European Commission

Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Nonylphenol

Scientific Committees
on Consumer Safety
on Health, Environmental and Emerging Risks

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ABSTRACT

For the draft dossier on Environmental Quality Standards on nonylphenol (revised from a previous dossier and EQS derivation of 2005), the SCHEER offers the following opinions:

The selected nonylphenol MAC QS offered in the dossier was derived using the deterministic approach to give a **MAC $QS_{fw\ eco}$ of 2.1 µg L^{-1}** and **MAC $QS_{sw\ eco}$ of 0.17 µg L^{-1}** which the SCHEER can support. The derivation of an AA QS for nonylphenol is complicated by the observation that linear and 4-tertiary isomers have very different endocrine disrupting properties. However, for regulatory purposes, it seems reasonable to assume all forms may be of the 4-tertiary variety to ensure that sufficiently protective QS are derived. Given the known vulnerability of certain groups to endocrine or reproduction related end-points, it was deemed appropriate to use the probabilistic approach with an SSD containing only 4 (particularly vulnerable) taxonomic groups. Following an AF of 5 to the HC5 of the SSD, this yielded an **AA $QS_{fw\ eco}$ of 0.037 µg L^{-1}** and **AA-$QS_{sw\ eco}$ of 0.0018 µg L^{-1}**. The SCHEER can endorse these values.

Given the high Kow for nonylphenol, it was necessary to derive a benthic organism related QS. Using the deterministic approach and an AF of 10 to an EC10 for *Lumbricus variegatus* this generated an **$QS_{sediment\ fw}$ of 1.3 mg kg^{-1}_{dw}** and **$QS_{sediment\ sw}$ of 260 µg kg^{-1}dw** following an AF of 50, both of which the SCHEER can support.

To protect predators from secondary poisoning the dossier uses NOAEL data from a rat study to derive freshwater **$QS_{biota\ fw\ sec\ pois}$ of 2.2 mg kg^{-1}** for fish, **$QS_{biota\ fw\ sec\ pois}$ of 0.64 mg kg^{-1}** for bivalves, for marine **$QS_{biota\ sw\ sec\ pois}$ of 0.73 mg kg^{-1}** for fish, **$QS_{biota\ sw\ sec\ pois}$ of 0.15 mg kg^{-1}** for bivalves. Using a BCF multiplied by the default BMF this translated to a **$QS_{biota\ fw\ sec\ pois}$** of **0.85 µg L^{-1} for fish**, a $QS_{biota\ fw\ sec\ pois}$ of 0.19 µg L^{-1} for bivalves in the surrounding water and a **$QS_{biota\ sw\ sec\ pois}$** of **0.28 µg L^{-1} for fish, a $QS_{biota\ sw\ sec\ pois}$** of **0.043 µg L^{-1} for bivalves** in saltwater. The SCHEER accepts these secondary poisoning QSs with the exception one of the $QS_{biota\ fw\ sec\ pois}$, which it calculates should be 0.09 µg L^{-1} for bivalves.

The dossier contains a **$QS_{biota\ hh}$** of **0.62 mg kg^{-1}** to protect human health with respect to fish consumption with an associated protective level of 0.28 µg L^{-1} for fish in the water and 0.18 µg L^{-1} for bivalves. The SCHEER is concerned there may have been an error in these calculations and so they cannot be endorsed yet. To protect human health from drinking water a **$QS_{dw\ hh}$** of **0.3 µg L^{-1}** already exists.

The AA-$QS_{fw\ eco}$ of 0.037 µg L^{-1} is the lowest most critical QS for the freshwaters. For marine waters the AA-$QS_{sw\ eco}$ is 0.0018 µg L^{-1}, which is lower. Given the generally abundant dilution of the marine environment, the SCHEER considers the AA-$QS_{fw\ eco}$ will be the more likely to be exceeded and this is the critical EQS.

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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[1].

2. TERMS OF REFERENCE

DG Environment now seeks the opinion of the SCHEER on the draft EQS for the proposed Priority Substances and the revised EQS for a number of existing Priority Substances. The SCHEER is asked to provide an Opinion for each substance. We ask that the SCHEER focus on:

1. Whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS;

2. Whether the most critical EQS (in terms of impact on environment/health) have been correctly identified.

[1] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/ba6810cd-e611-4f72-9902-f0d8867a2a6b/details

3. OPINION

It should be noted that in a separate synthesis Opinion, the SCHEER provide an analysis of weaknesses and unresolved issues common to all dossiers. This includes a discussion of the risk assessment method. The Opinion provided by SCHEER will be restricted to issues directly associated with the derivation of the different EQS.

Specific comments on the different sections of the dossier are listed below.

Section 7. Effects and quality standards

Section 7.1. Acute aquatic ecotoxicity

The dossier lists acute data for 33 freshwater species from 8 major taxonomic groups and 12 saltwater species from 8 major taxonomic groups. The results of a statistical evaluation indicate that, according to the EQS Technical Guidance (EC, 2018), the two-datasets cannot be combined.

