Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

5-6 rings PolyAromatic Hydrocarbons (PAHs)

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

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Register of Commission expert groups and other similar entities (europa.eu)

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ABSTRACT

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

The proposed dossier is a revision of a previous EQS dossier (2018) based on recent data and the procedure proposed in the new EQS Technical Guidance (2018). However, several sections of the dossier refer to old technical documents (2011). It is the opinion of the SCHEER that all the procedures must be updated, according with the 2018 EQS Technical Guidance.

For PAHs to be measured together with benzo[a]pyrene (BaP), the JRC selected an eight-component PAH mixture (BaP, benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenz[a,h]anthracene, benzo[g,h,i]perylene and chrysene) as described by EFSA (2008).

For BaP the SCHEER does not endorse the MAC-QSs, while the **AA-$QS_{freshwater, eco}$ and AA-$QS_{salt\ water, eco}$ of 0.022 µg** L^{-1} are endorsed by the SCHEER.
For benzo[b]fluoranthene and benzo[k]fluoranthene the **AA-$QS_{fw, eco}$ and AA-$QS_{sw, eco}$ of 0.017 µg L^{-1}** are endorsed by the SCHEER. The SCHEER agrees on using the same values for MAC-QSs.
For benzo[g,h,i]perylene the **AA-$QS_{fw, eco}$ of 0.0082 µg L^{-1}** and the **AA-$QS_{sw, eco}$ of 0.00082 µg L^{-1}** are endorsed by the SCHEER. The SCHEER agrees on using the same values for MAC-QSs.
For indeno[g,h,i]perylene, the MAC-QS and AA-QS cannot be derived due to the lack of data.

Toxicity data to derive a $QS_{biota, secpois}$ are available only for BaP. The method of the energy-normalised diet concentrations was correctly applied to the NOAEL of 5 mg kg_{bw}^{-1} d^{-1} obtaining a final **$QS_{biota, secpois, fw}$** of **0.67 mg kg_{ww}^{-1}** for fish, **0.60 mg kg_{ww}^{-1}** for crustaceans, and **0.19 mg kg_{ww}^{-1}** for bivalves, which are endorsed by the SCHEER. For the back-calculation to water concentration, the SCHEER does not endorse the $QS_{fw,biota}$ for fish due to inappropriate selection of the final BAF value for fish. The SCHEER endorses the **$QS_{fw, biota}$ for crustaceans** of **7.4 ng L^{-1}** and the **$QS_{fw, biota}$ for bivalves** of **5.7 ng L^{-1}**.

For human health, BaP is assumed as a suitable indicator for all PAHs. The SCHEER endorses the **$QS_{biota, hh}$ of 0.61 µg kg_{biota}^{-1} as BaP equivalent**. The SCHEER endorses this value. The SCHEER notes that a $QS_{water\ hh\ biota}$ has not been calculated.
The EU standard for drinking water for the sum of PAHs is equal to **0.1 µg L^{-1}** while for BaP it is equal to **0.01 µg L^{-1}**. The SCHEER is of the opinion that a $QS_{dw, hh}$ should be derived for BaP.
Different critical EQSs should be identified for the different chemicals. Considering the endorsed EQSs, the **$QS_{fw, biota}$ for bivalves = 5.7 ng L^{-1}** is identified for BaP and the **AA-$QS_{sw, eco}$ = 0.82 ng L^{-1}** is identified for benzo[g,h,i]perylene.

The SCHEER notes that in the dossier, contrary to what the title of the dossier suggests, 4-ring PAHs are also included.

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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 the 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.

Where there is disagreement between experts of WG Chemicals or there are other unresolved issues, we ask that the SCHEER consider additional points, identified in the cover note(s).
In some cases, especially where additional points are raised, additional documents may be provided. Some of the studies referred to in the dossiers are not publicly available. If the SCHEER needs to see these studies, it is invited to please contact DG Environment.

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

Generic questions to the SCHEER

- Have the EQS been correctly and appropriately derived, in the light of the available information and the TGD-EQS?
- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

Additional questions to the SCHEER

- Should the EU food limit be used instead of the scientifically derived $QS_{biota,\ hh\ food}$ from the human toxicological risk without further assessment? Alternatively, should the $QS_{biota,\ hh\ food}$ be derived and compared with the EU food limit and $QS_{biota\ secpois}$?

