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Implications for the sediment compartment of the Proposal for a Directive amending the Water Framework Directive, the Groundwater Directive and the Environmental Quality Standards directive with special focus on the proposed EQS for sediments for Priority Substance No. 30 Tributyltin.

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Summary

In this document, the direct and potential implications to sediments of the "proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy" are summarised. According to the first proposal for EQS for sediments included in the EQSD, which refers to Tributyltin, the derivation process for the proposed value of 1.3 µg/kg d.w. as presented in the corresponding data sheet are reviewed. Final personal considerations according to expert judgement are provided.

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Background

The Environmental Quality Standards (EQS) directive 2008/105/ EC (EC 2008) for priority substances was an important improvement for long-term water quality monitoring at the European level under the Water Framework Directive (WFD: EC 2000). However, until recently, the only mandatory requirement by the European Directives (EC 2000, 2008) for sediment and biota quality was that contamination levels should not increase significantly in the long-term (i.e., stand-still criterion).

In Directive 2013/39/EU (hence-forth, EQS directive: EC, 2013), by amending Directives 2000/60/EC and 2008/105/EC regarding priority substances in the field of water policy, it was established that EQS for priority substances in sediment and/or biota are required in water quality monitoring programs:

"Art. 4. For substances for which an EQS for sediment and/or biota is applied, Member States shall monitor the substance in the relevant matrix at least once every year, unless technical knowledge and expert judgment justify another interval."

"Art. 6. Member States shall arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota, giving particular consideration to the substances numbered 2, 5, 6, 7, 12, 15, 16, 17, 18, 20, 21, 26, 28, 30, 34, 35, 36, 37, 43 and 44 listed in Part A of Annex I, on the basis of the monitoring of surface water status carried out in accordance with Article 8 of Directive 2000/60/EC. Member States shall take measures aimed at ensuring, subject to Article 4 of Directive 2000/60/EC, that such concentrations do not significantly increase in sediment and/or relevant biota. Member States shall determine the frequency of monitoring in sediment and/or biota so as to provide sufficient data for a reliable long-term trend analysis. As a guideline, monitoring should take place every three years, unless technical knowledge and expert judgment justify another interval."

Tributyltin compounds (including tributyltin-cation (CAS 36643-28-4)) were included in Annex I ('X) as **No 30** entry in the list of priority substances in the field of water policy and identified as priority hazardous substance. EQS were included in Annex II for surface waters (Table 1). The value of the EQS for surface waters was so low that implementation of the EQS was problematic due to analytical issues. No EQS was included for biota or sediments in Annex II.

Table 1

No	Name of substance	CAS number (1)	AA-EQS (2) Inland surface waters (3)	AA-EQS (2) Other surface waters	MAC-EQS (4) Inland surface waters (3)	MAC-EQS (4) Other surface waters	EQS Biota (5)
(30)	Tributyltin compounds (Tributyltin cation)	36643-28-4	0.0002 µg/L	0.0002 µg/L	0.0015 µg/L	0.0015 µg/L	

(1) CAS: Chemical Abstracts Service. (2) This parameter is the EQS expressed as an annual average value (AA-EQS). Unless otherwise specified, it applies to the total concentration of all isomers. (3) Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies. (4) This parameter is the EQS expressed as a maximum allowable concentration (MAC-EQS). (5) Unless otherwise indicated, the biota EQS relate to fish. An alternative biota taxon, or another matrix, may be monitored instead, as long as the EQS applied provides an equivalent level of protection.

The EQSs for Tributyltin compounds (Tributyltin cation) were proposed on the grounds of the "Environmental Quality Standards (EQS) Substance Data Sheet Priority Substance No. 30 Tributyltin compounds (TBT-ion) CAS-No. 688-73-3 (36643-28-4). Final version Brussels, 15 January 2005" (EC 2005).

