



Scientific Committee on Health, Environmental and Emerging Risks SCHEER

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

Nickel and its compounds



The SCHEER adopted this document
during the plenary meeting on 22 December 2022

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, Raquel Duarte Davidson, Peter Hoet, Pim de Voogt, Rodica 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 \(europa.eu\)](https://europe.ec.europa.eu/en/experts-groups)

This Opinion has been subject to a commenting period of four weeks after its initial publication (from 12 October to 11 November 2022). Comments received during this period were considered by the SCHEER. For this Opinion, sections 7.2 and 7.3 were amended.

Keywords:

Metals, nickel, 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 - nickel and its compounds, 22 December 2022

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
L-2920 Luxembourg
SANTE-SCHEER@ec.europa.eu

©European Union, 2023

PDF ISSN 2467-4559 ISBN 978-92-68-06268-5 doi:10.2875/948747 EW-CA-23-005-EN-N

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 \(europa.eu\)](https://ec.europa.eu/sccheer/)

ABSTRACT

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

The proposed dossier is based on an EU RAR (2008) and a previous EQS dossier (2011) updated by inclusion of more recent data and according with the 2018 EQS Technical Guidance.

The probabilistic **MAC-QS_{fw,eco} = 8.2 µg L⁻¹** is endorsed by the SCHEER. The same value is proposed for marine water. However, it is the opinion of the SCHEER that these values should be revised using BLMs for the bioavailability normalisation.

The probabilistic **AA-QS_{bioavailable, fw} = 1.9 µg L⁻¹** is endorsed by the SCHEER.

The probabilistic **AA-QS_{sw,eco} = 3.1 µg L⁻¹** is endorsed by the SCHEER in absence of suitable BLMs for the marine environment.

The probabilistic **QS_{fw, sed} = 22 mg kg_{dw}⁻¹** is endorsed by the SCHEER. The same value is proposed for marine water.

For secondary poisoning, the **QS_{biota, secpois, fw} = 8.9 mg kg⁻¹_{ww} for fish and 2.6 mg kg⁻¹_{ww} for bivalves** are endorsed by the SCHEER. However, the SCHEER notes several mistakes in the text of the dossier.

The **QS_{biota, hh food} = 1.6 mg kg_{biota}⁻¹** is endorsed by the SCHEER. The back calculation to water is not performed due to uncertainties on the definition of BAF.

The existing European **drinking water standard of 20 µg L⁻¹** is endorsed by the SCHEER.

The most critical EQS has been identified as the **AA-QS_{bioavailable, fw} = 1.9 µg L⁻¹**.

TABLE OF CONTENTS

ACKNOWLEDGMENTS.....	2
ABSTRACT	4
1. BACKGROUND	6
2. TERMS OF REFERENCE.....	6
3. OPINION	7
Section 7. Effects and quality standards	7
Section 7.1. Acute aquatic ecotoxicity	8
Section 7.2. Chronic aquatic ecotoxicity	8
Section 7.3. Sediment ecotoxicology	9
Section 7.4. Secondary Poisoning	11
Section 7.5. Human health	11
4. CRITICAL EQS	12
5. SCHEER RESPONSES TO ADDITIONAL QUESTIONS PUT BY THE COMMISSION	12
6. LIST OF ABBREVIATIONS	14
7. REFERENCES	14

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:

Generic questions to the SCHEER

- Have the EQS been correctly and appropriately derived, in the light of the available information and the TGD-EQS?
- Has the most critical EQS (in terms of impact on environment/health) been correctly identified?

Additional questions to the SCHEER

Additional questions to the SCHEER can be found in the file "Environmental Quality Standards Dossier 'Nickel' for the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)", otherwise they are listed below:

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

- Does SCHEER agree with the assessment factor selected of 5 for the proposed MAC-QS_{eco} using the probabilistic approach?
- Does SCHEER agree with the assessment factor selected of 2 for the proposed bioavailable-AA-QS_{fw,eco} ?
- What is SCHEER Committee's opinion on the field and micro/mesocosm studies available on Nickel draft dossier?
- Does SCHEER agree with the assessment factor selected of 3 for the proposed bioavailable-AA-QS_{freshwater, sediments}?
- Does SCHEER agree with the proposed bioavailable-AA-QS_{mw,sed}?
- What is SCHEER Committee's opinion on the bioaccumulation factor used in the QS secondary poisoning derivation?

