



**Scientific Committee on Health, Environmental and Emerging Risks
SCHEER**

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

Chlorpyrifos



The SCHEER adopted this document
at its plenary meeting on 15-16 June 2022

ACKNOWLEDGMENTS

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[Register of Commission expert groups and other similar entities \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&plugin=1)

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ABSTRACT

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

The SCHEER agrees with the final **MAC-QS_{fw, eco} = 2.6 ng L⁻¹** and **MAC-QS_{sw, eco} = 0.52 ng L⁻¹**, derived with a probabilistic procedure, on the basis of the data provided in the dossier. However, it is the opinion of the SCHEER that the availability of reliable data in the literature should be carefully checked.

The SCHEER accepts with reservations the deterministic **AA-QS_{fw, eco} = 0.46 ng L⁻¹** and **AA-QS_{sw, eco} = 0.046 ng L⁻¹**. The availability of reliable chronic data, including mesocosm studies, should be carefully checked.

For sediment ecotoxicity, the equilibrium partitioning procedure is applied, considering the scarcity of data, giving the results of **QS_{sediment, fw EqP} = 0.014 µg kg⁻¹_{dw}** and **QS_{sediment, sw EqP_{dw}} = 0.0014 µg kg⁻¹_{dw}**. It is the opinion of the SCHEER that the procedure is correctly applied. However, the availability of reliable sediment data should be carefully checked.

For secondary poisoning, the method based on energy normalised diet concentrations is applied giving the results of **QS_{fw, biota, secpois} = 0.044 mg kg⁻¹** for fish and **QS_{fw, biota, secpois} = 0.012 mg kg⁻¹** for bivalves. The back-calculation to water was performed only for fish leading to a **QS_{fw, biota} = 1.1 ng L⁻¹**. No BCF values are available for molluscs.

To protect top-predators the calculated values are **QS_{biota, secpois, sw} = 0.0022 mg kg⁻¹** for fish and **QS_{biota, secpois, sw} = 0.0013 mg kg⁻¹** for molluscs. The back-calculation to water was performed only for fish leading to a **QS_{sw, biota} = 0.057 ng L⁻¹**.

It is the opinion of the SCHEER that the procedures are properly applied. Therefore, the SCHEER endorses all the QSs for secondary poisoning.

For human health, the value of **QS_{biota, hh} = 120 µg kg⁻¹_{biota}** and the **QS_{water, hh food} = 3.2 ng L⁻¹** are calculated, using the ADI of 0.001 mg kg_{bw}⁻¹ day⁻¹, proposed by EFSA (2014). However, in a more recent EFSA assessment (EFSA, 2019), no human health reference value could be derived due to potential genotoxicity and the fact that the effects seen at the LOAEL of the key study (rat DNT) are considered biologically relevant for children (developmental neurotoxicity) and no NOAEL could be identified. Therefore, the SCHEER is of the opinion that the ADI given in the dossier must be considered with reservation and the EQS regarded as provisional.

For the exposure *via* drinking water, the SCHEER agrees with the adoption of the general drinking water standard for pesticides (**QS_{dw, hh} = 0.1 µg L⁻¹**).

The most critical EQS (in terms of impact on environment/health) has been identified as the **AA-QS_{sw, eco} = 0.046 ng L⁻¹**.

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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 SCHEER¹.

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.

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

Section 7 – Effects and Quality Standards

The EQSs proposed in the 2005 EQS dossier have been revised, considering recent literature data. However, the criteria used for the evaluation and the selection of new data were not described. This had been done for most other dossiers and it is the opinion of the SCHEER that it would have been useful here, particularly in relation to the comments made in the next sections.

Section 7.1 – Acute Aquatic Ecotoxicity

The dataset reports a relatively large amount of data on several taxonomic groups. However, chlorpyrifos is an intensively studied compound and many more studies than those listed in the dossier are available in the literature. Therefore, it is the opinion of the SCHEER that a clarification on the criteria for the selection of data is necessary.

The SCHEER agrees with the selection of the 96h LC50 on *Hyalella azteca* of $0.0138 \mu\text{g L}^{-1}$ as the most sensitive acute value.

Therefore, the $\text{MAC-QS}_{\text{fw,eco}} = 0.00138 \mu\text{g L}^{-1}$ (to be rounded to $0.0014 \mu\text{g L}^{-1}$) obtained with the deterministic procedure by applying an AF of 10 to the LC50 on *H. azteca* is endorsed by the SCHEER.

Considering the availability of data on marine species from three taxonomic groups (crustaceans, mollusks and fish), the use of an additional AF is not necessary. Therefore, the $\text{MAC-QS}_{\text{sw,eco}} = 0.0014 \mu\text{g L}^{-1}$ is also endorsed by the SCHEER.