In the 2005 EQS Substance Data Sheet was stated that, based on K_{oc} values between approximately 320 and more than 1,500,000 resulting in log Kp_{susp} values between 1.5 and 5.2, "the trigger for the derivation of a sediment quality standard is met, although not unequivocally." Nevertheless, a $PNEC_{sediment}$ (≈ $QS_{sediment}$) of 0.0046 µg/kg (wet weight) corresponding to 0.02 µg/kg (dry weight) was calculated using the equilibrium partitioning (EP) method. This method is proposed in the absence of toxicity data for sediment dwelling organisms. "*The values derived by the EP-method should only be considered as tentative standards. In order to refine the quality standards for the sediment compartment long term tests conducted with benthic organisms are required. For the time being no reliable effects based* $QS_{sediment}$ *can be derived*."

As stated in the disclaimer of the data sheet, the derivation follows the standard methodologies foreseen in the EU Technical Guidance Document for EQS derivation, it has been discussed with experts in the field and it has been reviewed and approved by an appointed scientific committee. A review process is foreseen in *Art. 16(4) of the Water Framework Directive*, in which new technical and scientific information is evaluated and implemented if deemed necessary.

Proposal for amendments

In the 26.10.2022 COM(2022) 540 final 2022/0344 (COD), Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy, following Art. 8 of the EQSD requiring the Commission to review Annex X to the WFD (the list of priority substances) (EC 2022a), two proposed modifications have direct and potential implications to sediments:

- Former *'Article 3 Environmental quality standards, Paragraph 1 :*

1. Without prejudice to paragraph 1a, Member States shall apply the EQS laid down in Part A of Annex I for bodies of surface water, and shall apply those EQS in accordance with the requirements laid down in Part B of Annex I.

1a. Without prejudice to the obligations arising under this Directive in the version in force on 13 January 2009 and in particular the achievement of good surface water chemical status in relation to the substances and the EQS listed therein, Member States shall implement the EQS laid down in Part A of Annex I as regards:

(i) the substances numbered 2, 5, 15, 20, 22, 23, 28 in Part A of Annex I, for which revised EQS are set, with effect from 22 December 2015, with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2021 by means of programmes of measures included in the 2015 river basin management plans produced in accordance with Article 13(7) of Directive 2000/60/EC; and

(ii) the newly identified substances numbered 34 to 45 in Part A of Annex I, with effect from 22 December 2018, with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2027 and preventing deterioration in the chemical status of surface water bodies in relation to those substances. For this purpose, Member States shall, by 22 December 2018, establish and submit to the Commission a supplementary monitoring programme and a preliminary programme of measures covering those substances. A final programme of measures in accordance with Article 11 of Directive 2000/60/EC shall be established by 22 December 2021 and shall be implemented and made fully operational as soon as possible after that date and not later than 22 December 2024

The following paragraph is added:

*'(iii) the substances numbered 5, 9, 13, 15, 17, 21, 23, 24, 28, **30**, 34, 37, 41, 44 in Part A of Annex I, for which **revised EQS are set**, and the newly identified substances numbered 46 to 70 in Part A of Annex I, with effect from … [OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Directive], with the aim of preventing deterioration in the chemical status of surface water bodies and of achieving good surface water chemical status in relation to those substances.';*

- Former *'Article 3 Environmental quality standards, Paragraph 2 :*

2. For the substances numbered 5, 15, 16, 17, 21, 28, 34, 35, 37, 43 and 44 in Part A of Annex I, Member States shall apply the biota EQS laid down in Part A of Annex I.

For substances other than those referred to in the first subparagraph, Member States shall apply the water EQS laid down in Part A of Annex I.

Substituted by:

*2. With regard to substances for which a biota EQS or a sediment EQS is laid down in Part A of Annex I, Member States shall apply such biota EQS or **sediment EQS**.*

With regard to substances other than those referred to in the first subparagraph, Member States shall apply the water EQS laid down in Part A of Annex I.'

Potential implications for sediments:
For tributyltin, it is assumed in the impact assessment (EC 2022b) that the amendment of existing EQS is to more stringent EQS. However, the change is not a more stringent EQS but the introduction of an EQS for sediment that is set at 1.3 µg/kg dry weight. According to Art.3 Parag. 2, this sediment EQS shall be applied. TO NOTE: the proposed sediment EQS is subject to confirmation in the light of the opinion requested from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

A detailed review of the EQS data sheet is included below.

