 ng/L. Some countries even report LOQs > 100 * proposed EQS.

Dissolved silver data have successfully been generated in the past using more sensitive analytical techniques. As an example: Peters et al. (2011) reported a 6-month monitoring programme in rivers and effluents from 84 sites across England and Wales, covering a wide range of aquatic systems with potential exposures to silver, and included aquatic systems downstream from silver users. For this study, ICP-MS was used, and an updated protocol was developed to allow a low level detection of dissolved silver concentrations (Limit of Detection (LOD) of 2.2 ng/L and LOQ of 6.6 ng/L). This shows that it is possible to measure low dissolved silver levels but specific analytical techniques are needed. This study further concluded that the concentrations of dissolved silver are low: about 80% of all samples from the 84 sites had dissolved silver concentrations below 6 ng/l and none of the sites had mean dissolved silver concentrations that exceeded 40 ng/l. The mean of the maximum dissolved silver concentrations reported at each site (reflected as the regional background concentration and calculated according to REACH guidance) was calculated as 6 ng/l (dissolved silver).

Additional evidence of silver concentrations in the aquatic compartment, measured at appropriate LOQs can be found in the open literature (e.g. Wen et al. 2002; Johnson et al. 2014). In this respect, and as further supporting evidence on typical background ranges of silver in aquatic systems, we would like to refer to Reimann and Birke (2010), who reported a median and 75th percentile of dissolved silver concentration in bottled waters below the LOD of 2 ng/l, and to Salminen et al. (2005), who report a 95th percentile for dissolved silver concentration in European surface waters of about 10 ng/l.

In their Position Paper, the SCHEER also identified several issues with the evaluation of environmental concentrations in the EQS dossiers, a.o.:

- "*The underlying empirical monitoring data are not provided as part of the dossier. In some cases, the basic information on the sample characteristics (spatial distribution, seasonality, proximity to contamination sources, etc.) is not made available. This renders an assessment of data quality, reliability and relevance impossible*".
- "*In many cases, the data originate from only a small number of EU MSs, with more than 70% based on two or three countries. These data are not sufficient to allow conclusions to be drawn on EU-wide exposures and risks.*" In the MEC section in the EQS dossier for silver, the risk assessment is based on monitoring data from 9 MSs. However, 67% of the dataset comes from only two countries. In contrast, The study by Arijs et al. 2022 concludes that silver does not pose a risk to the freshwater environment in five countries where a meaningful data assessment is possible.
- "*Concentration values are often below the analytical limits of detection and quantification (LODs and LOQs), even sometimes up to 90% of the data are below the LOQs and LODs.*" This is also the case for silver: in the MEC section in the EQS dossier for silver, 93% of the data are unquantified (see Table 6.3.3).

Overall, we want to emphasise the precious metals industry's commitment to achieving a good ecological and chemical status of EU waters and to keeping improving the assessment of risk posed by metals in waters through the most updated scientific knowledge and methods.

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ABOUT THE EPMF

Since 2007, the European Precious Metals Federation has supported European companies working with gold, silver, rhenium, and the six metals referred to as the Platinum Group including platinum, palladium, osmium, rhodium, ruthenium, and iridium.

Our 35 Member Companies and 3 national associations include world leaders in extraction, refining, and recycling of precious metals. They also include a highly diverse range of companies involved in consumer and industrial applications that touch the lives of European citizens from jewelry to financial investments to the mobile phones in their pockets to the catalytic converters in their vehicles to the solar panels and rapid chargers at their homes.

As the European body for advocacy, the EPMF facilitates the interface between policy makers, regulatory authorities, and the precious metals industry on a wide range of issues.

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