3. OPINION

SCHEER provided a general discussion concerning the procedure and derivation of the EQS values and related topics and highlighted unresolved issues and weaknesses that are common to more than one substance and dossier.

For PAHs to be measured together with benzo[a]pyrene (BaP), the JRC selected an eight-component PAH mixture (BaP, benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenz[a,h]anthracene, benzo[g,h,i]perylene and chrysene) as described by EFSA (2008). The SCHEER notes that in the dossier, contrary to what the title of the dossier suggests, 4-ring PAHs are also included.

In the disclaimer of the dossier, it is said that the biota section and the drinking water section have been revised due to new data available after 2005 and to the new Technical Guidance for EQS derivation updated in 2018 (EC, 2018). In addition, several new MAC values have been proposed. Several sections of the dossier refer to old technical documents (EC, 2003; Lepper, 2004). It is the opinion of the SCHEER that all the procedures must be updated, according with the 2018 TGD. Specific comments on the different sections of the dossier are listed below.

Section 6 – Effect data (aquatic environment)

The toxicity data presented for some of the PAHs on fresh and saltwater organisms and toxicity data mammals and birds are referring to studies done prior to 2005. This is in contradiction with the statements of the disclaimer.

For all PAHs, with the exception of benzo[a]anthracene, chrysene, and dibenz[a,h]anthracene (Verbruggen *et al.*, 2011a, 2011b; Verbruggen, 2012), the existing MAC values were retained (cf. 2011 Dossier).

Section 7 – Calculation of quality standards

Section 7.1 –Quality standards for water

7.1. Acute and chronic aquatic ecotoxicity

Ecotoxicity data reported in the Tables 7.1 to 7.4 in the dossier were extracted exclusively from the finalised version of CTPHT EU-RAR (E.C., 2008a), (Verbruggen *et al.*, 2011a, 2011b; Verbruggen, 2012).

All data reported were considered valid for the purpose of conducting an effects assessment, *i.e.* they could be given a reliability index (Klimisch code) of 1 or 2, or they could be given a reliability index (Klimisch code) of 2 or 3 and therefore be considered useful as supporting information for an effects assessment. Information on reliability was retrieved from the finalised version of CTPHT EU-RAR (E.C., 2008a), (Verbruggen *et al.*, 2011a, 2011b; Verbruggen, 2012).

To avoid confusion, the SCHEER suggests that the same terminology used in the Technical Guidance for Deriving Environmental Quality Standards (EC, 2018) be used in the dossier: AA-$QS_{fw,\ eco}$, AA-$QS_{sw,\ eco}$, MAC-$QS_{fw,\ eco}$, MAC-$QS_{sw,\ eco}$

All QS values are based on a deterministic approach because there was insufficient data to allow for a probabilistic approach.

Benzo[a]pyrene (BaP)
Acute studies for freshwater species are available for crustaceans and fish. Chronic studies for freshwater species are available for algae, crustaceans, and fish. In addition, chronic studies for marine species are available for molluscs, echinoderms, and fish.

The acute test by Bisson *et al.* (2000) on *Daphnia magna* did not result in any toxic effects. The 48h-EC_{50} of 2.7 $\mu g L^{-1}$ for crustacean *D. magna* can however be used as an endpoint for MAC-$QS_{water,\ eco}$ derivation. The SCHEER does not agree with this MAC-$QS_{water,\ eco}$ because the EC50 is indicated as >2.7 $\mu g\ L^{-1}$ in the Bisson study. Another value is 96h LC_{50}=5 $\mu g\ L^{-1}$ on *D. pulex* (Trucco *et al.*, 1983). Assessment factors of 10 and 100 can reasonably be applied on this data to derive $MAC_{fw,\ eco}$ and $MAC_{sw,\ eco}$, of 0.27 and 0.027 $\mu g\ L^{-1}$ respectively. The SCHEER agrees with the AF but does not endorse the QS because the selected EC_{50} cannot be accepted.

Many chronic data are available that correspond to studies where no effects were observed. The EC_{10} of 0.22 $\mu g\ L^{-1}$ for shell development of the marine mollusc *Crassostrea gigas* is used as the most critical endpoint to use for AA-$QS_{water,\ eco}$ derivation. Because additional chronic toxicity data are available for two groups of typical marine species, the assessment factor deemed necessary for both freshwater and marine water is 10. The **AA-$QS_{fw,\ eco}$ and AA-$QS_{sw,\ eco}$ of 0.022 µg** L^{-1} are endorsed by the SCHEER.