The Impact Assessment Report accompanying the proposal (EC 2022b) includes the following relevant information on the issue:

- Tributyltin is, together with mercury, nickel, industrial chemicals PBDEs, PAHs (incl. Fluoranthene) and Nonylphenol, among the top 15 most frequently reported priority substances causing failure to achieve good chemical status in surface water bodies and therefore remain highly relevant (1988 water bodies from 18 different member states have reported EQS exceedances, with a range of measured concentrations of 0.261 (0-100) µg/L (mean(min-max)).

- The proposed policy option for tributyltin is to revise the EQS where necessary based on new scientific data. The benefits of an EQS amendment outweigh the costs.

- According to the existing EQS, the current distance to target[1] is large in scale and medium in magnitude. An increase in distance to target is expected for the newly proposed EQS but the

[1] 'Distance to target' refers to the size of the gap between the baseline situation and the target considered within the policy option. The 'distance to target' assessment followed a two-step process:

1) the substances considered under each option were assigned to groups (large / medium / small) based on the predicted geographic scale (i.e. how many water bodies might fail chemical status; how many MS might need to take measures) and the magnitude (i.e. how far above the thresholds do concentrations rise) of the current gap. The general criteria for these groupings:
    - Small: predicted exceedances in ≤33% of MS; mean monitored concentrations ≥0 and ≤33% over the new QS.

overall distance to target is medium. For these substances only limited or no additional measures are expected. TO NOTE: it is stated that the distance to target is assessed based on data from JRC substance dossiers submitted to the SCHEER. However, the update data sheet for this substance (EC 2022c) does not include monitoring data.

- According to existing regulatory framework and use/emissions (ban as biocide in anti-fouling paint applied to commercial vessels, pleasure craft and mariculture equipment; diffuse sources from past uses. EQSD, GWD, DWD, International Convention on the Control of Harmful Anti-fouling Systems on Ships), the emissions reduction is estimated at 10-30%, mainly driven by the EQSD.

- The environmental impact of the newly proposed EQS: updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.

- Economic impact:

Cost: the proposed EQS is more stringent for biota. Given use has ceased. Likely measures include upgrade of WWTWs and natural attenuation. The costs of the former will be captured by the revised UWWT Directive. NOTE: there are inconsistencies in that the proposed EQS is derived for sediment, not biota. It is not more stringent, but newly introduced.

Benefit: avoided health costs for aquaculture and ecosystem services.

- Social impact: no specific social impacts identified.

- Overall balance: on the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferable.

- It is noted that the legislation currently provides member states with a period of time to comply with the newly listed substances and the modified TVs, going beyond the 2027 deadline for achieving good chemical status set in the WFD. For revised surface water EQS this additional time was set at 6 years (2021, plus 12 more years in case of technical infeasibility or disproportionate cost).

- Former '*Article 3 Environmental quality standards, Paragraph 6 :*

"6. Member States shall arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota, giving particular consideration to the substances numbered 2, 5, 6, 7, 12, 15, 16, 17, 18, 20, 21, 26, 28, 30, 34, 35, 36, 37, 43 and 44 listed in Part A of Annex I, on the basis of the monitoring of surface water status carried out in accordance with Article 8 of Directive 2000/60/EC. Member States shall take measures aimed at ensuring, subject to Article 4 of Directive 2000/60/EC, that such concentrations do not significantly increase in sediment and/or relevant biota."

Substitute by:

'Member States shall arrange for the long-term trend analysis of concentrations of those priority substances identified in Part A of Annex I as substances that tend to accumulate in sediment and/or biota, ***on the basis of monitoring in sediment or biota*** *as part of the monitoring of*

- Medium: predicted exceedances in >33 and ≤66% of MS; mean monitored concentrations >33 and ≤66% over the new QS.
- Large: predicted exceedances in >66% of MS; mean monitored concentrations >66% over the new QS.

2) The baseline situation is taken into consideration. For substances for which an amendment of the EQS is proposed, the baseline situation is represented by the current gap between concentrations measured in surface water and existing EQS, whereas the target is the new scientifically recommended EQS.

surface water status carried out in accordance with Article 8 of Directive 2000/60/EC. Member States shall take measures aimed at ensuring, subject to Article 4 of Directive 2000/60/EC, that such concentrations do not significantly increase in sediment and/or relevant biota.'