Deterministic approach

The lowest acute freshwater value was the 96h-EC_{50} of 20.7 µg L^{-1} for the crustacean *Hyalella azteca*. Applying an AF of 10, a **MAC-$QS_{fw, eco}$ of 2.07 µg L^{-1} (**which can be rounded to **2.1 µg L^{-1})** was obtained. For marine waters, data was available for seven invertebrates and four fish studies. The lowest datum was the 96 h-LC_{50} of 17 µg L^{-1} for the fish *Pleuronectes americanus*, and applying an AF of 100, obtaining a **MAC-$QS_{sw, eco}$ equal to 0.17 µg L^{-1}**. The dossier argues that an AF of 100 is necessary because of the high standard deviation for similar groups (two orders of magnitude difference across the invertebrates) and a general lack of knowledge of the mechanism of acute toxicity.

Probabilistic approach

The saltwater dataset did not contain sufficient data to set up an SSD. The probabilistic approach was performed only with freshwater acute data with 33 species and 8 taxonomic groups. The absence of higher plants was deemed acceptable because some other studies showed them not to be sensitive. An HC_5 value of 53 µg $L^{-1}$was obtained. In the acute dataset, an AF of 7 was used obtaining a MAC-$QS_{fw, eco}$ equal to 7.57 µg/L. Given that the deterministic approach gave a lower QS value, it was considered appropriate to base the standard that way.

Overall, the SCHEER notes the different approaches (deterministic and probabilistic) yielded similar tentative QS values, which was reassuring, and endorses the MAC-QS offered above from the deterministic approach.

Section 7.2 Chronic aquatic ecotoxicity

Deterministic approach

The dossier lists 24 chronic studies that are considered reliable, including alga, plant, crustacea, mollusc, worm, insect larva, fish, and frog.

The lowest NOEC value of 0.13 µg L^{-1} came from a 60 d *Oncorhynchus mykiss* study. Given the breadth of the dataset covering fish crustacea and algae, an AF of 10 could be used to provide a tentative AA-$QS_{fw\ eco}$ of 0.013 µg L^{-1} (13 ng L^{-1}).

Chronic data was available for only three marine invertebrates (one crustacean, two molluscs), with the lowest value being 0.3 µg L^{-1}, so a value could be derived from the freshwater 0.13 µg L^{-1} value. The dossier argues, with a reasoning that was hard to follow, that an AF of 100 rather than 50 should be applied because of the presence of the zebra mussel in the freshwater dataset. This would give a possible AA-$QS_{sw\ eco}$ of 0.0013 µg L^{-1} (1.3 ng L^{-1}).

Probabilistic approach (SSD method)
The dataset did not cover 8 taxonomic groups. However, because the mode of action and toxicity is understood for fish molluscs and amphibians (toxicity but not mode of action known for crustacea), it was considered an SSD could be used (that included freshwater and marine species) that would be protective of the most vulnerable members of the freshwater ecosystem. When an SSD was drawn from the data from these four groups, a good fit was seen and an HC_5 of 182 ng L^{-1} could be derived. Thus, with an AF of 5, this would give an **AA-$QS_{fw\ eco}$** of 36.5 ng L^{-1} (to be rounded to **37 ng L^{-1}**). Using the same HC_5 value, an **AA-$QS_{sw\ eco}$** of 1.82 ng L^{-1} (to be rounded to **1.8 ng L^{-1}**) was offered following an AF of 100. The AF of 100 was selected against the background of limited chronic marine data being available. Whilst the deterministic tentative AA-QS are slightly lower than from the probabilistic method, the dossier considers the QS derived from the probabilistic method more reliable. The SCHEER endorses this preference, noting the good fit of the SSD curve, and supports these probabilistic derived AA-QS values.

Section 7.3: Sediment ecotoxicology

Given that nonylphenol has both a LogKow and logKoc >3, we can presume sorption to sediments will occur and hence potential exposure to sediment dwelling organisms. The conversion of the lowest EC_{10} value for a worm (a classic sediment dwelling organism) of 5.5 mg kg^{-1} with a test OC of 2.1% with a standard sediment OC content of 5% would equate to a LC_{10} EU normalised of 13.1 mg kg^{-1}. The TGD would recommend an AF of 10, given the extent of sediment organism chronic ecotoxicity data that was available. Applying this AF leads to a **$QS_{sediment\ fw}$** of 1.31 mg kg^{-1} (to be rounded to **1.3 mg kg^{-1}**). On the basis of the existing chronic ecotoxicity for 4 taxa (3 groups), an AF of 50 could be recommended for a protective level for marine organisms giving a **$QS_{sediment\ sw}$ of 0.26 mg kg^{-1}.** Both these $QS_{sediment}$ can be endorsed by the SCHEER.

