Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

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

Triclosan

The SCHEER adopted this document
By written procedure on 16 January 2023

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ABSTRACT

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

The SCHEER endorses the deterministic values for **MAC-$QS_{fw, eco}$ of 0.019 µg L^{-1} and MAC-$QS_{sw, eco}$ of 0.0019 µg L^{-1}**. The SCHEER does not endorse the SSD-derived values for MAC-$QS_{fw, eco}$ of 0.068 µg L^{-1} and MAC-$QS_{sw, eco}$ of 0.0068 µg L^{-1} because the pH of several of the tests that formed the basis of the probabilistic derivation has not been mentioned or measured, which is a critical test condition considering the pKa of triclosan. The SCHEER is of the opinion that where the pH of test studies was not available, the test results should not have been used in the probabilistic derivation.

The SCHEER confirms that the QS_{sed} values have been correctly calculated from the database in the Draft dossier. The SCHEER endorses the resulting **AA-QS_{fw-sed}= 180 µg kg^{-1}** and **AA-QS_{sw-sed}= 18 µg kg^{-1}.**

The SCHEER does not endorse the $QS_{biota, secpois,fw}$ of 0.89 mg kg^{-1}_{ww} for fish and 0.26 mg kg^{-1}_{ww} for bivalves and the resulting $QS_{fw, biota}$ for fish (0.79 µg L^{-1}) and $QS_{fw, biota}$ for bivalves (0.23 µg L^{-1}) because according to the SCHEER the calculations of DEE and $C_{energy\ normalised}$ are erroneous and because the SCHEER does not agree with the adequacy of the reference value (RfD) used. Consequently the SCHEER endorses neither the $QS_{biota, secpois,sw}$ obtained after lipid normalisation nor the back-calculations to water ($QS_{sw, biota}$ for fish and bivalves).

The SCHEER does not endorse the proposed $QS_{biota\ hh}$ and $QS_{biota\ hh\ food}$ values, because the SCHEER does not agree with the adequacy of the reference value used as TL_{hh}.

The most critical EQS (in terms of impact on environment/health) could not be identified by the SCHEER because the overall set of QSs endorsed by the SCHEER is incomplete as a result of the shortcomings mentioned above.

The SCHEER notes that antimicrobial resistance thus far is not considered in the derivation of the QS and recommends that a section on how to deal with AMR be included in the Technical Guidelines.

The SCHEER recommends further investigation of triclosan's effects on reproduction and on endocrine sensitive endpoints so that these effects can be included in the assessment of the ecotoxicity of Triclosan in the near future.

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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 on Deriving EQS (TG-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 TG-EQS;
2. whether the most critical EQS (in terms of impact on environment/health) have been correctly identified.

For each substance, a comprehensive EQS dossier is or will be available. 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.

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

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 several other substances and dossiers.

According to the 'Appendix 15-Triclosan' received by the SCHEER, two documents were submitted to the SCHEER, viz. the Triclosan EQS dossier and a document entitled 'MEC Triclosan'. However, the SCHEER received a single dossier entitled 'JRC_Draft EQS Dossier_Triclosan_21.12.2021_final' (from now on referred to as 'Draft dossier'). Specific comments on the sections of the dossier are listed below.

Section 7 – Effects and Quality Standards

The criteria for the selection of acute and chronic data for the derivation of EQS are described in the Draft dossier. Literature data before 2017 were taken from the Triclosan dossier (2017) and from a data search for the period 2017-2021, using the US EPA's Abstract Sifter/PubMed. Forty-two selected studies were assessed for their relevance and reliability by the JRC using the in-house developed JRC Literature Evaluation Tool (LET), which is based on the CRED evaluation method (Moermond *et al.*, 2016), and by reliability class assignment (Klimisch *et al.*, 1997). Subsequently, key data were selected taking into account the following considerations:

- *A single endpoint per species was selected based on the lowest relevant endpoint observed. If multiple reliable values were available for the same species and the same endpoint originating from similar tests, the geometric mean was considered for acute and chronic data.*
- *Unbound values were not used directly for the EQS derivation but were considered as supporting information when selecting the assessment factor.*