Benzo[b]fluoranthene and Benzo[k]fluoranthene
Usable data to derive the QS for benzo[b]fluoranthene are scarce. Because the two substances are mostly reported together and have structural similarities, it is proposed to combine benzo[b]fluoranthene and benzo[k]fluoranthene ecotoxicological data to derive a common $QS_{water,\ eco}$. The SCHEER agrees with the proposal.

Acute data are available for bacteria (*Vibrio fisheri*) and invertebrates (*D. magna)*. No acute data is available for fish for benzo[b]fluoranthene and benzo[k]fluoranthene while fish is shown to be the most sensitive taxa in the chronic dataset. Therefore, it is decided to set the MAC-$QS_{water,\ eco}$ at the level of the AA-$QS_{water,\ eco}$. The SCHEER agrees with the approach.

As regards chronic toxicity, data are available for algae, crustaceans and fish. In addition, additional marine data are available for molluscs and specific marine taxa echinoderm. The lowest EC_{10} value is found for *Brachydanio rerio* at 0.17 $\mu g\ L^{-1}$. Because additional chronic toxicity data are available for two groups of marine species, the assessment factor deemed

necessary for both freshwater and marine water is 10, leading to a **$AA\text{-}QS_{fw,\ eco}$ and $AA\text{-}QS_{sw,\ eco}$ of 0.017 µg L^{-1}**. The SCHEER endorses the QSs.

Benzo[g,h,i]perylene
The lowest EC_{10} of 0.082 µg L^{-1} is found for reproduction of *Ceriodaphnia dubia*. Assessment factors of 10 and 100 were applied to this data to derive the **$AA\text{-}QS_{fw,\ eco}$ and $AA\text{-}QS_{sw,\ eco}$, at 0.0082 and 0.00082 µg L^{-1}**, respectively. The SCHEER agrees with these values.

The $MAC\text{-}QS_{fw,eco}$ and $MAC\text{-}QS_{sw,\ eco}$ should be set at the same concentrations, because no data on acute toxicity are available, other than unbounded values (above higher concentration tested) on bacteria, invertebrates and fish. The SCHEER agrees with this approach.

Indeno[1,2,3-cd]pyrene
The acute data set for indeno[1,2,3-cd]pyrene (only one unbounded value on bacteria) is not sufficient to derive MAC-QS values. The chronic base-set (data on algae and crustaceans) is also incomplete for indeno[1,2,3-cd]pyrene, with missing information on chronic toxicity to fish. Therefore, no quality standard can be derived. The SCHEER agrees with this decision.

Section 7.2 –Secondary poisoning

Data on the PAH toxicity to birds are scarce and Final CTPHT EU-RAR (E.C., 2008a) states that "from these data it is not possible to derive a NOAEL for birds for either of the PAHs". Also, the relevant toxicity data to mammals are limited. Almost all of the long-term studies reported were designed to assess carcinogenic potency of PAH and are not considered appropriate for secondary poisoning assessment.

Toxicity data to derive a $QS_{biota,\ secpois}$ are available only for BaP. The lowest value, relevant at a population level, is the 90-day NOAEL for reproduction in rats (decreased sperm count) of **5 mg kg_{bw}^{-1} d^{-1}.**

According to the EQS Technical Guidance (E.C., 2018), the **NOAEL of 5 mg kg_{bw}^{-1} d^{-1}** is expressed as a diet concentration normalised to the energy (caloric) content of food. This value is the amount of food an animal must consume to meet its energy requirements, also referred to as its daily energy expenditure (DEE; kJ/d). DEE was calculated as:

$$logDEE\ [kJ/d] = 0.8136 + 0.7149 * log\ bw\ [g]$$

A geometric mean bodyweight (bw) value of 235 g (Liang et al., 2012, cited in US-EPA, 2017) was substituted in the Equation 1 to calculate a DEE of 322.6 kJ d^{-1}.

