Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Fluoranthene

The SCHEER adopted this document
during the plenary meeting on 22 November 2022

ACKNOWLEDGMENTS

Members of the Working Group are acknowledged for their valuable contribution to this opinion. The members of the Working Group are:

The SCHEER members:
Marian Scott (Chair), Marco Vighi (Rapporteur), Thomas Backhaus, Teresa Borges, Pim de Voogt, Peter Hoet, Rodica Mariana Ion

The external experts:
Andrew Johnson, Jan Linders

All Declarations of Working Group members are available at the following webpage:
Register of Commission expert groups and other similar entities (europa.eu)

This Opinion has been subject to a commenting period of four weeks after its initial publication (from 14 October to 11 November 2022). Comments received during this period were considered by the SCHEER. For this Opinion, no comment was received.

Keywords:
Fluoranthene, Water Framework Directive, environmental quality standards

Opinion to be cited as:
SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Final Opinion on Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive - fluoranthene, 22 November 2022

About the Scientific Committees (2022-2026)
Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.
These committees are the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The Scientific Committees review and evaluate relevant scientific data and assess potential risks. Each Committee has top independent scientists from all over the world who are committed to working in the public interest.
In addition, the Commission relies upon the work of other Union bodies, such as the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHEER
This Committee, on request of Commission services, provides Opinions on questions concerning health, environmental and emerging risks. The Committees addresses questions on:
- health and environmental risks related to pollutants in the environmental media and other biological and physical factors in relation to air quality, water, waste and soils.
- complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health, for example antimicrobial resistance, nanotechnologies, medical devices and physical hazards such as noise and electromagnetic fields.

SCHEER members
Thomas Backhaus, Roberto Bertollini, Teresa Borges, Wim de Jong, Pim de Voogt, Raquel Duarte-Davidson, Peter Hoet, Rodica Mariana Ion, Renate Kraetke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott, Emanuela Testai, Marco Vighi, Sergey Zacharov

Contact
European Commission
DG Health and Food Safety
Directorate B: Public Health, Cancer and Health security
Unit B3: Health monitoring and cooperation, Health networks
L-2920 Luxembourg
SANTE-C2-SCHEER@ec.europa.eu

PDF ISSN 2467-4559 ISBN 978-92-68-06276-0 doi:10.2875/54876 EW-CA-23-009-EN-N

The Opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The Opinions are published by the European Commission in their original language only.
SCHEER - Opinions (europa.eu)

ABSTRACT

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

The SCHEER did not receive any additional questions related to this substance.

Based on the available acute and chronic ecotoxicological data, the dossier shows that the MAC-QS-values are lower than the AA-QS-values. Therefore, the MAC-QS-values are set equal to the AA-QS-values. The following values can be endorsed by the SCHEER: **AA-$QS_{fw,eco}$ = MAC-$QS_{fw,eco}$ = 0.12 µg L^{-1} and AA-$QS_{sw,eco}$ = MAC-$QS_{sw,eco}$ = 0.012 µg L^{-1}**. These results are based on the SSD-curves of the combined freshwater and marine water datasets.

The sediment ecotoxicology section has been revised based on comments of the SCHER in 2011. Although the dossier rounded the AA-QS from 2.05 to 2.0, the SCHEER is of the opinion that the value should be 2.1 mg kg^{-1}_{dw}. The SCHEER endorses the values for freshwater and marine water of **AA-$QS_{fw,sed}$ = 2.1 mg kg^{-1}_{dw} and AA-$QS_{sw,sed}$ = 2.1 mg kg^{-1}_{dw}.**

The SCHEER agrees with the secondary poisoning section in the dossier and endorses the determined values: **$QS_{biota,secpois,ww}$ were 8.92 mg kg^{-1}_{ww} (rounded to 8.9 mg kg^{-1}_{ww}) for fish, 8.0 mg kg^{-1}_{ww} for crustaceans, and 2.59 mg kg^{-1}_{ww} (rounded to 2.6 mg kg^{-1}_{ww}) for bivalves).** The related QSwater,biota are determined at **4.96 µg L^{-1} (rounded to 5.0 µg L^{-1}) for fish**, was equal to **0.993 µg L^{-1} (rounded to 1.0 µg L^{-1}) for crustaceans, and 1.71 µg L^{-1} (rounded to 1.7 µg L^{-1}) for bivalves**. These values are endorsed by the SCHEER. With respect to human health and based on a study with benz[a]pyrene and read across a virtual Safe Dose (VSD) of 5.0 10^{-4} mg kg^{-1}_{bw} d^{-1} is applied to estimate the **$QS_{biota,hh}$ =6.1 µg kg^{-1}_{biota}** and the back-calculated water-based **$QS_{water,\ hh\ food}$= 7.6 x 10^{-4} µg L^{-1}** . The SCHEER endorses these values. For the exposure *via* drinking water, the general drinking water standard for fluoranthene (**$QS_{dw,hh}$ = 0.1 µg L^{-1}**) has been adopted. The SCHEER agrees with this conclusion.