The SCHEER responds to these questions at the end of the Opinion.

3. OPINION

It should be noted that in a separate synthesis Opinion, the SCHEER provides an analysis of weaknesses and unresolved issues common to all dossiers. This includes a discussion of the risk assessment method and of SCHEER's concern regarding the completeness of the data used for the estimation of the different QS values.

In the final version of the dossier on Nickel (July 2022), the previous relevant documents, which represent the basis for the present document, are listed:

- The European Union Risk Assessment Report (EU RAR) approved in May 2008 (EC, 2008); the RAR was evaluated by the Scientific Committee on Health and Environmental Risks (SCHER 2009) that judged it as a very high-quality report and endorsed almost all conclusions, with some suggestions for further improvement (e.g., improving the sections on the sediment compartment, and on risk for soil organisms).
- The EQS draft dossier of 2011, proposing AA-QS_{fw, bioavailability} of 2 µg/L, AA-QS_{sw} of 8.6 µg/L and MAC-QS of 34 µg/L. The dossier was also reviewed by the SCHER (SCHER, 2011) that endorsed the proposed QS, highlighting the need for update in function of new information (e.g., higher tier data).
- The EQS draft dossier of 2017, considering recent information, including higher tier data.

The present version has been updated by including recent data (from 2017 to 2021) and according to the last version of the EQS Technical Guidance 2018 (EC, 2018).

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

Section 7. Effects and quality standards

The SCHEER agrees with the procedures for the collection and selection of data.

Section 7.1. Acute aquatic ecotoxicity

Extensive datasets are provided for freshwater (102 species) and marine (35 species) acute toxicity data. There was no statistically significant difference between the acute sensitivities of freshwater and marine organisms. Therefore, in accordance with the EQS TGD (EC, 2018), the two datasets were combined. The SCHEER agrees with the procedure.

Although biotic ligand models (BLMs) for Ni exist and were used in previous reports (e.g., EU RAR, 2008), the dossier states that "*User-friendly acute NiBLM models for freshwater and saltwater are not available*". Therefore, the MAC-QSs have been derived on the basis of the dissolved metal, not normalised on the bioavailable fraction.

It is the opinion of the SCHEER that the proposed QS should be considered preliminary, limited to dissolved Ni. Existing BLMs should be considered, to produce bioavailable QS, whenever possible. This is also strongly recommended by the EQS Technical Guidance 2018 (EC, 2018).

A deterministic MAC-QS_{fw,eco} is based on the lowest acute effect value available, the 96h-EC₅₀=14 µg L⁻¹ for larval development of the echinoderm *Evechinus chloroticus*. Considering the large dataset available, an AF of 10 is applied leading to a **MAC-QS_{fw,eco} = 1.4 µg L⁻¹**. The SCHEER agrees with the proposed deterministic QS.

The large dataset is suitable for the application of the probabilistic approach. The SSD curve provides an HC₅= 41 µg L⁻¹. By applying an AF of 10, according to the TGD, a MAC-QS_{fw,eco} = 4.1 µg L⁻¹ is obtained. However, considering the large dataset (135 species covering 12 major taxonomic groups), an AF of 5 is suggested, leading to a **MAC-QS_{fw,eco} = 8.2 µg L⁻¹**. The SCHEER agrees with the proposed probabilistic QS.

For the marine environment, considering that the standard deviation of the log transformed L(E)C₅₀ values is > 0.5, an AF of 100 is applied to the 96h-EC₅₀= 14 µg L⁻¹ on the echinoderm *Evechinus chloroticus*, according to the TGD, leading to a MAC-QS_{sw,eco}= 0.14 µg L⁻¹. However, according to the TGD, an AF of 10 may be applied if representative species for the most sensitive taxonomic group are included in the data set. Considering that the dataset includes 12 taxonomic groups, it is the opinion of the SCHEER that an AF of 10 is more appropriate. Therefore, the SCHEER proposes a deterministic **MAC-QS_{sw,eco} = 1.4 µg L⁻¹**, same as for freshwater. The SCHEER also noted that a value of 0.14 µg L⁻¹ is close to the natural background concentrations.

For the probabilistic approach, the same procedure applied for freshwater is proposed, leading to a **MAC-QS_{sw,eco} = 8.2 µg L⁻¹**. The SCHEER agrees with the proposed probabilistic QS.