The data were selected based on the LET reliability score, i.e. only data with reliability 1 or 2 were selected. Several studies with a reliability score of 2 were however not included in the final selection, based on considerations that are reflected in the Appendix 2: 'Comments from Triclosan dossier 2017'. In these considerations an additional reliability class RI 1-4, according to the Klimisch (1997) criteria of the several studies is discussed based on aspects like test conditions, such as cosolvent concentration, pH, etcetera, and nominal or actual concentration. The non-included studies with LET=2 were used as 'Supporting information' instead. It is the opinion of the SCHEER that the criteria are acceptable for the selection of the ultimate dataset used; however, it should be explicitly clarified in the dossier which data were transferred from the main table in the appendix to the table in chapter 7. Moreover, the SCHEER is aware of studies that are not mentioned in Appendix 1 (e.g., Johansson et al, 2014, Eriksson *et al.*, 2015), illustrating a lack of transparency of how studies were selected for the dossier.

Section 7.1 – Acute Aquatic Ecotoxicity

In the table reporting acute toxicity data, data on algae (both fw and sw), (cyano) bacteria (fw and sw), vascular plants (fw), protozoa (fw), crustaceans (fw and sw), fish (fw), and amphibians are reported. The data sets for freshwater and marine species were pooled.

The pH of some studies is discussed (Appendix 2 of the Dossier), but it is not clearly explained whether to include or discard studies where no pH data are available. This is a relevant point because of triclosan's pKa (7.9-8.0), which is close to environmental pH values. The SCHEER recommends rejecting studies that did not explicitly mention the pH of the study. According to the TGD (EU 2018, p.144)*" Test results should be rejected when the*

toxicity in a given study is not caused by the compound alone, but also by a pH change. Hence, results from tests with ionisable compounds performed in buffered media (providing sufficient buffering capacity) are more reliable than those performed without a buffer. Studies that explicitly measure pH after addition of the toxicant are most useful in this respect." It is not clear to the SCHEER if this type of evaluation has been conducted in the dossier. For this reason, the SCHEER cannot endorse the current probabilistic derivation of MAC-$QS_{fw,eco}$ and recommends recalculating the SSD with those studies where pH data was included.

For the deterministic derivation of the EQS, a study was selected that mentioned the test pH and therefore the resulting EQS is acceptable for the SCHEER. The lowest value reported in the acute dataset result is the mean of ErC_{50} for the green alga *Scenedesmus vacuolatus* of 1.85 µg L^{-1}.

In agreement with the EQS Technical Guidance (2018), for the deterministic approach the dossier proposes an assessment factor (AF) of 100 for derivation of the MAC-QS, because at least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, crustaceans and algae) is reported in the dataset. The initial **MAC-$QS_{fw, eco}$** estimate presented in the dossier is thus equal to **0.019 µg L^{-1}** (rounded value). Based on the data provided by the dossier, the SCHEER can agree with the AF proposed, but recommends that the motivation why this AF is used, namely that the standard deviation in the data is larger than 3, be mentioned in the dossier.

For marine waters, the marine dataset is not complete, lacking data for saltwater fish species. However, combining the freshwater and the marine water datasets, species representing three trophic levels are represented and an AF of 1000 can be applied. The SCHEER endorses the resulting initial **MAC-$QS_{sw, eco}$ = 0.0019 µg L^{-1}**.

For both MAC-$QS_{sw,eco,}$ the probabilistic procedure was also applied since there were short-term data for species from 8 taxa. According to the TGD, a reduced SSD (that was used in the Dossier) can be used (i) if the mode of action is known, and (ii) if (in relation to known mode of action) sufficient data are available on the most sensitive taxonomic group. The SCHEER is of the opinion that using a reduced dataset can only be warranted if the mode of action is known (see page 44 of the TG). In the case of triclosan, although algae are identified as the most sensitive species, similarities have been described between fatty acid and lipid synthesis pathways in bacteria, algae, and plants. Therefore, plants are susceptible to receptor-mediated responses to triclosan (Fulton *et al.*, 2009; Brain *et al.*, 2008). Therefore, the SCHEER considers the procedure acceptable.

