



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

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

Dicofol



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:

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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-SCHEER@ec.europa.eu

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ABSTRACT

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

The current review of the dicofol dossier was carried out after comments of the SCHER in 2011 that indicated a need to reassess the QS_{biota} value in the light of the available literature. According to the dossier, only changes have been made to accommodate the original comments of the SCHER. This resulted in new values for QS_{biota} and $QS_{biota, sec\ pois}$ specifically for marine waters being recommended. The SCHEER agrees with this approach.

The SCHEER is of the opinion that the dicofol dossier should be updated taking into account available data on ecotoxicology taken from the pesticide dossier and from newly available data from the last ten years.

It is the opinion of the SCHEER that the procedures on secondary poisoning are properly applied. The SCHEER agrees that secondary poisoning is relevant for dicofol. The SCHEER is of the opinion that the procedures available for the derivation of $QS_{biota, secpois, fw}$ are correctly applied. Therefore, the SCHEER endorses the values for $QS_{biota, secpois, fw}$ of **110 $\mu\text{g kg}_{ww}^{-1}$ for fish** and **$QS_{biota, secpois, sw} = 4.6 \mu\text{g kg}_{ww}^{-1}$ for fish**, respectively.

For human health, the value of **$QS_{biota, hh} = 270 \mu\text{g kg}_{biota}^{-1}$** is calculated, using the ADI of $0.0022 \text{ mg kg}_{bw}^{-1} \text{ d}^{-1}$. The dossier calculates the **$QS_{water, hh, food}$ as $0.01 \mu\text{g L}^{-1}$** . The SCHEER endorses this conclusion.

For the exposure *via* drinking water, the SCHEER agrees with the adoption of the general drinking water standard for pesticides (**$QS_{dw, hh} = 0.1 \mu\text{g L}^{-1}$**).

The SCHEER is not able to advise yet on the most critical EQS because the dossier of dicofol should be updated.

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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.

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.

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.

Because the SCHEER was asked specifically to evaluate the revision of the QSs that relate to EQS for secondary poisoning of top predators ($QS_{\text{secpois,biota}}$) and for human health due to food uptake ($QS_{\text{biota,hh}}$), the SCHEER did not evaluate other QSs in the Dossier. Those other QSs were originally evaluated in 2011.

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

Section 3.1 – Environmental Quality Standard (EQS)

The SCHEER notes that in the table on Proposed QS of 2022 the second 'Corresponding AA-EQS in [freshwater] [$\mu\text{g/l}$]' should be read as 'Corresponding AA-EQS in [marine water] [$\mu\text{g/l}$]'.

Section 7.1 – Acute and chronic aquatic ecotoxicology

Dicofol is a pesticide that is not registered in the EU anymore. Nevertheless, aquatic ecotoxicity data available from that dossier could have been included as well. The SCHEER notes that since 2010, many more studies should be available. The SCHEER, therefore, recommends an update of the dossier including the aquatic ecotoxicity data and thus potentially revising all other QSs for dicofol.

Section 7.5 – Secondary Poisoning

The 2011 evaluation of the SCHER invited the Commission to search for additional information concerning secondary poisoning. The current dossier fills this gap. The SCHEER appreciates the new dossier with these additional data.

The dossier determines two possible studies presenting a useful NOEC for the derivation of the $QS_{\text{biota,secpois}}$: the NOEC of $1 \text{ mg kg}_{\text{ww}}^{-1}$ for *Falco sparverius* and the NOAEL of $2.5 \text{ mg kg}_{\text{bw}}^{-1} \text{ d}^{-1}$ for *Anas platyrhynchos*. Using Equation 1, the normalised energy content for *A. platyrhynchos* appears to be lower than for *F. sparverius*. Therefore, the first species is chosen to take forward in the calculations. The SCHEER supports this procedure.

The critical food item is considered to be fish. Following the parameter selection according to the TGD (energy content dry weight and moisture fraction of 73.7%), a $C_{\text{food item}}$ of $1.1135 \text{ mg kg}_{\text{ww}}^{-1}$ for fish is determined. The SCHEER also agrees with this result.

$$\begin{aligned} C_{\text{energy normalized}} &= C_{\text{diet}} / (\text{energy content}_{\text{diet,dw}} * (1 - \text{moisture fraction}_{\text{diet}})) \\ &= C_{\text{diet}} / \text{energy content}_{\text{diet,dw}} \end{aligned} \quad \text{Equation 1}$$

In which:

$$\begin{aligned} C_{\text{energy normalised}} &= \text{normalised energy used by the organism in } \mu\text{g kJ}^{-1} \\ C_{\text{food item}} &= \text{energy content of food in } \text{mg kg}_{\text{ww}}^{-1} \text{ (see below)} \end{aligned}$$

$QS_{\text{biota,sec pois, fw}}$ = quality standard for secondary poisoning in mg kg^{-1} in this case the NOAEL of $2.5 \text{ mg kg}_{\text{bw}}^{-1} \text{ d}^{-1}$ was used.

For the marine environment the $QS_{\text{biota,secpois,sw}}$ is calculated according to:

$$QS_{\text{biota,secpois}} = (\text{lowest chronic value}/(\text{AF} \cdot \text{BMF}_{\text{b/m}})) \cdot (\text{lipid weight fraction}_{\text{fish}}/\text{lipid weight}_{\text{b/m}})$$

Equation 2

The SCHEER supports the final calculated result: $QS_{\text{biota,secpois,sw}} = 4.62 \text{ } \mu\text{g kg}_{\text{ww}}^{-1}$ for fish (rounded to **$QS_{\text{biota,secpois,sw}} = 4.6 \text{ } \mu\text{g kg}_{\text{ww}}^{-1}$ for fish**).

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 ($\text{mg kg}_{\text{biota}}^{-1}$)
- 0.2 = default fraction of TL_{hh} related to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies ($\text{ADI} = 0.0022 \text{ mg kg}_{\text{bw}}^{-1} \text{ d}^{-1}$)
- 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 $QS_{\text{biota, hh}} = 269.9 \text{ } \mu\text{g kg}_{\text{biota}}^{-1}$ (to be rounded to **$QS_{\text{biota, hh}} = 270 \text{ } \mu\text{g kg}_{\text{biota}}^{-1}$**) is calculated,. The SCHEER endorses this value.

The dossier calculated the $QS_{\text{water, hh, food}}$, using a BAF of 25,000. The SCHEER agrees with this selection and endorses the calculated value of **$QS_{\text{water, hh food}}$ of $0.01 \text{ } \mu\text{g L}^{-1}$** .

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

Given the current Dossier, the SCHEER is not able to advise on the most critical EQS, because of missing data, although the dossier indicates that the $QS_{\text{biota,sec.pois}}$ could be the most critical QS, but the final value should be established only after the recommended update of the dossier for dicofol.

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
EQS	Environmental Quality Standards
NOAEL	No Adverse Effect Level
NOEC	No Effect Concentration
QS	Quality Standard
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.