Potential implications for sediments:

In total, 20 substances other than TBT are identified as substance that tends to accumulate in sediment and/or biota and for which Member States shall arrange for monitoring in sediment or biota: Anthracene, Cadmium and its compounds, C10-13 Chloroalkanes, Chlorpyrifos, DEHP, Hexachlorocyclohexane, Isoproturon, Lead and its compounds, Pentachlorobenzene, Quinoxyfen, Cypermethrin, Azythromycin, Bifenthrin, Chlarithromycin, Deltamethrin, Diclofenac, Erythromycin, Esfenvalerate, Ibuprofen and Permethrin.

For none of these other substances EQS for either sediment or biota are proposed.

It is assumed that it will be a choice of Member States in which matrix monitoring will be carried out.

The Impact Assessment Report accompanying the proposal (EC 2022b) mentions sediments 12 times, one referring to the presence of microplastics in EU rivers and lakes (p. 23), the potential increase of concentrations of pharmaceuticals from wastewater in sediment among other environmental compartments (p. 24), the accumulation of silver (p. 28) and nano silver (p. 52), and on the potential use of dredging for the removal of substances bound to sediments in waterbodies, which can be relatively cheap or very costly, depending on the level of after treatment required" (p. 56).

In addition, the environmental benefits of the proposed amendments include: "Cleaner sediments should result in less potential for re-dissolution of pollutants in the water column and reduced uptake of harmful substances by plants and animals." The economic benefit "Cleaner sediment negating the need for remediation or dredging. This recognises that a number of the candidate substances are less soluble and likely to concentrate within suspended solids, and then within sediments and biota in the natural environment."

Critical review of the Tributyltin EQS draft dossier 2022 prepared by the JRC (EC 2022c) and accompanying documents.

The following documents have been considered:

EC (2005). Environmental Quality Standards (EQS) Substance Data Sheet. Priority Substance No. 30. Tributyltin compounds (TBT-ion) CAS-No. 688-73-3 (36643-28-4). Final Version of 15.01.2005. Brussels (BE).

EC (2022). Environmental Quality Standards (EQS) Substance Data Sheet Priority Substance No. 30 Tributyltin compounds (TBT-ion) CAS-No. 688-73-3 (36643-28-4). Final version Brussels, 15 January 2005. Revised 14 June 2022. Brussels (BE)[2].

SCHEER (2023). Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" Tributyltin Compounds. Final Opinion adopted on 9 March 2023[2].

Comments on draft EQS dossier on Tributyltin 14.06.2022[2].

[2] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/61475d52-e234-48c6-a52d-eb98bfba5897?p=1&n=10&sort=modified_DESC Last accessed 26.04.2023

Van Herwijnen R. (2012). Environmental risk limits for organotin Compounds. RIVM report 607711009/2012. Available on-line at: https://www.rivm.nl/bibliotheek/rapporten/607711009.pdf

Danish Environmental Protection Agency (2021). Fastsættelse af kvalitetskriterier for vandmiljøet TBT (Tributyltin-kation) CAS nr. 36643-28-4. Available on-line at: https://mst.dk/media/229173/tbt_36643-28-4.pdf

S. Sahlin & M. Ågerstrand (2018). Tributyltin – TBT. Sediment EQS derivation. ACES report number 29. Department of Environmental Science and Analytical Chemistry, Stockholm University. Available on-line at: FULLTEXT01.pdf (diva-portal.se)

The review carried out in 2022 for the Tributyltin EQS dossier mainly addressed 1) the addition of recent legislation to Section 2, and 2) the update of section 8.2 on the derivation of a $QS_{sediment}$ using the most recent literature and following the most recent review of the Guidance Document No: 27 Technical Guidance Document For Deriving Environmental Quality Standards (EU TGD, EC 2018).

Here only section 8.2 and relevant information for $QS_{sediment}$ derivation are reviewed.