Since the probabilistic procedure should be preferred to the deterministic one if it is sufficiently reliable and statistically sound, it is the opinion of the SCHEER that the final **MAC-QS = 8.2 µg L⁻¹** should be proposed for both fresh and marine waters.

Section 7.2. Chronic aquatic ecotoxicity

Freshwater and marine water chronic ecotoxicity datasets have been kept separate because, according to the TGD (EC, 2018), pooling of freshwater and saltwater data should be avoided when availability corrections have been applied. The SCHEER agrees with this procedure, considering that, for freshwater chronic data, BLM has been applied.

For freshwater, the dataset from the EU RAR (EC, 2008) (214 endpoints, 31 species and 9 major taxonomic groups) was implemented with data from the 2011 dossier and additionally with more recent data. All data were normalised using suitable BLMs. The SCHEER is aware that the BLM approach may be updated and improved, covering the variability of European water chemistry conditions. Therefore, the SCHEER recommends

that, for further revisions of the metal dossiers, the most recent updates of the BLM would be applied.

Microcosm and field studies are also available and were taken into account in the discussion of the selection of the AF.

By applying a probabilistic approach to the bulk of data, an HC5 of $3.7 \mu\text{g L}^{-1}$ is calculated. In the dossier the value is rounded, but the SCHEER is of the opinion that this is not correct.

According to the TGD, an AF from 1 to 5 may be applied to the HC5. Considering the large dataset available together with some residual uncertainties, an AF of 2 is proposed, resulting in a probabilistic $\text{AA-QS}_{\text{bioavailable, fw}} = 2 \mu\text{g L}^{-1}$. The SCHEER agrees with the procedure; however, it suggests a not-rounded value of $1.9 \mu\text{g L}^{-1}$. Therefore, the value of **$1.9 \mu\text{g L}^{-1}$** for the **$\text{AA-QS}_{\text{bioavailable, fw}}$** is endorsed by the SCHEER.

A deterministic AA-QS is not proposed in the dossier for freshwater. It is the opinion of the SCHEER that the reason for that should be justified.

For the marine water too, a large dataset is available by combining the EU RAR dataset with more recent data (30 species and 8 major taxonomic groups). Due to the lack of a reliable BLM for marine water, data are not normalised for bioavailability. The SCHEER agrees with the approach.

The deterministic approach is applied to the lowest chronic value (80h-EC10 of $5.5 \mu\text{g L}^{-1}$ for the crustacean *Acartia sinjiensis*). An AF of 10 is applied, resulting in a deterministic **$\text{AA-QS}_{\text{sw}} = 0.55 \mu\text{g L}^{-1}$** . The deterministic QS is endorsed by the SCHEER.

By applying a probabilistic approach to the bulk of data, an HC5 of $9.2 \mu\text{g L}^{-1}$ is obtained.

According to the TGD, an AF from 1 to 5 may be applied to the HC5. Considering the large dataset available together with some residual uncertainties, an AF of 3 is proposed, resulting in a probabilistic **$\text{AA-QS}_{\text{sw,eco}} = 3.06 \mu\text{g L}^{-1}$** (rounded to **$3.1 \mu\text{g L}^{-1}$**). The SCHEER agrees with the procedure and endorses the $\text{AA-QS}_{\text{sw,eco}}$.

Since the probabilistic procedure should be preferred to the deterministic one if it is sufficiently reliable and statistically sound, it is the opinion of the SCHEER that the final **$\text{AA-QS}_{\text{sw,eco}} = 3.1 \mu\text{g L}^{-1}$** should be proposed for marine waters.

Section 7.3. Sediment ecotoxicology

Sediment toxicity of metals is strongly affected by the availability patterns of metals in this compartment. Due to the lack of information on these patterns, sediment toxicity was not adequately addressed in the 2008 EU RAR.

There is evidence in the literature that sediment acid volatile sulphide (AVS) concentration is a key parameter affecting metal availability (Di Toro et al. 1990, 1992; Schlekot et al. 2016).

In the dossier, normalisation of available data is performed using the equation below (Vangheluwe et al. 2013):

$$EC20_{RWC} = EC20_{test} \left[\frac{AF_{RWC}}{AF_{test}} \right] ^{slope}$$

Where RWC is a reasonable worst-case scenario for sediment characteristics, AF is the abiotic factor (e.g., AVS) affecting availability, and the slope is those of the concentration-toxicity curve.