The SCHEER suggests the **$QS_{water,\ hh\ food}$ = 7.6 x 10^{-4} µg L^{-1}**as the most critical EQS for the substance fluoranthene.

TABLE OF CONTENTS

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.
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).
For each substance, a comprehensive EQS dossier is or will be available. DG Environment is providing three EQS dossiers ahead of the 3-4 March SCHEER Plenary and expects to provide most of the remaining dossiers over the next three months. The dossiers contain much more information than simply the draft EQS; the SCHEER is asked to focus on the latter.

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

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.

3. OPINION

In a separate synthesis Opinion, the 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.

The SCHEER recalls that the SCHER Opinion (2011) criticised the value of the AF used for the establishment of the $QS_{sw,sed}$ and notes that the dossier takes into account that Opinion and has adjusted the QS accordingly.

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

Section 7 – Effects and Quality Standards

The dossier is a revision of the 2005 EQS factsheet, which was considered not totally consistent with the 2011 TGD on EQS and has now been revised using the 2018 TGD.

In addition, the SCHEER notes that the dossier refers several times to an unpublished report (in preparation) by Verbruggen (2012), whilst this report is already published and is also listed as a published report in the reference list.

The dossier notes that the toxicity of PAHs is affected by UV-light. Therefore, these effects are also considered in the dossier.

Unfortunately, the dossier uses a numbering system for its sections that differs from many other dossiers. The SCHEER adopts here its own standard numbering, that will, in the opinion of the SCHEER, prevent confusion.

Section 7.1 – Acute Aquatic Ecotoxicity (7.1.1 in the dossier)

The SCHEER agrees with the decision to combine the datasets for freshwater and marine water organisms as in this case sufficient data are available for an analysis of the difference in sensitivities, which was not evident in the data.

Deterministic approach

Based on the selection of the acute ecotoxicity data, the dossier defines the 96h-LC50 of 0.1 µg L^{-1} for *Pleuronectus americanus* as the most sensitive value. With an AF of 10 for freshwater and of 100 for marine water, this leads to a MAC-$QS_{fw,eco}$ of 0.01 µg L^{-1} and a $MAC_{sw,eco}$ of 0.001 µg L^{-1}.

Probabilistic approach

For the application of the probabilistic approach, data are available for ten taxonomic groups, which is sufficient. The SSD approach reveals an HC5 of 0.99 µg L^{-1}. As the toxicity data are all obtained in the presence of UV-light, a maximal AF of 10, proposed by the Technical Guidance for acute data, is applied to account for the uncertainty. The SCHEER endorses this approach. The dossier then proposes to determine an equal MAC-QS for freshwater and marine water of 0.099 µg L^{-1}. The reasoning for this as presented in the dossier is unclear to the SCHEER. Therefore, the SCHEER proposes a MAC-$QS_{fw,eco}$ of 0.099 µg L^{-1} and a MAC-$QS_{sw,eco}$ of 0.0099 µg L^{-1}.

Final MAC-QS

The SCHEER is, in conclusion, of the opinion that the SSD was constructed using the most sensitive species and, therefore, that the SSD-derived MACs should prevail over the deterministic MACs. The values of the MAC-$QS_{fw,eco}$ = 0.099 µg L^{-1} and the MAC-$QS_{sw,eco}$ = 0.0099 µg L^{-1} can be derived according to the SCHEER. The SCHEER supports these results. However, as will be shown in section 7.2, these values should not be endorsed as MAC-QSs for fluoranthene.

Section 7.2 – Chronic Aquatic Ecotoxicity (also 7.1.1 in the dossier)

The combined freshwater and marine water datasets in the dossier contain results of eight taxonomic groups, which is considered sufficient.

Deterministic approach

The lowest value in the dataset was found to be a 10d-NOEC of 1 µg L^{-1} for *Hyalella azteca*. By applying an AF of 10, the AA-$QS_{fw,eco}$ of 0.1 µg L^{-1} is determined. This result is endorsed by the SCHEER. The AA-$QS_{sw,eco}$ is then determined by applying an additional AF of 10. This gives the value for AA-$QS_{sw,eco}$ of 0.01 µg L^{-1}. This result is also endorsed by the SCHEER.