However, because of the reasons explained above about the need for considering pH, some of the data used for the probabilistic procedure should not have been used. Therefore, it is the opinion of the SCHEER that the probabilistically derived values cannot be endorsed.

Section 7.2 – Chronic Aquatic Ecotoxicity

For the derivation of AA-$QS_{fw,eco}$, data from cyanobacteria (1 species), algae (5 species), aquatic vascular plants (2 species), molluscs (1 species), crustaceans (3 species), insects (1 species), fish (4 species), and amphibians (2 species) were available. In addition, the reliable saltwater long-term dataset includes algae (2 species), and echinoderms (1 species). The datasets from freshwater and salt water were merged. Finally, data from two mesocosm studies were available. The resulting NOECs from the mesocosm studies were below 0.1 µg L^{-1}.

A discussion between industry experts and Member State experts is presented in an annex to the Draft dossier and focuses on thyroidal hypertrophy and hindlimb length test-EC10s for *Xenopus* sp. According to the Draft dossier there was "a reluctance" to use histopathological endpoints, and endocrine effects were therefore disregarded, although the

dossier confirms that such effects might be an issue and the low values (i.e., high toxicity) obtained for amphibians and snails, that were not considered in the derivation of the AAs, could be explained by such effects. It is the opinion of the SCHEER that the available data on amphibians and snails should not be disregarded. As a result, a deterministic value should be recalculated. At the same time, any studies which have not reported the pH should be excluded.

The lowest long-term test result selected was a value of 0.78 µg L^{-1}. This value is the geometrical mean of the results from two different studies: Drottar *et al.* (1998) and CIBA-Geigy study 43118, for which no reference is provided. From the Table 9.2 provided in the appendix to the Draft dossier it appears that this value is the geometric mean obtained from two different tests with the same species: *Desmodesmus subspicatus* (CIBA 1995; CIBA 1997; with reliabilities of 2 and 1, respectively), which is in agreement with the TG. However, neither of the two refs appear in the reference list of the Draft dossier. In the table with selected values for chronic effects (p.26-27 of the Draft dossier) this geometric mean is given together with two refs Drottar & Krüger (1998), Ciba-Geigy (1997). The Drottar & Krüger (1998) study is on *Anabaena*, however. The Draft dossier does not provide information on the pH conditions of these two studies, and it was not possible for the SCHEER to obtain and check these references. The value was correctly calculated but the SCHEER recommends that the Draft dossier provides the appropriate references and the pH of the tests so that these can be checked by evaluators.

An AA-$QS_{fw,eco}$ = 0.078 µg L^{-1} is proposed, obtained with the deterministic procedure by applying an AF of 10. Similarly, for the marine environment, the deterministic approach, using an additional AF of 5 since the data set includes one marine species, results in an AA-$QS_{sw,eco}$ = 0.016 µg L^{-1}. According to the SCHEER, these values have been derived correctly but cannot be endorsed because of the shortcomings noted above.

The application of the SSD method results in an HC_5 of 0.58 µg L^{-1}, to which an AF of 5 is applied to result in an AA-$QS_{fw,eco}$ of 0.116 µg L^{-1} (rounded to 0.12 µg L^{-1}). The SCHEER does not endorse this value for the same reasons as given above for the probabilistic derivation of MAC values. In addition, the SCHEER notes that the critical paragraph in the Draft dossier (directly below the second figure with the number 71.3) contains several mistakes. The text refers to an SSD on cyanobacteria and green algae alone (this is also erroneously reported in the caption of figure 71.3) while the SSD used is on all 22 data from the table at pages 26-28, including the data on amphibians. Moreover, the text states: ”while an SSD, snails and amphibians would show a clearly non-normal distribution”. This contradicts what is stated in the previous paragraph, where the normal distribution of the total dataset is confirmed. The whole section is confusing and contains numerical errors, and therefore needs rewriting in the opinion of the SCHEER.

Mesocosm study results were also available. The calculation from the available LOEL of 0.5 µg L^{-1} (for periphyton response) resulted in a NOEC of 0.1 µg L^{-1}. Next, an AF of 5 was applied to the NOEC resulting in an **AA-$QS_{fw\ eco}$ equal to 0.02 µg L^{-1}**. The SCHEER endorses these values.