It is the opinion of the SCHEER that the normalisation procedure is suitable.

The normalisation was applied to sediment toxicity data for which sediment data suitable

for the application of the equation were available. This led to a dataset of 8 species and 4 major taxonomic groups.

The deterministic approach is applied to the lowest normalised value (EC10 of 75.9 mg kg_{dw}⁻¹ for biomass to *Hyalella azteca*). An AF of 10 is applied, resulting in a deterministic **QS_{fw, sed} = 7.6 mg kg_{dw}⁻¹**. The deterministic QS is endorsed by the SCHEER.

The probabilistic approach, based the available data set, gives a bioavailability-based HC5 of 108.17 mg kg_{dw}⁻¹. An AF is not proposed in the dossier, considering some uncertainties and disagreements in the discussion among stakeholders and experts of different MS, also considering that no clear indications are reported in the TGD about the AF selection for SSDs based on sediment toxicity data. Therefore, a specific question on that issue is asked to the SCHEER.

It must be noted that the general requirements for SSD indicated in the TGD (at least 10 NOECs/EC10s values, from different species covering at least 8 taxonomic groups) are not met. However, for sediments, these requirements are difficult to meet, due to the absence of several important taxonomic groups. Therefore, an SSD developed on 8 species and 4 taxonomic groups may be assumed as acceptable for sediments. The SCHEER agrees with this approach.

By applying an AF of 5, a QS_{sed} = 22 mg kg_{dw}⁻¹ is obtained.

In the dossier it is mentioned that some MS experts observed that, by applying an AF of 5 the resulting QS_{sed} would be higher than many ambient concentrations in Europe (see section 6 of the dossier). Therefore, an AF of 3 or 1 is proposed, leading to QS_{sed} of 36 or 108 mg kg_{dw}⁻¹ respectively.

The SCHEER notes that, although the SSD for sediment may be considered as acceptable, the database used has substantial uncertainty. In any case, even applying an AF of 5, the resulting QS is about three times higher than those obtained using the deterministic procedure.

Moreover, looking at the minimum-maximum range of Ni concentrations in European sediments (table at page 11 of the dossier), the QS of 22 mg kg_{dw}⁻¹ is lower than the maximum values reported but is about one order of magnitude higher than the minimum values reported. On the other hand, even the AA-QS_{fw} is lower than some measured concentrations in Europe.

The SCHEER is aware that the behaviour of metals in the environment, and in particular in chemically complex matrix like sediments, is a difficult issue requiring an in-depth knowledge of sediment characteristics which is rarely available. This led, in many cases, to the need for precautionary approaches.

Therefore, it is the opinion of the SCHEER that an AF of 5 is suitable, leading to a **QS_{fw, sed} = 22 mg kg_{dw}⁻¹**.

Since the probabilistic procedure should be preferred to the deterministic one if it is sufficiently reliable and statistically sound, it is the opinion of the SCHEER that the final **QS_{fw, sed} = 22 mg kg_{dw}⁻¹** should be proposed.

For marine sediment data, normalisation for availability is not possible, therefore, data cannot be merged with freshwater data.

The deterministic approach is used by applying an AF of 10 to the 15d NOEC on *Amphiascus tenuiremis* of 68 mg kg_{dw}⁻¹, leading to a QS_{sw, sed} = 6.8 mg kg_{dw}⁻¹. It is the opinion of the SCHEER that the deterministic approach is properly applied. Hence, the QS_{fw, sed} should be used for both the marine and freshwater compartments. The SCHEER agrees with this observation. Therefore, a **QS_{sw, sed} = 22 mg kg_{dw}⁻¹** is proposed.

Section 7.4. Secondary Poisoning

The procedure used in the 2011 dossier is firstly reported but not used for deriving QS. The reason for reporting this procedure is unclear. Then, the $QS_{\text{biota, secpois}}$ derivation in 2022 is described.

Two different toxicity values are considered and compared in the dossier:

- a NOAEL of $1.1 \text{ mg.kg}^{-1}_{\text{bw.d}^{-1}}$ for a 2-generation reproductive study on rat (exposed through gavage);
- a NOEC of $200 \text{ mg kg}_{\text{ww}}^{-1}$ in food for a 90-d test on mallard (*Anas platyrhynchos*).

