Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (DL-PCBs)

The SCHEER adopted this document
Via written procedure on 24 January 2023

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 8 December to 13 January 2023). Comments received during this period were considered by the SCHEER. For this Opinion, no comment was received and the text did not change.

Keywords:
Dioxins, 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", Polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (DL-PCBs), 24 January 2023

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
Office: HTC 03/073 L-2920 Luxembourg
SANTE-C2-SCHEER@ec.europa.eu

ISSN ISBN
doi ND

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 "Polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (DL-PCBs)" is reviewed by the SCHEER according to the general mandate on EQS dossiers.

In the dossier only the biota sections (7.2 and 7.3) have been revised. However, the SCHEER recommends that section 7.1 (QS for water and sediments) should also be revised.

The SCHEER endorses the **$QS_{biota,\ secpois,\ fw}$ = 3.0 x 10^{-4} µg WHO_{2005} TEQ kg_{ww}^{-1} for fish**.

Due to the difficulties for defining a unique BMF value the $QS_{biota,\ secpois,\ sw}$ was not calculated. The SCHEER is of the opinion that at least a provisional/precautionary $QS_{biota,secpois,sw}$ should be proposed.

The SCHEER endorses the **$QS_{biota,\ hh,\ food}$ = 35 pg WHO_{2005} TEQ kg_{biota}^{-1}.**

The SCHEER agrees with the calculated value of $QS_{dw,\ hh}$ = 2.0 pg L^{-1} but disagrees with the conclusion of the dossier of not using this value as a standard due to the lipophilic properties of dioxin-like compounds.

Considering that the QS for water and sediment and for drinking water were not derived, the most critical EQS cannot be indicated by the SCHEER.

Finally, it is the opinion of the SCHEER that the $QS_{biota,\ hh\ food}$ should be adopted instead of the existing EU food limit for dioxin-like compounds.

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.

2.1. 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 limits 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

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.

For dioxins, the EQSs proposed in the 2011 EQS dossier have been revised considering the new Technical Guidance for EQS derivation updated in 2018 (EC, 2018) and recent literature data. In particular, the biota sections (7.2 and 7.3) have been revised.

However, given the environmental relevance of these chemicals, it is the opinion of the SCHEER that section 7.1 (QS for water and sediments) is also worth revising.

Assuming that PCDDs, PCDFs and DL-PCBs have the same mode of action, the development of the QS for the three groups o chemicals has been based on the Toxic Equivalence concept, using the toxic equivalency factors (TEFs) proposed by WHO (Van den Berg *et al.*, 2006). The SCHEER agrees with the approach.

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

Section 7. Effects and Quality Standards

Section 7.1. Acute and chronic aquatic ecotoxicity

7.1.1. Organisms living in the water column and 7.1.2. Sediment dwelling organisms

The dossier states that because of their hydrophobic nature, dioxins and dioxin-like compounds ultimately become associated with particulate matter and/or bioaccumulate in aquatic organisms. This determines uncertainties and difficulties of setting EQS. In an opinion on the 2011 dossier, it was recommended by the Scientific Committee on Health and Environmental Risks (SCHER, 2011) that biomarkers and other biological monitoring tools should be recommended in the case of dioxins assessment for water and sediment matrices.

A section on the relevance of biological monitoring for deriving water and sediment quality standard was already present in the 2011 dossier. However, no attempts for deriving a standard were made.

As a conclusion, QS (chemical or biological) for water and sediments are not proposed.

Is it the opinion of the SCHEER that, despite their hydrophobicity, the possibility of the presence of dioxin-like chemicals (in soluble or total form) in water as well in sediments,

at potentially dangerous levels, must not be disregarded. Therefore, the SCHEER recommends that QS for water and sediment would be derived.

Section 7.2. Secondary poisoning

The NOAEL of 4.7 x 10^{-7} mg-WHO_{2005} TEQ kg^{-1}_{bw} d^{-1} for survival of kits in mink (Bursian et al., 2013) is selected. In this study, PCB-126 represented the 74% of the total TEQ.

According with the EQS Technical Guidance (EC, 2018), the method based on energy-normalised diet concentrations is applied. The DEE (daily energy expenditure) is calculated with the following equation:

$$\log DEE\ [kJ/d] = 0.8136 + 0.7149 \cdot \log bw[g]$$

The bodyweight for adult male minks used in the experiment (erroneously indicated as rats in the dossier) is 1,186 g, leading to a DDE=1026 kJ d^{-1}.

The energy-normalised diet concentration is calculated with the following equation:

$$C_{energy\ normalised}\ [\mathrm{mg/kJ}] = dose \cdot \frac{bw\ (kg)}{DEE}$$

where the dose is the toxicological endpoint. The result is $C_{energy\ normalised}$ = 5.4 *10^{-10} mg kJ^{-1}.

The energy-normalised endpoint is converted into concentrations in the prey that is considered as the critical food item in the food chain, using the following equation:

$$C_{food\ item}\ [\mathrm{mg/kg_{ww}}] = C_{energy\ normalised}\ [\mathrm{mg/kJ}] \cdot Energycontent_{fooditem,dw} \cdot \left(1 - moisturefraction_{fooditem}\right)$$

The energy contents on a fw basis of 21 kJ g_{dw}^{-1} for fish and 19.3 kJ g_{dw}^{-1} for bivalves, and the respective moisture fractions of 73.7% and 91.7% were used (E.C., 2018). The result is: $C_{food\ item}$ = 2.9 x 10^{-6} mg kg_{ww}^{-1} for fish and 8.7 x 10^{-7} mg kg_{ww}^{-1} for bivalves. The procedure is correct, except for some minor differences probably due to approximation (correct values: 3.0 x 10^{-6} mg kg_{ww}^{-1} and 8.4 x 10^{-7} mg kg_{ww}^{-1} respectively).