In so far as the marine environment is concerned, the SCHEER agrees with the calculations of the AA-$QS_{sw,\ eco}$ = 0.023 µg L^{-1} (rounded value) obtained with the SSD approach through the application of an AF of 5 to the HC_5 and an additional AF of 5 because one specific marine taxonomic group (Echinodermata) is present in the dataset. However, the SCHEER does not endorse the numerical values as a result of earlier remarks.

Final QS water

The SCHEER cannot comment on the final QS. Both AA values proposed in the Dossier, AA-QS_{fw} (0.02 µg L^{-1}) and AA-QS_{sw} (0.023 µg L^{-1}) are higher than the respective MAC values proposed (MAC-$QS_{fw,\ eco}$ = 0.019 µg L^{-1}, MAC-$QS_{sw,\ eco}$ = 0.0019 µg L^{-1}). The technical guidance instructs in such cases setting the MAC-QS equal to the AA-QS. This is indeed

proposed in the Draft dossier for the MAC-$QS_{fw,\ eco}$, but not for the MAC-$QS_{sw\ eco}$. It is not clear to the SCHEER why this is not done for the MAC-$QS_{sw\ eco}$.

However, as pointed out above, the SCHEER does not endorse the AA values derived in the Dossier because the pH of some of the studies is either not measured or not reported. Moreover, freshwaters and marine waters have different pH values and such differences should be taken into account when evaluating toxicity test results. The SCHEER, therefore, cannot evaluate if AA values exceed the proposed MAC values.

Section 7.3 – Sediment Ecotoxicity

For the derivation of the sediment QS, the Draft dossier, test results for nine species are provided in the sediment ecotoxicity data set (Table 9.3 in Appendix 1). Reliability scores are given for seven of these tests, varying from 2-4. The Tamura *et al.* (2013) long-term (20d) study was the only study given a reliability index of 2. The Draft dossier does not clarify if the reliability index was the sole criterion used for selecting the NOEC used for deriving the QS.

For sediment dwelling organisms, a value of EC_{10} = 7 mg kg^{-1} for *Chironomus yoshimatsui* (Tamura *et al.* 2013) has thus been selected. The Draft dossier comments that it is not clear whether the concentrations in that study had been measured or are nominal, but used the data nevertheless. However, the SCHEER checked the original reference and noted that the concentrations had been measured by appropriate analytical methods and therefore concludes that the data from the Tamura *et al.* (2013) study are acceptable. This study was performed using a sediment with a total organic carbon content of 2%.

Much lower data (both NOECs of 7.5 µg kg^{-1}) observed for embryonal development in a study with a bivalve and a sea urchin (Pusceddu *et al.*, 2018) were rejected because it was deemed questionable if larval development is relevant as the eggs are shed into the water and the larvae are pelagic. The reliability of the Pusceddu *et al.* study was given a score of 4. The SCHEER agrees with the decision to exclude the Pusceddu *et al.* study.

In accordance with the EQS Technical Guidance (EC, 2018), the NOEC value has been normalised to a standard organic carbon content of 5%. The normalised NOEC is thus equal to 17.5 mg $(0.05\ kg)^{-1}$ OC (350 mg kg^{-1} OC).

The AA-$QS_{freswater\text{-}sed}$ is derived by applying an AF of 100 to the normalised NOEC, because only one reliable long-term test is reported in the dataset. Accordingly, a final **AA-$QS_{fw\text{-}sed}$= 180 µg kg^{-1}** (rounded value) is obtained.

For the marine environment, an AF of 1000 is applied on the same NOEC, leading to an **AA-$QS_{sw\text{-}sed}$= 18 µg kg^{-1}** (rounded value). The SCHEER notes that the value expressed per kg OC (350 mg kg^{-1} OC) in the Draft dossier is wrong and should be corrected to 350 µg kg^{-1} OC.

The SCHEER confirms that the QS value has been correctly calculated using the database in the dossier.