The NOEC on mallard is a concentration in food and is erroneously reported as $\text{mg.kg}^{-1}_{\text{bw}}$ and as $\text{mg.kg}^{-1}_{\text{bw.d}^{-1}}$ in the tables on pages 42 and 47 respectively.

The NOAEL of $1.1 \text{ mg.kg}^{-1}_{\text{bw.d}^{-1}}$ has water as vehicle. The dossier assumes that the mass fraction of Ni dose absorbed from the gastrointestinal tract is 27% for drinking water and 0.7% for food. Therefore, the absorbed Ni dose in the rat experiment is $0.297 \text{ mg.kg}^{-1}_{\text{bw.d}^{-1}}$. To absorb the same dose through food the total dietary dose would be $42.4 \text{ mg.kg}^{-1}_{\text{bw.d}^{-1}}$.

According to the EQS Technical Guidance (EC, 2018), the method of energy-normalised diet concentrations is applied. The calculation, using a NOAEL of $42.2 \text{ mg kg}_{\text{bw}}^{-1}\text{d}^{-1}$ is reported in detail and is properly performed, leading to a $C_{\text{energy normalised}}$ of $32.30 \text{ } \mu\text{g kJ}^{-1}$.

Another calculation is made starting from the NOEC for mallard of $200 \text{ mg kg}_{\text{ww}}^{-1}$ and using the "method B" of the technical guidance, to be applied to concentrations in the diet. In this case, the calculation (not reported in detail) leads to a $C_{\text{energy normalised}}$ of $16.13 \text{ } \mu\text{g kJ}^{-1}$. It is the opinion of the SCHEER that the value is correct. Being lower than the previous one, this value was used for further calculations.

Then, the $C_{\text{food item}}$ is calculated, according to the Technical Guidance, using the following equation:

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

The energy contents and the moisture fractions used were $21 \text{ kJ/g}_{\text{dw}}$ and 73.7% for fish, and $19.3 \text{ kJ/g}_{\text{dw}}$ and 91.7% for bivalves, respectively. The energy contents in the dossier are erroneously indicated as kJ/g_{fw} .

The obtained $C_{\text{food item}}$ were $89.09 \text{ mg/kg}_{\text{ww}}$ for fish and $25.83 \text{ mg/kg}_{\text{ww}}$ for bivalves. It is the opinion of the SCHEER that the calculation is correct. However, many errors in the text make the dossier confused and difficult to follow.

An AF of 10 was applied to the $C_{\text{food item}}$, obtaining a **$QS_{\text{biota, secpois, fw}} = 8.9 \text{ mg kg}^{-1}_{\text{ww}}$ for fish and $2.6 \text{ mg kg}^{-1}_{\text{ww}}$ for bivalves**. The QSs are endorsed by the SCHEER. However, the SCHEER notes several mistakes in the text of the dossier.

Considering that nickel does not biomagnify, the $QS_{\text{biota, secpois}}$ assessment for marine waters has been omitted. The SCHEER agrees with this decision.

Considering several uncertainties associated with BAF values, no back-calculation to water is proposed in the dossier. The SCHEER agrees with this decision.

Section 7.5. Human health

For the protection of human health risk *via* consumption of fishery products, after describing the procedures used in the 2008 EU RAR and in the 2011 dossier, the $QS_{\text{biota, secpois}}$ is derived according to the procedure described in the EQS Technical Guidance (EC, 2018), based on the following equation:

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

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 TL_{hh} allocated to fishery products consumption
- TL_{hh} = threshold limit from mammalian studies (ADI or TDI) ($\text{mg kg}^{-1}_{\text{bw}} \text{d}^{-1}$)
- 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).

Using a TDI of 13 $\mu\text{g kg}_{\text{bw}}^{-1}$ proposed by EFSA (2020), a $QS_{\text{biota, hh food}} = 1595.09 \mu\text{g kg}_{\text{biota}}^{-1}$ (rounded to **$QS_{\text{biota, hh food}} = 1.6 \text{ mg kg}_{\text{biota}}^{-1}$**) is obtained.

The QS is endorsed by the SCHEER.

Due to uncertainties about the definition of BAF for Ni, the back calculation to water is not proposed in the dossier. The SCHEER agrees with this decision.

For the protection of human health risk *via* consumption of drinking water, the existing European **drinking water standard of 20 $\mu\text{g L}^{-1}$** is proposed. The SCHEER agrees with this decision.