Criteria triggering the derivation of $QS_{sediment}$

According to the EU TGD (EC 2018), substances require an assessment for a sediment standard if the organic carbon adsorption coefficient (K_{OC}) if Log K_{OC} or Log K_{OW} ≥ 3. In addition, evidence of high toxicity to aquatic organisms or sediment-dwelling organisms or evidence of accumulation in sediments from monitoring would also trigger derivation of a sediment EQS.

While the 2005 TBT dossier (EC 2005) included a range of K_{oc} and Kp_{susp} values, concluding the derivation of a sediment quality standard was triggered "although not unequivocally", the 2022 review includes additional sorption coefficients to sediments from more recent studies summarised in the RIVM Report "Environmental risk limits for organotin compounds" (Van Herwijnen 2012). RIVM report includes an average Log K_{OC} of 4.5 of 33 values. RIVM additionally assessed the quality of the studies from which the Log K_{OC} were retrieved taking into consideration that the Log K_{OC} is critical in the derivation of $QS_{sediment}$ using the Equilibrium Partitioning approach. The outcome of the quality assessment is documented in Appendix 1 of Van Herwijnen (2012). The SCHEER agrees that enough evidence is available for tributyltin compounds to require a sediment assessment based on lipophilicity (Log K_{OW} > 3) and sorption to sediment (Log K_{OC} 2.5-6.2). *This conclusion seems supported by the evidence in the reviewed data sheet (EC 2022c). The reliability of the K_{OC} has not been further assessed in the context of this review.*

Effect data collection

The *quality (reliability and relevance)* of the effect data collection has been assessed in the reviewed data sheet (EC 2022c) through an appropriate method for assessing aquatic ecotoxicological data for regulatory use (the in-house developed JRC Literature Evaluation Tool (LET) based on the CRED evaluation method (EC 2018)). A quality class which establishes the suitability of each effect data entry for EQS derivation is attributed to each entry.

The EC 2022 dossier summarises the effect data collection in the Appendix, and a summary table is included with valid effect data for EQS derivation. It is noted that many of the studies have several limitations and departures from standard test protocols that compromise to a certain extent their reliability (e.g. reduced number of test concentrations). This is important for all entries in the data collection, but particularly important for the critical study which forms the basis of the EQS derivation using the deterministic approach. In the case of the critical datum used for the sediment EQS derivation (Duft et al. 2003), the publication does not report information on negative toxicity control performance to assess whether reproduction was appropriate for healthy

organisms. Additionally, the reproductive effect endpoint is expressed as percentage of solvent control response, no raw data is available to assess the response in negative controls. Expert judgement plays a key role in quality assessments of ecotoxicological data and it could be argued whether these limitations and/or missing information are critically compromising the quality of studies/endpoints used in EQS derivation. However, there is agreement in the outcome of the quality assessment between the EC 2022 dossier and the dossiers prepared by Denmark and Sweden, the three concluding that the study is suitable for EQS derivation. Nevertheless, for the sake of transparency, further information should be included referring to the overall quality of the effect data collection (e.g. as in the Swedish report).

Pooling marine and freshwater effect data

The effect dataset for freshwater includes chronic sediment toxicity data for five species belonging to four taxonomic groups: crustaceans, insects, molluscs and annelid worms (note that *Tubifex tubifex* is a freshwater worm, not a marine species). The effect dataset for marine waters includes effect data for four species belonging to four taxonomic groups: crustaceans, annelids, echinoderms and higher plants. According to the EU TGD (EC 2018), freshwater and marine data can be combined to derive both freshwater and saltwater QSs if there is no statistical difference among the fresh and marine data collections. If the data set is too small to judge statistical difference, then by default the data should be pooled. For the derivation of the TBT EQS the marine and freshwater data sets have been pooled, but it is not clearly stated under which grounds pooling was supported.

SCHEER does not support pooling of freshwater and marine data, according to the EC 2022 statement in p. 17 that “marine species are less sensitive than freshwater species. It should be highlighted that due to a higher salinity and pH, the bioavailability of tributyltin in marine waters is reduced compared to freshwaters, resulting in fewer free cations in the marine environment [39].” However, the Danish EQS derivation pooled freshwater and saltwater effect data based on absence of significant statistical differences. This point should be further addressed and clarified, because if pooling is accepted, the SSD approach may be used for EQS derivation.