Section 7.5 - Secondary Poisoning

Due to the high Kow (log Kow=4-5), triclosan is likely to be accumulated. The experimental BCFs available vary highly, i.e., between 2.7 and 8700 L kg^{-1}. The high variability may be explained by the metabolic/excretion potential of some species. However, since the trigger value of BCF=100 is exceeded (in some instances), there is a need for the evaluation of 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:

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

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

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

where the dose is the toxicological endpoint.

For triclosan, a LOAEL for mice (25 mg $kg_{bw}^{-1}d^{-1}$) is selected from a 90d repeated dose study. This value was divided by 2 because according to the Technical Guidance, a NOAEL is preferred over a LOAEL. Using a value of 27.5 g, corresponding to the bodyweight of mice, a DEE of 66.4 kJ d^{-1} and a $C_{energy\ normalised}$ of 4.8 µg kJ^{-1} is obtained. The SCHEER checked these values and from the same data calculated a DEE of 69.6 kJ d^{-1} corresponding to a $C_{energy\ normalised}$ of 4.9 µg kJ^{-1}. According to the SCHEER, an error in the calculation was made.

More importantly, the SCHEER does not agree with the selection of the LOAEL from the mice study and recommends using instead the NOAEL of 8 mg kg^{-1}_{bw} d^{-1} derived from two-generation studies in rats (as in section 7.6) adopted by the SCCS (SCCS, 2022) - for the assessment of secondary poisoning, as the endpoints are relevant at the population level (reproduction effects modulated by hormone levels).

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 (here fish and bivalves).

The SCHEER does not agree with the converted threshold concentrations in the prey (for fish: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 26.77 and for bivalves: $C_{food\ item}$ [mg kg_{ww}^{-1}] = 7.76, because of errors in the calculation of DEE and $C_{energy,normalised}$.

Therefore, the values of $QS_{biota,secpois,fw}$ of 0.89 mg kg_{ww}^{-1} for fish and 0.26 mg kg_{ww}^{-1} for bivalves, obtained by applying an AF of 30 to the $C_{food\ item}$, are not endorsed by the SCHEER.

For the calculation of the $QS_{fw,\ biota}$, the dossier proposes to divide the $QS_{biota,secpois,fw}$ by a BAF. A BAF of 1130 was used in the equation:

$$QS_{water,\ biota} = QS_{biota,\ secpois} / BAF$$

thus obtaining a value of $QS_{fw,\ biota}$ for fish equal to 0.79 µg L^{-1}, while the $QS_{fw,\ biota}$ for bivalves is equal to 0.23 µg L^{-1}.

The SCHEER does not endorse these values because of the calculation errors referred to above and because an alternative NOAEL should have been used, and recommends recalculating the $QS_{water,\ biota}$.

For the marine environment, the SCHEER agrees with the Draft dossier that biomagnification in top predators can occur for triclosan. The $QS_{biota,\ secpois,fw}$ obtained after lipid normalisation (fish, 5% or bivalves, 1%) were 0.22 mg kg^{-1} for fish and 0.013 mg kg^{-1} for bivalves. Finally, the back-calculation to water led to a $QS_{sw,\ biota}$ for fish equal to 0.020 µg L^{-1} and 0.011 µg L^{-1} for bivalves. The SCHEER cannot endorse these values because of the reasons given above.

Section 7.6 – Human Health

For the human health risk *via* the 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 (ADI or TDI) (mg kg^{-1}_{bw} d^{-1})
- 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 SCHEER cannot support the RfD obtained from the baboon chronic dietary study (Drake and Buxtorf (1976), cited in USEPA (2008)) used for the TL_{hh} because the SCHEER considers that this animal model and the effects observed are not adequate to assess the toxicity of triclosan. Instead, the SCHEER recommends use of the NOAEL of 8 mg kg^{-1}_{bw} d^{-1} derived from two-generation reproduction studies in rats considered by the SCCS to be appropriate for safety assessment of triclosan (SCCS, 2022).

The $QS_{biota,\ hh}$= 36.81 mg kg^{-1}_{biota} (to be rounded to 37 mg kg^{-1}_{biota}) and the $QS_{water,\ hh\ food}$ = 32.57 µg L^{-1} (to be rounded to 33 µg L^{-1}) are correctly calculated according to the SCHEER. These values are, however, not endorsed by the SCHEER because of the reasons given in the preceding paragraph.