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- $QS_{\text{bioavailable, fw}} = 1.9 \mu\text{g L}^{-1}$** . It must be considered that this value is expressed as bioavailable concentration in water.

5. SCHEER RESPONSES TO ADDITIONAL QUESTIONS PUT BY THE COMMISSION

Does SCHEER agree with the assessment factor selected of 5 for the proposed MAC- QS_{eco} using the probabilistic approach?

As already clarified in the text of the Opinion, the SCHEER agrees with the selected AF of 5.

Does SCHEER agree with the assessment factor selected of 2 for the proposed bioavailable-AA- $QS_{\text{fw,eco}}$?

The extension of the dataset could suggest a lower AF. However, considering some residual uncertainties, the SCHEER agrees with the selected AF of 2.

What is SCHEER Committee's opinion on the field and micro/mesocosm studies available on Nickel draft dossier?

Micro/mesocosm and field studies are always characterised by high variability and uncertainty. Therefore, they must be evaluated with care. However, they are extremely useful for evaluating if QS, derived from laboratory studies, may be really protective for complex biological communities. In the case of higher tier studies available on nickel, in spite of some uncertainties, they support the hypothesis that an AF of 1 on the chronic HC5 is not protective enough and an AF of 2 is necessary.

Does SCHEER agree with the assessment factor selected of 3 for the proposed bioavailable-AA-QS_{freshwater, sediments}?

It is the opinion of the SCHEER that, considering the uncertainties deriving from the reduced dataset used for the SSD curve on sediments, an AF of 5 is more adequate. More details supporting this preference are reported in the text of the Opinion.

Does SCHEER agree with the proposed bioavailable-AA-QS_{sw, sed}?

The SCHEER agrees that no evidence exists to suggest different sensitivity between marine and freshwater sediment organisms. Moreover, for freshwater, a QS calculated with the probabilistic procedure is accepted, that is substantially higher from those calculated with the deterministic one.

Therefore, the SCHEER agrees with the proposal of the stakeholder experts of using the same QS for fresh and marine water. However, it must be those calculated with an AF of 5 (i.e., 22 mg kg_{dw}⁻¹), and not those proposed by the stakeholder experts calculated with an AF of 1 (i.e., 109 mg kg_{dw}⁻¹).

What is SCHEER Committee's opinion on the bioaccumulation factor used in the QS secondary poisoning derivation?

Considering several uncertainties associated with BAF values of nickel, and particularly considering that, in the case of metals, bioaccumulation and bioconcentration may be variable with concentration, in the dossier BAF is not used for back calculation for secondary poisoning, as well as for human health. The SCHEER agrees with this decision.

6. LIST OF ABBREVIATIONS

AA-QS	Annual Average Quality Standard
ADI	Acceptable Daily Intake
AF	Application Factor
AMR	Anti-Microbial Resistance
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification Factor
EC50	Effective Concentration 50%
EQS	Environmental Quality Standards
HC5	Hazardous Concentration 5%
MAC-QS	Maximum Acceptable Concentration Quality Standard
MIC	Minimum Inhibitory Concentration
NOAEL	No Observed Adverse Effect Level
SSD	Species Sensitivity Distribution

7. REFERENCES

EUROPEAN COMMISSION (EC). 2008. European Union risk assessment report on nickel, nickel sulphate, nickel carbonate, nickel chloride, nickel dinitrate, Denmark, Final report May 2008. Prepared by Denmark, Danish Environmental Protection Agency on behalf of the European Union.

EUROPEAN COMMISSION (EC). 2018. Technical Guidance for Deriving Environmental Quality Standards. Guidance Document No. 27, Updated version 2018. Document endorsed by EU Water Directors at their meeting in Sofia on 11-12 June 2018.

SCHER. 2008. Scientific opinion on the risk assessment report on nickel, nickel carbonate, nickel chloride, nickel dinitrate, nickel sulphate; indirect exposures part, CAS 7440-02-0; 3333-67-3; 7718-54-9; 13138-45-9; 7786-81-4, 15 July 2008.

SCHER. 2011. Scientific Committee on Health and Environmental Risks (SCHER) Opinion on "Chemicals and the Water Framework Directive: Draft Environmental Quality Standards" Nickel. Health & Consumer Protection, Directorate- General, European Commission. 25 May 2011