Probabilistic approach

The SSDs for acute and chronic toxicity appear to be quite similar. The resulting HC5 for the chronic dataset gives a value of 0.6 µg L^{-1} and applying the maximal AF of 5, proposed by the Technical Guidance for chronic data, because of the uncertainty due to the UV-intensity during the experiments, an AA-$QS_{fw,eco}$ of 0.12 µg L^{-1} can be derived and an additional AF of 10 for marine water gives AA-$QS_{sw,eco}$ of 0.012 µg L^{-1}. It should be noted here that this is in deviation with the dossier proposal where the MAC-$QS_{fw,eco}$, the MAC-$QS_{sw,eco}$, the AA-$QS_{fw,eco}$ and the AA-$QS_{sw,eco}$ are all proposed to be equal with a value of 0.12 µg L^{-1}. The SCHEER does not support that view.

Final AA-QS

In comparing the results of the deterministic and the probabilistic approach, the SCHEER, however, notes that the values of the chronic AA-QSs are higher than the acute MAC-QSs. In such cases the TGD prescribes that the MAC-QSs should be set equal to the AA-QSs. This procedure is endorsed by the SCHEER. In the opinion of the SCHEER, the following values should be endorsed: **AA-$QS_{fw,eco}$ = MAC-$QS_{fw,eco}$ = 0.12 µg L^{-1} and AA-$QS_{sw,eco}$ = MAC-$QS_{sw,eco}$ = 0.012 µg L^{-1}**.

Section 7.3 – Sediment Ecotoxicity (7.1.2 in the dossier)

The SCHEER notes with satisfaction that earlier comments of the SCHER have been taken into account in the Opinion of 30 March 2011 to lower the AF for marine water from 50 to 10. In addition, the SCHEER endorses the normalisation procedure to a 5% organic carbon content.

The SCHEER agrees with the decision to pool the data on sediment ecotoxicology as a statistical test showed the validity of this action.

With respect to the derived AA-$QS_{fw,sed}$ and AA-$QS_{sw,sed}$, the SCHEER endorses the values in the dossier, supporting the reasoning to derive the equal quality standards equally for freshwater and marine water. Therefore, the SCHEER is in agreement with the proposed

values: **AA-$QS_{fw,sed}$ = 2.1 mg kg^{-1}_{dw} and AA-$QS_{sw,sed}$ = 2.1 mg kg^{-1}_{dw}** both based on the 14d-$EC10_{reproduction}$ =41 mg kg^{-1}_{dw} for the organism *Schizopera knabeni*, which after normalisation leads to 21 mg kg^{-1}_{dw}, applying an AF of 10 for freshwater and marine water, which is in agreement with the suggestion of SCHEER (2011). Finally, it is not clear to the SCHEER why the value of 41 was reduced to 20 in the normalisation. This should be 20.5 rounded to 21.

The SCHEER also agrees with the decision made in the dossier not to apply the EP-method, as sufficient data are available for fluoranthene.

Section 7.5 – Secondary Poisoning (7.2 in the dossier)

The section on Secondary Poisoning has been completely changed compared to the 2011 version. The SCHEER agrees with this change.

Specific studies for fluoranthene are scarce in the scientific literature. However, a useful NOAEL of 125 mg $kg^{-1}_{bw}d^{-1}$ was identified. The SCHEER supports this value as the basis for the calculation of the $QS_{biota,sec\ pois,fw}$.

The SCHEER agrees with the statement in the dossier that fluoranthene has a potential risk of bioaccumulation with a BCF ≥ 100 and a Kow ≥ 3.

The calculation follows the TGD using the daily energy expenditure (DEE). The following equations are used:

$$log\ DEE = 0.8136 + 0.7149 * log\ bw \qquad Equation\ 1$$

$$C_{energy\ normalised} = dose * (bw / DEE) \qquad Equation\ 2$$

$$QS_{biota,sec\ pois,fw} = lowest\ chronic\ value\ or\ HC5 / AF \qquad Equation\ 3$$

$$QS_{water,biota} = QS_{biota,\ secpois,fw} / BAF \qquad Equation\ 4$$

In which:

DEE = daily energy expenditure in kJ d^{-1}

bw = body weight in g, in this case 25.75 g

$C_{energy\ normalised}$ = normalised energy used by the organism in µg kJ^{-1}

$C_{food\ item}$ = energy content of food in mg kg^{-1}_{ww} (see below)

$QS_{biota,sec\ pois,fw}$ = quality standard for secondary poisoning in mg kg^{-1} in this case the NOAEL of 125 mg $kg^{-1}_{bw}d^{-1}$ was used

$QS_{water,biota}$ = quality standard for biota in mg kg^{-1}

BAF = biomagnification factor (see below).