The NOAEL of 5 mg kg_{bw}^{-1} d^{-1} was then normalised to the energy content of food as follows:

$$C_{energy\ normalised}\ [mg/kJ] = \text{dose} * (bw\ [kg]/DEE)$$

The obtained $C_{energy\ normalised}$ was equivalent to 3.64 µg kJ^{-1}.
Subsequently, the concentration of BaP in a specific food item (fish, crustacean and bivalves) was calculated according to:

$$C_{food\ item}\ [mg/kg_{ww}] = C_{energy\ normalised}\ [mg/kJ] * \text{energy content}_{food\ item,\ dw} * (1\text{-moisture fraction}_{food\ item}) = C_{energy\ normalised}\ [mg/kJ] * \text{energy content}_{food\ item,\ fw}$$

The energy contents on a fresh weight basis for fish of 21 kJ g_{dw}^{-1} and 19.3 kJ g_{dw}^{-1} for bivalves, and the respective moisture fractions of 73.7% for fish and 91.7% for bivalves were used (EC, 2018). The obtained $C_{food\ item}$ were 20.12 mg kg_{ww}^{-1} for fish, 18.04 mg kg_{ww}^{-1} for crustaceans and 5.83 mg kg_{ww}^{-1} for bivalves.

An AF of 30, obtained by combining an AF of 3 for the use of a subchronic NOAEL and an AF of 10 for the deterministic use of the lowest NOAEL, according with the TGD (EC, 2018), was applied to the $C_{food\ item}$, obtaining a final **$QS_{biota,\ secpois,\ fw}$ of 0.67 mg kg_{ww}^{-1} for fish, 0.60 mg kg_{ww}^{-1} for crustaceans, and 0.194 mg kg_{ww}^{-1} for bivalves** (rounded to **0.19**)**.** The SCHEER endorses the QSs.

For the back-calculation to water concentration, the $QS_{water,\ biota}$ was calculated as follows:

$$QS_{water,\ biota} = QS_{biota,\ secpois} / BAF$$

Experimentally derived BAF values for BaP for fish and crustaceans are reported in the dossier (Tables 9.1.2 and 9.1.3 in the Appendix I). For fish, a geometric mean value of 6,056.8 L kg_{ww}^{-1} and a BAF of 1,000 L kg_{ww}^{-1} for *Acanthogobius flavimanus* are selected. The geometric mean between these two values gives a BAF for fish of 2,461 L kg_{ww}^{-1}. This value is finally selected in the dossier.

The SCHEER does not endorse the BAF value for fish, due to lack of clarity and statistical rigour concerning the approach used to combine the different data values in table 9.1.2, and in particular the final geometric mean calculation.

For crustaceans, a BAF of 81,133 L kg_{ww}^{-1} was obtained from the geometric mean of the BAF of 121,900 L kg_{ww}^{-1} for benthic omnivore crab *Callinectes sapidus* and of 54,000 L kg_{ww}^{-1} for *Hemigrapsus penicillatus*. For molluscs, a geometric mean BAF equal to 33,839 L kg_{ww}^{-1} was calculated from the concentrations reported in Takeuchi *et al.* (2009).

Applying the BAF value of 2,461 L kg^{-1}, the $QS_{fw,biota}$ for fish was equal to 272.4 ng L^{-1}, while applying the BAF of 81,133 the **$QS_{fw,\ biota}$ for crustaceans** was equivalent to **7.4 ng L^{-1}**. Applying the BAF of 33,839 L kg^{-1}, the **$QS_{fw,\ biota}$ for bivalves** was equivalent to **5.74 ng L^{-1}** (rounded to **5.7**). For the reasons explained above, the SCHEER does not endorse the $QS_{fw,biota}$ for fish, while the SCHEER endorses the QSs for crustaceans and bivalves.

The dossier concludes that, considering that BaP is not a biomagnifying molecule, the critical food item is not fish, but bivalves and crustaceans, therefore there is no need to derive a $QS_{biota,\ secpois,\ sw}$. It is the opinion of the SCHEER that more evidence should be provided on the absence of biomagnification for BaP.

The secondary poisoning has been evaluated only for BaP. The SCHEER is of the opinion that other PAHs could also be considered, if data become available. As information on the other PAHs is not sufficient, the QS_{biota} for BaP could be applied to the other PAHs as a precautionary value.

