



**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



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## 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<sub>fw,eco</sub> = MAC-QS<sub>fw,eco</sub> = 0.12 µg L<sup>-1</sup> and AA-QS<sub>sw,eco</sub> = MAC-QS<sub>sw,eco</sub> = 0.012 µg L<sup>-1</sup>**. 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<sup>-1</sup><sub>dw</sub>. The SCHEER endorses the values for freshwater and marine water of **AA-QS<sub>fw,sed</sub> = 2.1 mg kg<sup>-1</sup><sub>dw</sub> and AA-QS<sub>sw,sed</sub> = 2.1 mg kg<sup>-1</sup><sub>dw</sub>**.

The SCHEER agrees with the secondary poisoning section in the dossier and endorses the determined values: **QS<sub>biota,secpois,ww</sub> were 8.92 mg kg<sup>-1</sup><sub>ww</sub> (rounded to 8.9 mg kg<sup>-1</sup><sub>ww</sub>) for fish, 8.0 mg kg<sup>-1</sup><sub>ww</sub> for crustaceans, and 2.59 mg kg<sup>-1</sup><sub>ww</sub> (rounded to 2.6 mg kg<sup>-1</sup><sub>ww</sub>) for bivalves**. The related QS<sub>water,biota</sub> are determined at **4.96 µg L<sup>-1</sup> (rounded to 5.0 µg L<sup>-1</sup>) for fish, was equal to 0.993 µg L<sup>-1</sup> (rounded to 1.0 µg L<sup>-1</sup>) for crustaceans, and 1.71 µg L<sup>-1</sup> (rounded to 1.7 µg L<sup>-1</sup>) 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<sup>-4</sup> mg kg<sup>-1</sup><sub>bw</sub> d<sup>-1</sup> is applied to estimate the **QS<sub>biota,hh</sub> = 6.1 µg kg<sup>-1</sup><sub>biota</sub>** and the back-calculated water-based **QS<sub>water,hh food</sub> = 7.6 x 10<sup>-4</sup> µg L<sup>-1</sup>**. The SCHEER endorses these values. For the exposure via drinking water, the general drinking water standard for fluoranthene (**QS<sub>dw,hh</sub> = 0.1 µg L<sup>-1</sup>**) has been adopted. The SCHEER agrees with this conclusion.

The SCHEER suggests the **QS<sub>water,hh food</sub> = 7.6 x 10<sup>-4</sup> µg L<sup>-1</sup>** as the most critical EQS for the substance fluoranthene.

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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<sup>1</sup>.

## 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.

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<sup>1</sup> <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  $0.1 \mu\text{g L}^{-1}$  for *Pleuronectes 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  $0.01 \mu\text{g L}^{-1}$  and a  $MAC_{sw, eco}$  of  $0.001 \mu\text{g L}^{-1}$ .

#### 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  $0.99 \mu\text{g L}^{-1}$ . 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  $0.099 \mu\text{g L}^{-1}$ . The reasoning for this as presented in the dossier is unclear to the SCHEER. Therefore, the SCHEER proposes a  $MAC-QS_{fw, eco}$  of  $0.099 \mu\text{g L}^{-1}$  and a  $MAC-QS_{sw, eco}$  of  $0.0099 \mu\text{g L}^{-1}$ .

## 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<sub>fw,eco</sub> = 0.099 µg L<sup>-1</sup> and the MAC-QS<sub>sw,eco</sub> = 0.0099 µg L<sup>-1</sup> 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<sup>-1</sup> for *Hyaella azteca*. By applying an AF of 10, the AA-QS<sub>fw,eco</sub> of 0.1 µg L<sup>-1</sup> is determined. This result is endorsed by the SCHEER. The AA-QS<sub>sw,eco</sub> is then determined by applying an additional AF of 10. This gives the value for AA-QS<sub>sw,eco</sub> of 0.01 µg L<sup>-1</sup>. 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<sup>-1</sup> 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<sub>fw,eco</sub> of 0.12 µg L<sup>-1</sup> can be derived and an additional AF of 10 for marine water gives AA-QS<sub>sw,eco</sub> of 0.012 µg L<sup>-1</sup>. It should be noted here that this is in deviation with the dossier proposal where the MAC-QS<sub>fw,eco</sub>, the MAC-QS<sub>sw,eco</sub>, the AA-QS<sub>fw,eco</sub> and the AA-QS<sub>sw,eco</sub> are all proposed to be equal with a value of 0.12 µg L<sup>-1</sup>. 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<sub>fw,eco</sub> = MAC-QS<sub>fw,eco</sub> = 0.12 µg L<sup>-1</sup> and AA-QS<sub>sw,eco</sub> = MAC-QS<sub>sw,eco</sub> = 0.012 µg L<sup>-1</sup>.**

