Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive"

Tributyltin Compounds

The SCHEER adopted this document
during its plenary meeting on 9 March 2023

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All Declarations of Working Group members are available at the following webpage:
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ABSTRACT

The dossier on Environmental Quality Standards for "tributyltin" is reviewed by the SCHEER according to the general mandate on EQS dossiers.

For TBT, the request to the SCHEER was limited to scrutinizing the QS for benthic organisms. The SCHEER does not endorse the suggested value of 0.3 µg TBT kg_{dw}^{-1} for $QS_{sediment,fw,eco}$, which is calculated by applying an AF of 50 to the lowest experimental toxicity value of 15.8 µg kg_{dw}^{-1}. Instead, the SCHEER calculates a rounded value of **1.6 µg TBT kg_{dw}^{-1} for $QS_{sediment,fw,eco}$**, by applying an AF of 10, according to the TGD. The SCHEER endorses the value of **1.6 µg TBT kg_{dw}^{-1} also as $QS_{sediment,sw,eco}$**, but considers this value preliminary until marine data for the most sensitive taxonomic group (sediment-dwelling molluscs) are available.

Marine and freshwater test systems differ in their sensitivity, likely due to a lower bioavailability of TBT in marine sediments. This prohibits the pooling of marine and freshwater data for the purpose of estimating a joint SSD. As the individual data collections for marine and freshwater organisms, respectively, are insufficient for an SSD estimation, the SCHEER is of the opinion that currently no probabilistic QS values can be derived for TBT in sediments. The most critical EQS value for sediments is the deterministic value of **1.6 µg TBT kg_{dw}^{-1}** for $QS_{sediment,fw,eco}$ as well as $QS_{sediment,sw,eco}$. In line with the mandate, no further comparison was drawn with other QS values.

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1. BACKGROUND

Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify Priority Substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (EQS) for those substances in water, sediment and/or biota. In 2001, a first list of 33 Priority Substances was adopted (Decision 2455/2001) and in 2008, the EQS for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). WFD Article 16 requires the Commission to periodically review the list. The first review led to a Commission proposal in 2011, resulting in the adoption of a revised list in 2013 containing an additional 12 Priority Substances. Technical work to support a second review has been underway for some time, and several substances have been identified as possible candidate Priority Substances. The Commission will be drafting a legislative proposal, with the aim of presenting it to the Council and the Parliament sometime around mid-2022.

The technical work has been supported by the Working Group (WG) Chemicals under the Common Implementation Strategy for the WFD. The WG is chaired by DG Environment and consists of experts from Member States, EFTA countries, candidate countries and several European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.).

Experts nominated by WG Members (operating as individual substance Expert Groups and through the Sub-Group on Review of Priority Substances, SG-R) have been deriving EQS for the possible candidate substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in others there is disagreement about one or other component of the draft dossier.

The EQS for a number of existing priority substances are currently also being revised. The EQS derivation has been carried out in accordance with the Technical Guidance Document on Deriving EQS (TGD-EQS) reviewed by the SCHEER.

2. TERMS OF REFERENCE

DG Environment seeks the opinion of the SCHEER on the draft EQS for tributyltin (TBT) compounds.

Generic questions to the SCHEER

- Have the EQS for benthic communities in fresh and marine waters ($QS_{sediment}$) been correctly and appropriately derived, in the light of the available information?
- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

Additional questions to the SCHEER

- Should an additional AF be added to consider the ED properties of this substance?

3. OPINION

The SCHEER notes that sections 1 to 8.1. and 8.3. to 8.6 have not been updated since 2005, although new data on the environmental fate and effects of tributyltin compounds have become available in the literature. Furthermore, the text of the dossier refers partly to repealed Directives and websites that do not exist anymore. SCHEER therefore recommends updating the full dossier to address these shortcomings and to base the QS values for water on the full body of evidence now available.

In the following, the SCHEER only comments on the new section 8.2. regarding the EQS values for benthic communities.