For the application of the probabilistic approach, data are available for seven taxonomic groups with the exclusion of higher plants, which is one of the groups that should be represented in the SSD curve according to the Technical Guidance (EC, 2018). However, the SCHEER agrees with the assumption that, for chlorpyrifos, primary producers are not sensitive groups, while the most sensitive groups (arthropods) are largely represented. Therefore, the SCHEER agrees with the application of the probabilistic approach applied to the most sensitive group, according to the Technical Guidance. The best fitting curve was obtained with the SSD curve built on 24 arthropod data, excluding the outlier *Neocaridina denticulata*, whose low sensitivity is not justified.

Therefore, the $\text{MAC-QS}_{\text{fw,eco}} = 0.0026 \mu\text{g L}^{-1}$, obtained with the probabilistic procedure by applying an AF of 10 to the HC5 of $0.026 \mu\text{g L}^{-1}$ is endorsed by the SCHEER. The $\text{MAC-QS}_{\text{sw,eco}} = 0.00052 \mu\text{g L}^{-1}$ obtained with the probabilistic procedure by applying an AF of 50 to the HC5 of $0.026 \mu\text{g L}^{-1}$ is also endorsed by the SCHEER.

As final MAC-QS, the dossier proposes to choose those based on the probabilistic approach constructed with the most sensitive taxonomic group (arthropods) as more robust values. It is the opinion of the SCHEER that the procedure is properly applied. Therefore, the SCHEER agrees with the final **MAC-QS_{fw,eco} = 2.6 ng L⁻¹** and **MAC-QS_{sw,eco} = 0.52 ng**

L^{-1} derived on the basis of the data provided in the dossier. However, it is the opinion of the SCHEER that more data are available in international databases and that the availability of reliable data should be carefully checked.

Section 7.2 – Chronic Aquatic Ecotoxicity

The dataset reports only seven chronic values, four for freshwater organism and three for marine organisms, one of them for marine sediments. Three of them derive from the 2005 EQS dossier and two other values are relatively old (1990 and 1996). This is very surprising considering that the number of ecotoxicity values available for chlorpyrifos in the literature is enormous. In the US EPA ECOTOX dataset, more than 8500 values are reported, more than 4500 of them are more recent than 2005.

Based on these data, an AF of 10 is applied to the 35-d NOEC for growth of *A. bahia* and an **AA-QS_{fw, eco} = 0.00046 µg L⁻¹ or 0.46 ng L⁻¹** is derived with the deterministic approach. For the marine environment an additional factor of 10 is applied, leading to an **AA-QS_{sw, eco} = 0.000046 µg L⁻¹ or 0.046 ng L⁻¹**. The probabilistic approach is not applied due to insufficient data to meet the criteria.

It is the opinion of the SCHEER that the procedure is properly applied, based on the data provided in the dataset. However, the availability of reliable chronic data, including mesocosm studies, should be carefully checked.

The SCHEER is aware that these low QSs may be problematic for analytical detection.

Section 7.3 – Sediment Ecotoxicity

Two acute and one chronic marine sediment data are available in the dossier. No data for freshwater sediment are available in the dossier. Based on these data, a QS_{sediment, fw} and a QS_{sediment, sw} both equal to 0.66 µg kg⁻¹ are calculated.

Considering the scarcity of sediment data, the equilibrium partitioning procedure is also applied giving the result of the **QS_{sediment, fw EqP} = 0.0143 µg kg⁻¹_{dw}**, (to be rounded to **0.014 µg kg⁻¹_{dw}**) and a **QS_{sediment, sw EqP} = 0.00143 µg kg⁻¹_{dw}** (to be rounded to **0.0014 µg kg⁻¹_{dw}**).

The procedures are properly applied based on the data provided in the dataset. However, as for the previous QSs, it is the opinion of the SCHEER that the availability of reliable sediment data should be carefully checked.

Section 10 - Secondary Poisoning

The method followed in the dossier, according with the EQS Technical Guidance (EC, 2018), is that based on energy-normalised diet concentrations. The calculation is based on the following procedure: The DEE (daily energy expenditure) is calculated with the following equation that represents the regression (experimentally determined) between DEE and body weight in mammals:

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

The energy-normalised diet concentration can now be calculated with the following equation:

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

where the dose is the toxicological endpoint.

For chlorpyrifos, the 2-year-NOAEL of 0.1 mg kg_{bw}⁻¹ d⁻¹ for neurotoxicity for rats was used. This value was also used for deriving the ADI of 0.001 mg kg_{bw}⁻¹ d⁻¹ by EFSA (2014).