Section 7.4 – Human health

According to the EQS Technical Guidance (EC, 2018), PAHs show the toxic properties fitting the criteria to derive a $QS_{biota,\ hh}$.

EFSA (2008), evaluated 16 PAH molecules showing genotoxic and/or carcinogenic effects concluding at the time that eight PAHs (BaP, benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, chrysene, dibenz[a,h]anthracene and indeno[1,2,3-cd]pyrene) were the only possible indicators of carcinogenic potency of PAHs in food.

In seafood products and in bivalves in particular, BaP concentrations were consistent, although not predominant, and were the most commonly detected PAHs in seafood products chrysene and benzo[a]anthracene (EFSA, 2008); also, the most important exposure route for the carcinogenic PAHs were cereals and cereal products, as well as seafood and seafood products.

BaP shows the strongest carcinogenicity among all PAHs in all food categories. It can be concluded that, for fishery products, BaP is a suitable indicator for all PAHs.

It was proposed in the dossier that the cancer risk associated with exposure to PAHs via diet should be based on the calculation of a Virtually Safe Dose (VSD) for BaP of 5 ng kg^{-1}_{bw} d^{-1} (Kroese *et a*l 2001)As the BaP is the PAH with highest carcinogenicity potency, it is generally accepted that the cancer risk calculated based on the BaP VSD will be sufficiently protective and should be used to derive the cancer risk for all PAHs using the Relative Potency Factor (RPF) approach (as BaP equivalents). In case BaP is taken as PAH-indicator, it is proposed to use a correction factor of 10 to account for uncertainties in relation to cancer risks induced by all PAHs, resulting in a VSD of 0.5 ng kg_{bw}^{-1} d^{-1}. The SCHEER endorses this approach.

The SCHEER agrees with using the VSD for deriving the QS_{hh} for BaP.

According to the EQS Technical Guidance (E.C., 2018), $QS_{biota,\ hh}$ is calculated as follows:

$$QS_{biota,\ hh} = (0.2*TL_{hh})/0.00163$$

where TL_{hh} = VSD = 0.005 µg kg_{bw}^{-1} d^{-1}.

The resulting **$QS_{biota,\ hh}$** was equal to **0.61 µg kg_{biota}^{-1} as BaP equivalent.** The SCHEER endorse this value.

The SCHEER notes that a $QS_{water\ hh\ biota}$ has not been evaluated and the SCHEER recommends that it should be.

Human Health via consumption of drinking water

The EU standard for drinking water for the sum of PAHs is equal to **0.1 µg L^{-1}** (Directive (EU) 2020/2184), while for BaP it is equal to **0.01 µg L^{-1}**. The SCHEER is of the opinion that a $QS_{dw,\ hh}$ should be derived for BaP.

4. CRITICAL EQS

It is the opinion of the SCHEER that different critical EQSs should be identified for the different chemicals. In light of the endorsed EQSs, the following critical EQSs may be identified:

- for benzo[a]pyrene: **$QS_{fw,\ biota}$ for bivalves = 5.7 ng L^{-1}**; however, it must be noted that the $QS_{water\ hh\ biota}$, probably much lower, has not been calculated;
- for benzo[g,h,i]perylene: **AA-$QS_{sw,\ eco}$ = 0.82 ng L^{-1}**.

5. Additional questions to the SCHEER

- Should the EU food limit be used instead of the scientifically derived $QS_{biota,\ hh\ food}$ from the human toxicological risk without further assessment? Alternatively, should the $QS_{biota,\ hh\ food}$ be derived and compared with the EU food limit and $QS_{biota\ secpois}$?

The SCHEER does not recommend that the EU food limit be used instead of the scientifically derived $QS_{biota\ hh\ food}$. The SCHEER recommends that the $QS_{biota,\ hh\ food}$ should be derived in any case and used.

6. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
BAF	Bioaccumulation Factor
B[a]P	Benzo[a]pyrene
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	body weight
DEE	Daily Energy Expenditure
dw	dry weight
EC	Effect Concentration
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
HC	Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
NOEL	No Effect Level
PAH	Polycyclic Aromatic Hydrocarbons
PPP	Plant Protection Products
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TEF	Toxic Equivalency Factor
TGD	Technical Guidance Document
TL	Threshold Level
TU	Toxic Unit
VSD	Virtually Safe Dose
ww	wet weight

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