Section 8.2 - Quality standard for sediment

Tributyltin compounds have been identified in the dossier as chemicals for which a sediment assessment is required, due to their lipophilicity (log K_{OW} > 3) and sorption to sediment (log K_{OC} 2.5-6.2). The SCHEER agrees with this conclusion.

Deterministic QS derivation

The finally selected data on the ecotoxicity to sediment dwelling organisms are presented in table 8.2.1, comprising 5 data for freshwater organisms from 3 taxonomic groups and 5 data for marine organisms from 4 taxonomic groups. The value indicating the highest toxicity (most sensitive organism/end-point) is reported in a study by Duft *et al.* (2003), which provides an EC_{10} of 2.98 µg Sn kg_{dw}^{-1} for the freshwater snail *Potamopyrgus antipodarum*, for the endpoint development (unshelled embryos). 2.98 µg Sn kg_{dw}^{-1} (molecular weight = 118.71 g mol^{-1}) corresponds to 7.28 µg TBT kg_{dw}^{-1} (molecular weight =290.05 g mol^{-1}). The SCHEER therefore suggests to use a value of 7.3 µg TBT kg_{dw}^{-1} instead of the value of 7.2 µg TBT kg_{dw}^{-1} that is currently used in the dossier.

This concentration is normalized from the organic carbon content used in the Duft *et al.* study (2.3%) to an organic carbon content of 5% by applying the following formula

$$\text{TEST RESULT}_{\text{EU standard sed}} = \frac{\text{TEST RESULT}_{test\ sed} \cdot f_{\text{oc,EU standard sed}}}{f_{oc,test\ sed}}$$

which results in a final concentration value of 15.83 µg TBT kg_{dw}^{-1}, if calculated with a value of 7.28 µg TBT kg_{dw}^{-1} for the EC_{10} of *P. antipodarum*.

This value is reported in table 8.2.1. as 15.86 µg kg_{dw}^{-1}, while in the text this concentration is presented as 15.5 µg kg_{dw}^{-1}. The SCHEER recommends using an identical rounded value of 15.8 µg kg_{dw}^{-1} throughout the table and text.

The concentration data in table 8.2.1. are provided in the unit "EU standardised (µgTBT kg^{-1}) (5%OC)". The SCHEER suggests specifying that those values refer to dry weight and to provide the concentration units as "EU standardised (µgTBT kg_{dw}^{-1})(5%OC)".

The SCHEER does not endorse the value of 0.3 µg TBT kg_{dw}^{-1} for $QS_{sediment,fw,eco}$, which is calculated by applying an AF of 50 to an experimental value of 15.8 µg TBT kg_{dw}^{-1}. This is because the dossier erroneously refers to table 13 of the TGD for selecting an AF of 50.

However, the AFs to be used for freshwater data are actually presented in table 11 of the TGD (page 101). According to this table, an AF of 10 (and not 50) is to be applied if "Three long term tests (NOEC or EC_{10}) with species representing different living and feeding conditions" are available. Given that data for freshwater crustaceans, insects and molluscs are presented in table 8.2.1. of the dossier, the SCHEER instead calculates a sediment **$QS_{sediment,fw,eco}$** value of 15.8/10=1.58 µg TBT kg_{dw}^{-1}, rounded to **1.6 µg TBT kg_{dw}^{-1}**.

The TGD requests the pooling of freshwater and marine data for the setting of QS values for marine sediments, but only under the condition that no systematic differences in toxicity exist (TGD, section 5.2.4, page 109). However, it is explicitly stated in the JRC dossier (page 17) that the data indicate a lower sensitivity of marine test systemsbecause of a reduced bioavailability in marine systems. This prohibits, in principle, the pooling of data from freshwater and marine systems.