Section 7.5 Secondary Poisoning

Considering the data on $LogK_{ow}$ (higher than 3), the criteria are met to assess secondary poisoning. A 90 d NOAEL of 15 mg $kg^{-1}_{\ bw}$ d^{-1} for a 326 g rat was selected as the most suitable starting point for an ingestion value that would be protective of higher predators. This concentration has to be converted to a nonylphenol value per food energy content (becoming 0.012 mg nonylphenol KJ^{-1}). Given that as food sources, fish, mussels, birds and mammals offer 5523, 1602 and 77331 kJ kg^{-1}_{fw} of energy respectively, this was converted to 66.2, 19.2 and 87.9 mg nonylphenol kg^{-1}_{ww}. Given an AF of 3 and an additional factor of 10 gives a final AF of 30 as per the TGD, this generated **$QS_{biota\ sec\ pois\ fw}$** of 2.21(rounded to **2.2**) **mg kg^{-1}_{diet} for fish** and **0.64 mg kg^{-1}_{diet} for bivalves** which are endorsed by the SCHEER

As no BAF values are known, this was calculated as BCF (3400 L kg^{-1}_{ww} for bivalves and 1300 L kg^{-1}_{ww} for fish from Table 5.1) multiplied by the BMF. In the absence of an experimental BMF, following the TGD, where a $LogK_{ow}$ exceeds 5 (Table 5.1) and the fish BCF <2000, a BMF of 2 may be used. So, the partner protective water levels to ensure levels are kept below those that could transfer to the prey, and which might ultimately

harm the predator, were calculated as **0.85 µg L^{-1} for freshwater fish** and 0.19 µg L^{-1} for freshwater bivalves. The SCHEER questions the proposed $QS_{biota\ fw\ sec\ pois}$ of 0.19 µg L^{-1} for bivalves. If the BMF of 2 is taken into account, this should be a **$QS_{biota\ fw\ sec\ pois}$** of **0.09 µg L^{-1}** for bivalves.

For the marine environment, the $C_{food\ item}$ of and 87.9 mg nonylphenol kg^{-1}_{ww} for birds and mammals was used (see above) with an AF of 30 and BMF of 2. Then a normalisation stage according to the lipid content of birds/mammals relative to fish and bivalves was used, giving a **$QS_{biota\ sec\ pois\ sw}$** of 0.733 mg kg^{-1}_{diet} **for fish (0.73 mg kg^{-1}_{diet})** and 0.147 mg kg^{-1}_{diet} **for bivalves (0.15 mg kg^{-1}_{diet})**, which are endorsed by the SCHEER. The equivalent water values were calculated as **0.28 µg L^{-1} for saltwater fish** and **0.043 µg L^{-1} for saltwater bivalves**.

Section 7.6 Human health

Protecting humans from nonylphenol in the diet:

The available TDI is 5 µg $kg_{bw}^{-1}d^{-1}$ and using the TGD values of a 0.2 fraction of fish in the diet with a 95th percentile consumption of 0.00163 kg_{fish} kg^{-1}_{bw} d^{-1} (for a person of 70 kg) results in a $QS_{biota\ hh}$ of 613.5 µg kg^{-1}. Working back from the predicted BAF (see secondary poisoning above), the SCHEER would calculate where $QS_w = QS_{biota}/(BCF x BMF)$: 613.5/(1300x2) = 0.26 (for fish), rather than the associated protective level of 0.28 µg L^{-1} in the water for fish offered in the dossier. For bivalves, the SCHEER calculates: 613.5/(3400x2) = 0.09 rather than the 0.18 µg L^{-1} offered in the dossier. The SCHEER requests the European Commission to re-check these calculations for the protection of human health via food consumption.

To protect human health from drinking water, a standard of 0.3 µg L^{-1} has already been set, which the SCHEER supports.

4. CRITICAL EQS

The AA-$QS_{fw\ eco}$ of 0.037 µg L^{-1} is the lowest most critical QS for the freshwaters. For marine waters, the AA-$QS_{sw\ eco}$ is 0.0018 µg $L^{-}1$, which is lower. The AA-$QS_{sw\ eco}$ was actually derived from the AA-$QS_{fw\ eco}$. Given the generally abundant dilution of the marine environment, the SCHEER considers the AA-$QS_{fw\ eco}$ will be the more likely to be exceeded and this is the critical EQS.

5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
AF	Application Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	Body weightEC_{50} Effect concentration that is necessary to cause half of the maximum possible effect
EQS	Environmental Quality Standard
HC*p*	Hazardous concentration affecting a certain percentage (*p*) of all the species in a distribution
LC_{50}	Lethal concentration, i.e., concentration that kills 50% of the tested species
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOEC	No observed effect concentration
N(O)AEL	No (observed) adverse effect level
OC	Organic carbon
SSD	Species Sensitivity Distribution
TL	Threshold Level
TGD	Technical Guidance Document on Deriving EQS
WFD	Water Framework Directive

6. REFERENCE

EC (European Commission), 2018. Technical Guidance for Deriving Environmental Quality Standards (TGD-EQS). Common Implementation Strategy for the Water Framework Directive. Guidance Document No. 27 Updated version 2018.