For the exposure *via* **drinking water**, the preferred regulatory standard of **0.1 µg L^{-1}** was adopted in the Draft dossier because no EU or WHO drinking water standards for triclosan were available. The SCHEER endorses this value.

Section 8 - Antimicrobial resistance

The SCHEER appreciates the notion that AMR is dealt with in the Dossier. However, this assessment is not used for the derivation of EQS. The SCHEER recommends that a section on how to deal with AMR should be included in the Technical Guidelines.

The SCHEER supports the assessment presented in the Draft dossier and considers that there is a theoretical risk of bacteria acquiring overall resistance against triclosan by several modes of action. Possible occurrence of triclosan-resistant bacteria in the wider environment (i.e., outside industrial facilities, hospitals, or laboratories) cannot be excluded and horizontal transfer of genes is possible. For example, Drury *et al.* (2013) concluded that "There was significant correlation between sediment triclosan concentration and the proportion of cultivable benthic bacteria that were resistant to triclosan, demonstrating that the levels of triclosan present in these streams was affecting the native communities. An artificial stream experiment confirmed that triclosan exposure could trigger increases in triclosan resistance within cultivable benthic bacteria".

In their Opinion on triclosan, the SCCS (SCCP/1251/09) addressed the issue of AMR and observed that triclosan is the most studied biocide with respect to bacterial resistance. The SCCS identified several distinct hazards: (i) the effect of triclosan on the triggering/regulation of resistance genes in bacteria (ii) the existence of defined mechanisms that can promote resistance and cross-resistance to biocides and antibiotics in bacteria, (iii) high concentrations of triclosan (compared to concentrations known to select for resistance in *in vitro* experiments) have been measured in certain environmental compartments and (iv) bacterial biofilms. The SCCS concluded that applications of triclosan that contribute to those high environmental concentrations cannot be properly identified nor quantified at

present and the presence of other chemicals (e.g., antibiotics, surfactants, other biocides, etcetera) in the environment, which may also affect microbial populations, would preclude assessing the effects of triclosan independently.

Endocrine disruption

Regarding the assessment of triclosan's endocrine disrupting potential on the reproductive system, it becomes clear that triclosan may cause adverse effects when the available *in vivo* and *in vitro* data are considered. Furthermore, it seems biologically plausible that the adverse effects observed *in vivo* could be caused by the endocrine modes of action found *in vitro*. However, since still very few studies have investigated endocrine sensitive reproductive endpoints *in vivo*, and there are conflicting results, the SCHEER recommends further investigation of triclosan's effects on reproduction and on endocrine sensitive endpoints across different taxonomic groups.

4. CRITICAL EQS

On the basis of the data provided in the dossier, the most critical EQS (in terms of impact on environment/health) could not be identified by the SCHEER, as the set of QSs proposed is considered incomplete since the SCHEER could not endorse several of the proposed QSs. From the values endorsed by the SCHEER, the lowest value is the **MAC-QS$_{sw, eco}$ = 0.0019** µg L^{-1}.

5. LIST OF ABBREVIATIONS

AA	Annual Average
ADI	Acceptable Daily Intake
AF	Assessment Factor
AMR	Antimicrobial Resistance
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
bw	Body weight
DEE	Daily Energy Expenditure
EC	Effect Concentration
EC_{50}	the concentration of a substance that causes half of the maximum possible effect
EFSA	European Food Safety Agency
EQS	Environmental Quality Standards
ErC_{50}	the concentration of test substance which results in a 50% reduction in growth rate (relative to the control)
LET	Literature Evaluation Tool
MAC	Maximum Acceptable Concentration
NOAEL	No Adverse Effect Level
NOEC	No Effect Concentration
OC	Organic Carbon
QS	Quality Standard
RfD	Reference Dose
SCCS	Scientific Committee on Consumer Safety
SPM	Suspended Particulate Matter
SSD	Species Sensitivity Distribution
TDI	Tolerable Daily Intake
TG	Technical Guidance (EC, 2018)
TL	Threshold Level
WG	Working Group (on Chemicals)

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