Derivation of $QS_{sediment}$ using the deterministic approach

As noted above, the critical datum used in EQS derivation using the deterministic approach presents a number of limitations. Although the same critical study is used for EQS derived by Sweden and Denmark, these limitations should be mentioned.

Regarding the selection of the Assessment Factor to apply, as highlighted by SCHEER at least three long-term tests with species representing different living and feeding conditions are available for freshwater and saltwater separately. An AF of 10 should be applied to the lowest credible effect datum.

Derivation of $QS_{sediment}$ using the probabilistic approach

SCHEER does not support the use of the probabilistic approach for EQS derivation because pooling of freshwater and marine effect data is not justified, while Denmark pooled data based on statistical considerations and used the probabilistic approach. The use of the probabilistic approach for EQS derivation is triggered by accepting to pool freshwater and marine effect data, therefore this point should be further addressed. If the probabilistic approach is used only for comparison purposes, it should be clearly stated.

It is also recommended to use different symbols in the Species Sensitivity Distribution in Fig. 8.2 for different taxonomic groups and for freshwater and saltwater and taxonomic groups. This would help assessing how freshwater data compare to marine organisms in terms of sensitivity. Nevertheless, the Danish report includes this differentiation, not pointing to a significant

overrepresentation of freshwater data in the lower range (in agreement with the absence of statistical differences in the marine and freshwater data sets).

It is noted from Fig. 8.2 that the that the Species Sensitivity Distribution also shows some limitations, as it is not fitting the sensitive data very good, the HC5 divided by the AF 5 is lower than the lowest endpoint divided by 10.

Field and mesocosm data

The EC 2022 dossier includes a section summarising the results of a microcosm study. The summary should conclude with a clear statement of whether the study is useful for EQS derivation or not. It is assumed that the study cannot be used for EQS derivation. However, it may provide supportive information on the sensitivity of nematodes, a taxonomic group not included in the effect data collection. This could be more clearly stated.

Additionally, Sweden reports on field data from a study on snails imposex at marinas and OSPAR data that could be potentially useful in sediment EQS derivation. These reports could not be located and reviewed, but the threshold for effects appears to be close to the proposed sediment EQS. These data should have been included in the EC 2022 data sheet, given the restrictions in the quality of the effect data set.

Proposed sediment EQS

The different $QS_{sediment}$ values for protecting benthic species for each derivation method included in the EU TGD (EC 2018) are summarized in the table below. According to the EU TGD for EQS derivation, the most reliable extrapolation method for each substance should be used. In all cases, data from spiked sediment toxicity tests are preferred over the EP approach.

While Denmark proposed their SKK (in Danish acronym) according to the $QS_{sed,SSD}$ at 1.3 µg/kg d.w. and this was endorsed by HELCOM, Sweden proposes a sediment EQS at 1.6 µg/kg d.w. from the $QS_{sed,AF}$.

	Freshwater µg/kg d.w. 5% OC (AF)	Marine µg/kg d.w. 5% OC (AF)
$QS_{sed,SSD}$ [a]	1.3 (5)	
$QS_{sed,AF}$	1.6 (10)	1.6 (10)
Field effect threshold [7] [b]		2
$QS_{sediment,EqP}$ (from EC 2005) [c]	0.02	
$QS_{sediment,EqP}$ (from SE report) [b]	0.4	

[a] The use of the probabilistic approach would only be possible after justification that merging freshwater and saltwater effect data is possible.

[b] Used as supportive information, for comparison purposes.

[c] Tentative value. Derivation method differs from EU TGD 2018.

It is noted that the AF applied for the derivation of the QS_{sed} in the deterministic approach is the lowest to be applied in the deterministic approach according to the EU TGD (EC 2018), when at least three different taxonomic groups are included in the long-term effect data collection and if the species tested likely include the most sensitive taxonomic group. For TBT, crustacean molluscs appear as the most sensitive group and drive the EQS derivation (critical datum). As stated above, several limitations have been identified for the critical study used in the derivation. If this study is disqualified for EQS derivation, an extra AF should be applied to account for the absence of effect data from the most sensitive taxonomic group. In that case, an AF of at least 50 would be recommended, which would likely lead to a similar level of QS_{sed} being proposed.