Using a value of 325.7 g, corresponding to the geometric mean of the default bodyweight (bw) of male and female rats, a DEE of 407.4 kJ d⁻¹ and a C_{energy normalised} of 0.08 µg kJ⁻¹ was calculated.

To derive thresholds for secondary poisoning, the energy-normalised endpoints should be converted into threshold concentrations in the prey that is considered as the critical food item in the food chain, using the following equation:

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

or:

$$C_{\text{food item}} [\text{mg/kg}_{\text{ww}}] = C_{\text{energy normalised}} [\text{mg/kJ}] * \text{energy content}_{\text{food item, fw}}$$

using an energy content of 5523 kJ kg_{fw}⁻¹ for fish and of 1602 kJ kg_{fw}⁻¹ for bivalves (RIVM, 2014), and applying an AF of 10 to the C_{food item}, the results are:

- **For fish: QS_{fw, biota, secpois} = 0.044 mg kg⁻¹**
- **For bivalves: QS_{fw, biota, secpois} = 0.012 mg kg⁻¹**

For the back-calculation to water, a BAF for fish of 38,686 is calculated, according to the EQS Technical Guidance (EC, 2018), from the BCF (3868.6 L kg_{ww}⁻¹,) multiplied by the default biomagnification factor (BMF=10 for chemicals with log Kow>5).

This led to a **QS_{fw, biota} for fish = 1.14 x 10⁻⁶ mg L⁻¹ (to be rounded to 1.1 ng L⁻¹).**

No data are available on the BCF for molluscs.

To protect top-predators, fish-eating birds and marine mammals, according to the EQS Technical Guidance (EC, 2018), the QS_{biota, secpois, fw} was divided using the default BMF_{b/m} of 10 kg_{ww} kg_{ww}⁻¹ and lipid normalised using default lipid dry weight fractions for birds/mammals (10%), fish (5%) or bivalves (1%). The results are:

- **For fish: QS_{biota, secpois, sw} = 0.0022 mg kg⁻¹**
- **For bivalves: QS_{biota, secpois, sw} = 0.00128 mg kg⁻¹ (to be rounded to 0.0013 mg kg⁻¹).** (not QS_{biota, secpois, fw}, as indicated in the dossier).

The back-calculation to water led to a **QS_{sw, biota} = 0.057 ng L⁻¹**, using the BAF for fish.

It is the opinion of the SCHEER that the procedure is properly applied. Therefore, the SCHEER endorses all the QSs for secondary poisoning.

The SCHEER is aware that these low QSs may be problematic for analytical detection.

Section 11 – 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:

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

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 (ADI or TDI) (mg kg⁻¹_{bw} d⁻¹)

- $0.00163 \text{ (kg}_{\text{fish}} \text{ kg}_{\text{bw}}^{-1} \text{d}^{-1})$ = estimated daily fishery products consumption (default 0.115 kg d^{-1}) per kg body weight (default 70 kg).

A $QS_{\text{biota, hh}} = 122.7 \text{ } \mu\text{g kg}^{-1} \text{biota}$ (to be rounded to **$QS_{\text{biota, hh}} = 120 \text{ } \mu\text{g kg}^{-1} \text{biota}$**) is calculated, using the ADI of $0.001 \text{ mg kg}_{\text{bw}}^{-1} \text{ day}^{-1}$, proposed by EFSA (2014).

For the back calculation of the $QS_{\text{water, hh food}}$ the estimated BAF on fish is used, leading to a **$QS_{\text{water, hh food}} = 0.00317 \text{ } \mu\text{g L}^{-1}$** (to be rounded to **$QS_{\text{water, hh food}} = 3.2 \text{ ng L}^{-1}$**).

It is the opinion of the SCHEER that the procedures are properly applied, on the basis of the quoted ADI. However, from a more recent EFSA assessment (EFSA, 2019), no human health reference value could be derived due to potential genotoxicity and the fact that the effects seen at the LOAEL of the key study (rat DNT) are considered biologically relevant for children (developmental neurotoxicity) and no NOAEL could be identified. Therefore, SCHEER is of the opinion that the ADI in the dossier must be considered with reservation and the EQS assumed as provisional.

For the exposure *via* drinking water, the general drinking water standard for pesticides (**$QS_{\text{dw, hh}} = 0.1 \text{ } \mu\text{g L}^{-1}$**) 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 **AA- $QS_{\text{sw, eco}} = 0.046 \text{ ng L}^{-1}$** .

However, it is the opinion of the SCHEER that other relevant and reliable data are available that should be further checked and assessed for the refinement of the Qs presented in the dossier. This could result in a change of the most critical EQS.

5. 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
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
PPP	Plant Protection Products
QS	Quality Standard
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TL	Threshold Level
ww	wet weight

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.

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