## 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<sub>fw,sed</sub> and AA-QS<sub>sw,sed</sub>, 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<sub>fw, sed</sub> = 2.1 mg kg<sup>-1</sup><sub>dw</sub> and AA-QS<sub>sw, sed</sub> = 2.1 mg kg<sup>-1</sup><sub>dw</sub>** both based on the 14d-EC10<sub>reproduction</sub> = 41 mg kg<sup>-1</sup><sub>dw</sub> for the organism *Schizopera knabeni*, which after normalisation leads to 21 mg kg<sup>-1</sup><sub>dw</sub>, 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<sup>-1</sup><sub>bwd</sub> was identified. The SCHEER supports this value as the basis for the calculation of the QS<sub>biota, sec pois, fw</sub>.

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:

$$\log DEE = 0.8136 + 0.7149 * \log bw \quad \text{Equation 1}$$

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

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

$$QS_{\text{water, biota}} = QS_{\text{biota, sec pois, fw}} / BAF \quad \text{Equation 4}$$

In which:

DEE = daily energy expenditure in kJ d<sup>-1</sup>

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

C<sub>energy normalised</sub> = normalised energy used by the organism in µg kJ<sup>-1</sup>

C<sub>food item</sub> = energy content of food in mg kg<sup>-1</sup><sub>ww</sub> (see below)

QS<sub>biota, sec pois, fw</sub> = quality standard for secondary poisoning in mg kg<sup>-1</sup> in this case the NOAEL of 125 mg kg<sup>-1</sup><sub>bwd</sub> was used

QS<sub>water, biota</sub> = quality standard for biota in mg kg<sup>-1</sup>

BAF = biomagnification factor (see below).

In the case of fluoranthene, the C<sub>food, item</sub> were not retrieved from the TGD but calculated directly from Verbruggen (2014): 267.73 mg kg<sup>-1</sup><sub>ww</sub> for fish, 240.11 mg kg<sup>-1</sup><sub>ww</sub> for crustaceans and 77.65 mg kg<sup>-1</sup><sub>ww</sub> for bivalves. The finally achieved **QS<sub>biota, sec pois, ww</sub> were 8.92 mg kg<sup>-1</sup><sub>ww</sub> (rounded to 8.9 mg kg<sup>-1</sup><sub>ww</sub>) for fish, 8.0 mg kg<sup>-1</sup><sub>ww</sub> for crustaceans, and 2.59 mg kg<sup>-1</sup><sub>ww</sub> (rounded to 2.6 mg kg<sup>-1</sup><sub>ww</sub>) for bivalves.** The SCHEER endorses these values. Using Equation 4 with the maximum BAF values found (1799 L kg<sup>-1</sup><sub>ww</sub> for fish, 8050 L kg<sup>-1</sup><sub>ww</sub> for the benthic omnivore crab *Callinectes sapidus*, and for molluscs, 1507 L kg<sup>-1</sup><sub>ww</sub>), the **QS<sub>water, biota</sub> were determined as 4.96 µg L<sup>-1</sup> (rounded to 5.0 µg L<sup>-1</sup>) for fish, was equal to 0.993 µg L<sup>-1</sup> (rounded to 1.0 µg L<sup>-1</sup>) for crustaceans, and 1.71 µg L<sup>-1</sup> (rounded to 1.7 µg L<sup>-1</sup>) 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:

$$QS_{\text{biota hh food}} = 0.2 \text{ TL}_{\text{hh}} / 0.00163$$

Where:

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

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

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

For the exposure *via* drinking water, the general drinking water standard for fluoranthene ( $QS_{\text{dw, hh}} = 0.1 \text{ } \mu\text{g L}^{-1}$ ) 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  $QS_{\text{water, hh food}} = 7.6 \times 10^{-4} \text{ } \mu\text{g L}^{-1}$ .

## 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

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