Some limitations to the application of the probabilistic approach have been also identified, questioning the use of this approach for the derivation of the proposed EQS.

Despite the different limitations highlighted above for each of the individual derivation methods, all conveyed into a QS_{sed} at the level of the proposed EQS (weight of evidence). In this sense, the QS_{sed} can be considered robust. According to SCHEER, higher uncertainty is attributed for the marine environment. The use of field data from marine observations should support the proposed sediment EQS.

Even if the difference between 1.3 and 1.6 µg/kg d.w. seems marginal, the setting of the field threshold at 2 µg/kg d.w. indicates that measured concentrations are likely within this range, and the proposal of a sediment EQS value at 1.3 or 1.6 µg/kg d.w. may make a big difference.

How bioavailability is addressed in the EQS derivation and implementation

Whereas bioavailability has been addressed to some extent by normalizing effect concentration and the proposed EQS sediment to 5 % OC, there are indications in the EC 2022 dossier and the Danish dossier that other factors such as pH and salinity have an impact on TBT bioavailability in sediments, in particular in saltwater. A specific section addressing bioavailability and associated modifying factors should have been included in the data sheet. This would have also supported any further normalization of effect data to account for differences in the sensitivity, e.g. for salinity.

Additionally, a short comment on whether normalization for the OC should be performed or not for the implementation of the proposed EQS is needed.

Some personal reflections

According to the points highlighted above, the data sheet for tributyltin would benefit from an additional review and update for including additional information and clarifications. This seems particularly important for a data sheet supporting the derivation of the first sediment EQS proposed within the EQSD. In addition to the points above, it is noted that the data sheet does not provide monitoring data for comparison with the reviewed EQS, which is cited in the Impact Assessment Report (EC 2022b).

It is clearly stated in the proposal for amendment of EQS (EC 2022a) that the proposed value of 1.3 µg/kg d.w. (5% TOC) is yet to be confirmed in the light of the opinion requested from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). Changes after the SCHEER opinion will either increase to 1.6 µg/kg d.w. the proposed EQS (value derived using the deterministic approach, the probabilistic approach was not endorsed by SCHEER), or even the sediment EQS for marine waters will be labelled as preliminary as proposed by the SCHEER because it is grounded on effect data for the most sensitive taxonomic group but for a freshwater organism, likely more sensitive than marine counterparts.

Regarding the first possibility, if one of the objectives of the proposal for amendment is the harmonisation of EQS among member states, it is likely that the sediment EQS will be aligned with the proposal for Sweden endorsed by OSPAR on a trial basis, which is set at 1.6 µg/kg d.w., or with Denmark, also endorsed by HELCOM, set at 1.3 µg/kg d.w.

Regarding the labelling of the proposed sediment EQS for marine waters as preliminary, it is not clear how a preliminary EQS can be included in the EQSD and the implications of that labelling for its implementation remain unclear. As stated in the EU TGD (EC 2018), sediment standards allow the assessment of good status alongside standards for other compartments. However, a simple pass/fail criteria approach is not always appropriate, especially when residual uncertainties in sediment standards are high, making compliance assessment difficult. In such cases, a tiered assessment framework is recommended for formal assessment of compliance using sediment EQSs. A first tier would use conservative sediment EQSs, followed by a more detailed assessment accounting for bioavailability or biological effects assessment when sediment EQS are not

met. Such tiered approach uses evidence to corroborate any risks indicated by exceedances of the sediment EQS before decisions to take remedial measures are set. More detailed information/guidance on how such tiered approach could/should be implemented for sediment assessments within the implementation of the WFD should be provided (e.g., as provided for the bioavailability correction of metal EQSs in a technical document, with validated methods). This may be relevant for TBT but also for other substances from the list of 20 labelled as tending to accumulate in sediment and/or biota and for which Member States may arrange for monitoring in sediment.

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