An AF of 10 is applied to the $C_{food\ item}$ for fish, obtaining a final **$QS_{biota,\ secpois,\ fw}$ = 3.0 x 10^{-4} µg WHO_{2005} TEQ kg_{ww}^{-1} for fish**. The SCHEER endorses the QS.

For the marine environment, top-predators are fish-eating birds and mammals. According to the EQS Technical Guidance (EC, 2018), the $C_{food\ item}$ should be obtained multiplying the $C_{energy\ normalised}$ by the energy content of 23.2 kJ kg_{dw}^{-1} for birds and mammals and a dry weight fraction of 31.6% (erroneously indicated in the dossier as lipid fraction). The value obtained should be divided by the BMF for birds or mammals ($BMF_{b/m}$) according to the equation below and the AF chosen.

However, considering that BMFs vary between the different dioxin congeners and chemical classes, and the difficulties in deriving a unique BMF value, the $QS_{biota,\ secpois,\ sw}$ was not calculated.

The SCHEER is aware of these difficulties. However, considering the relevance of these highly bioaccumulative and persistent chemicals and the risk that they may pose to the global marine environment, it is the opinion of the SCHEER that at least a precautionary proposal should be made, for example proposing a reasonable worst case BMF based on the available data. Therefore, the SCHEER is of the opinion that a provisional/precautionary $QS_{biota,secpois,sw}$ should be proposed.

Finally, the SCHEER notes that, in the text, there is some confusion between dry weight and lipid fraction. In the Technical Guidance it is described that the $QS_{biota,secpois,sw}$ should be normalised on the basis of lipid **or** dry weight. One must be aware that the values reported in the dossier are dry weight fractions of the different food items.

Section 7.3. Human health

Human health via consumption of fishery products

The dossier discusses some recent toxicity data and finally selected the TDI of 0.286 pg WHO_{2005}-TEQ kg^{-1}_{bw} d^{-1} (EFSA, 2018) as the starting value to derive the $QS_{biota,\ hh}$. The SCHEER agrees with the selection.

According to the EQS Technical Guidance, the $QS_{biota,\ hh,\ food}$ should be derived from the equation:

$QS_{biota,\ hh\ food}$ = 0.2 * TDI / 0.00163

where:

- 0.2 = default fraction of TDI allocated to fishery products consumption
- 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).

The result is **$QS_{biota,\ hh,\ food}$ = 3.5 x 10^{-5} µg WHO_{2005} TEQ kg_{biota}^{-1} or 35 pg WHO_{2005} TEQ kg_{biota}^{-1}.** The SCHEER endorses the QS.

Human health via consumption of drinking water

According to the EQS Technical Guidance (EC, 2018), a provisional drinking water QS can be calculated using Equation 4:

$QS_{dw,\ hh}$ = $(0.2*TL_{hh}*bw)/uptake_{dw}$

where a daily uptake of drinking water ($uptake_{dw}$) of 2 litres is chosen (EC, 2018). This corresponds to 0.029 L kg_{bw}^{-1} d^{-1}. The calculated value is $QS_{dw,\ hh}$ = 2.0 pg L^{-1}. The calculation is correct. However, the units should be indicated as pg WHO_{2005} TEQ L^{-1} instead of pg L^{-1}.

The dossier refers to the WHO dioxin guidelines that mentions: "*no water quality guidelines have been set for these substances because of their low water solubility*" and concludes that the calculation of a standard in water is not deemed relevant given DL-compounds lipophilic properties.

Considering that most chemicals of the three groups (including 2,3,7,8-T_4CDD) may have a water solubility value higher than 2.0 pg WHO_{2005} TEQ L^{-1}, the SCHEER does not agree with this conclusion.

4. Critical EQS

Considering that the QS for water and sediment and for drinking water were not derived, the most critical EQS cannot be indicated by the SCHEER.

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 limits 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 agrees that in the EQS TGD there is some contradiction about the need of biota standards if an EU food limit exists. However, the SCHEER agrees with the statements on page 92 of the EQS TGD: "*After conducting this refined assessment, the revised* $QS_{biota\ hh\ food}$ *is again compared to the* $QS_{biota\ secpois}$ *and the more stringent would be adopted as the overall* QS_{biota}*. If an EU Food Limit exists and it is lower than the refined* $QS_{biota\ hh\ food}$*, then this would be adopted*". Therefore, it is the opinion of the SCHEER that $QS_{biota,\ hh\ food}$ and $QS_{biota\ secpois}$ must be derived and compared with the EU food limit.

For dioxin-like compounds, the EU food limit is equal to 0.0065 µg TEQ kg^{-1} (2013/39/EU). This value is two orders of magnitude higher than the $QS_{biota,\ hh\ food.}$ Therefore, it is the opinion of the SCHEER that the latter should be adopted.

6. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	body weight
DEE	Daily Energy Expenditure
DL-PCB	Dioxin-Like Polychlorinated Biphenyls
dw	dry weight, or drinking water
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
PCDD	Polychlorinated Dibenzo Dioxin
PCDF	Polychlorinated Dibenzo Furan
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TL	Threshold Level
ww	wet weight

7. 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.

SCHER (2011). Opinion on "Chemicals and the Water Framework Directive: Draft Environmental Quality Standards" - Dioxins. Unpublished and provisional Scientific Committee on Health and Environmental Risks opinion adopted as its 12th plenary on 30 March 2011