In the case of fluoranthene, the $C_{food,item}$ were not retrieved from the TGD but calculated directly from Verbruggen (2014): 267.73 mg kg^{-1}_{ww} for fish, 240.11 mg kg^{-1}_{ww} for crustaceans and 77.65 mg kg^{-1}_{ww} for bivalves. The finally achieved **$QS_{biota,secpois,ww}$ were 8.92 mg kg^{-1}_{ww} (**rounded to **8.9 mg kg^{-1}_{ww})** for **fish, 8.0 mg kg^{-1}_{ww}** for **crustaceans, and 2.59 mg kg^{-1}_{ww} (**rounded to **2.6 mg kg^{-1}_{ww})** for **bivalves.** The SCHEER endorses these values. Using Equation 4 with the maximum BAF values found (1799 L kg^{-1}_{ww} for fish, 8050 L kg^{-1}_{ww} for the benthic omnivore crab *Callinectes sapidus*, and for molluscs, 1507 L kg-1_{ww}), the **$QS_{water,biota}$** were determined as **4.96 µg L^{-1} (**rounded to **5.0 µg L^{-1})** for **fish**, was equal to **0.993 µg L^{-1} (**rounded to **1.0 µg L^{-1})** for **crustaceans, and 1.71 µg L^{-1} (**rounded to **1.7 µg L^{-1})** for **bivalves**. These values are endorsed by the SCHEER.

Section 7.6 – Human Health

For the human health risk via consumption of fishery products, according to the procedure described in the EQS Technical Guidance (EC, 2018), the following equation is applied:

$$QS_{biota\ hh\ food} = 0.2\ TL_{hh} / 0.00163$$

Where:

- $QS_{biota\ hh,food}$ = Quality standard for human health via consumption of fishery products (mg kg^{-1}_{biota})
- 0.2 = default fraction of TL_{hh} related to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies (mg kg^{-1}_{bw} d^{-1}). In this case, a Virtual Safe Dose (VSD) of 5.0 10^{-4} mg kg^{-1}_{bw} d^{-1} was derived based on a test with benzo[a]pyrene using a Relative Potency Factor of 0.01. In additional AF of 10 was used as well.
- 0.00163 (kg_{fish} kg_{bw}^{-1} d^{-1}) = estimated daily fishery products consumption (default 0.115 kg d^{-1}) per kg body weight (default 70 kg).

A **$QS_{biota,hh}$ =6.1 µg kg^{-1}_{biota}** is calculated, using the VSD of 5.0 10^{-4} mg kg_{bw}^{-1} d^{-1}. The SCHEER endorses this value as the calculations were performed correctly and the best assumptions possible were used.

Using the BAF for crustaceans of 8,050 L $kg^{-1}_{ww,}$ a back-calculated water-based **$QS_{water,\ hh\ food}$ for crustaceans = 7.62 x 10^{-4} µg L^{-1}** (rounded to **7.6 x 10^{-4} µg L^{-1}**) is obtained. This value is endorsed by the SCHEER.

For the exposure *via* drinking water, the general drinking water standard for fluoranthene (**$QS_{dw,hh}$ = 0.1 µg L^{-1}**) has been adopted. The SCHEER agrees with this conclusion.

4. CRITICAL EQS

In light of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) has been identified as the **$QS_{water,\ hh\ food}$ = 7.6 x 10^{-4} µg L^{-1}.**

5. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
AF	Application Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
DEE	Daily Energy Expenditure
EC	Effect Concentration
EQS	Environmental Quality Standards
HC	Hazardous Concentration
LC	Lethal Concentration
MAC-QS	Maximum Acceptable Concentration Quality Standard
NOAEL	No Adverse Effect Level
QS	Quality Standard
SSD	Species Sensitivity Distribution
TL	Threshold Level
VSD	Virtual Safe Dose
ww	wet weight
UV-light	Ultraviolet light

6. REFERENCES

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.

RIVM (2014). New method for the derivation of risk limits for secondary poisoning. E.M.J. Verbruggen.

SCHER (2011). Scientific Committee on Health and Environmental Risks SCHER. Opinion on "Chemicals and the Water Framework Directive: Draft Environmental Quality Standards" Fluoranthene, Adopted 20110330.