Unfortunately, no data are available for benthic marine molluscs (most likely the most sensitive taxonomic group), which renders the marine dataset unsuitable on its own for deriving a valid QS for marine sediments. Given that freshwater test systems might be more sensitive, the SCHEER therefore agrees with the approach taken by the JRC to calculate also the deterministic $QS_{sediment,sw,eco}$ using the data for the freshwater snail *P. antipodarum* for the endpoint development (unshelled embryos). Applying an assessment factor of 10 to the value of 15.8 µg TBT kg_{dw}^{-1} results, via the deterministic method, in a **$QS_{sediment,sw,eco}$** of 15.8/10=1.58 µg TBT kg_{dw}^{-1}, rounded to **1.6 µg TBT kg_{dw}^{-1}**. The SCHEER recommends emphasising in the final TBT dossier that this value is preliminary and that toxicity data for marine sediment-dwelling molluscs are needed.

Probabilistic QS derivation

Due to the systematic differences in the freshwater and marine datasets, SCHEER does not endorse the pooling of the data for the purpose of deriving an SSD. Furthermore, section 5.2.1. of the TGD does not stipulate the pooling of freshwater and marine data for the derivation of a common SSD for sediments. The SCHEER therefore does not endorse the resulting HC_{05} values and concludes that the data currently do not allow to calculate any probabilistic QS value for sediments.

Questions to SCHEER

Have the EQS for benthic communities in fresh and marine waters ($QS_{sediment}$) been correctly and appropriately derived, in the light of the available information?

The SCHEER does not endorse the suggested deterministic $QS_{sediment,fw,eco}$ of 0.3 µg TBT kg_{dw}^{-1} and suggests to use a value of 1.6 µg TBT kg_{dw}^{-1} instead (see details above). The SCHEER endorses the suggested $QS_{sediment,sw,eco}$ of 1.6 µg TBT kg_{dw}^{-1} but recommends that it is explicitly flagged in the final TBT dossier as being preliminary.

The SCHEER does not endorse the probabilistic QS values, as the data indicate that marine and freshwater test systems have different sensitivities (and there are differences in bioavailability between the two water types), which prohibits the pooling of the data, and the separate datasets do not include a sufficient number of taxonomic groups.

Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

The most critical EQS value for sediments is the deterministic value of **1.6 µg TBT kg_{dw}^{-1}** for $QS_{sediment,fw,eco}$ as well as $QS_{sediment,sw,eco}$. As the parts of the dossier that concern the pelagic community, secondary poisoning and human health are not updated, the SCHEER has no comment on those sections.

Should an additional AF be added to consider the ED properties of this substance?

The TGD discusses the use of an additional AF in the context of ED properties in section 2.9.1., although only in the context of bird and mammal studies (not invertebrates). This is then reiterated and emphasised on page 43: "*When there are indications that a substance may cause adverse effects via disruption of the endocrine system of mammals, birds, aquatic or other wildlife species, the assessor should consider whether the assessment factor would be sufficient to protect against effects caused by such a mode of action, or whether a larger AF is needed (Section 2.9.1)*."

Given that the most sensitive assay and endpoint (development of embryos of the freshwater snail *P. antipodarum*) used in the dossier is capturing the endocrine properties of tributyl compounds and uses a representative of the taxonomic group that is most sensitive to tributyl compounds, the SCHEER is of the opinion that no additional AF is needed.

4. LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
AF	Application Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	body weight
dw	dry weight
EC_{10}	the concentration at which 10% of the organisms tested exhibit a statistically significant effect of the chemical
ED	Endocrine Disruption
EQS	Environmental Quality Standards
HC_{05}	Hazardous concentration affecting 5% of all the species in a distribution
NOAEL	No Adverse Effect Level
NOEC	No Observed Effect Level
OC	Organic Carbon
SSD	Species Sensitivity Distribution
QS	Quality Standard
WFD	Water Framework Directive

5. REFERENCES

DUFT, M., SCHULTE-OEHLMANN, U., TILLMANN, M., MARKERT, B., & OEHLMANN, J. 2003. Toxicity of triphenyltin and tributyltin to the freshwater mud snail *Potamopyrgus antipodarum* in a new sediment biotest. Environmental Toxicology and Chemistry: An International Journal, 22(1), 145-152. *https://doi.org/10.1002/etc.5620220119*

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