



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

"CHEMICALS AND THE WATER FRAMEWORK DIRECTIVE: DRAFT
ENVIRONMENTAL QUALITY STANDARDS"

Nickel

SCHER adopted this opinion at its 13th plenary on 25 May 2011

About the Scientific Committees

Three 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.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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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 (EQSs) 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 EQSs for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). The WFD Article 16 requires the Commission to review periodically the list of priority substances. Article 8 of the EQSD requires the Commission to finalise its next review by January 2011, accompanying its conclusion, where appropriate, with proposals to identify new priority substances and to set EQSs for them in water, sediment and/or biota. The Commission is now aiming to present its proposals to Council and the Parliament by June 2011.

The Commission has been working on the abovementioned review since 2006, with the support of the Working Group E (WG E) on Priority Substances under the Water Framework Directive Common Implementation Strategy. The WG E is chaired by DG Environment and consists of experts from Member States, EFTA countries, candidate countries and more than 25 European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.). A shortlist of 19 possible new priority substances was identified in June 2010. Experts nominated by WG E Members (and operating as the Sub-Group on Review of Priority Substances) have been deriving EQS for these substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in some others there is disagreement about one or other component of the draft dossier. Revised EQS for a number of existing priority substances are currently also being finalised.

The EQS derivation has been carried out in accordance with the draft Technical Guidance on EQS reviewed recently by the SCHER. DG Environment and the rapporteurs of the Expert Group that developed the TGD have been considering the SCHER Opinion and a response is provided separately.

2. TERMS OF REFERENCE

2.1 General requests to SCHER

DG Environment now seeks the opinion of the SCHER on the draft EQS for the proposed priority substances and the revised EQS for a number of existing priority substances. The SCHER is asked to provide an opinion for each substance. We ask that the SCHER focus on:

- 1. whether the EQS have been correctly and appropriately derived, in the light of the available information¹ and the TGD-EQS;**
- 2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.**

¹ The SCHER is asked to base its opinion on the technical dossier and the accompanying documents presented by DG Environment, on the assumption that the dossier is sufficiently complete and the data cited therein are correct.

Where there is disagreement between experts of WG E or there are other unresolved issues, we ask that the SCHER consider additional points.

Where there is disagreement between experts of WG E or there are other unresolved issues, the additional points to be considered by the SCHER are identified in the cover note(s), and additional documents are provided where necessary.

2.2 Specific requests on nickel

The SCHER is asked to consider the two generic questions in the request, as well as the following specific points.

The EQS dossier contains EQS for water but not yet for sediment; further data and analysis are required to derive an EQS for sediment in the longer term (this is explained in the dossier).

The dossier was agreed by the Sub-Group on Review in the form provided (dated October 2010). The nickel industry then informed the lead Member State (DK) of the imminent availability of higher-tier data obtained for REACH registration purposes that it considered might be used to reduce the AF to 1. The MS lead has reservations about some of the data, in particular regarding the results for snails in the meso(micro)cosm studies, and considers that the AF should remain as 2. Other Sub-Group experts have divergent opinions.

Industry has provided a summary of its studies (attached), which were conducted for it by the Fraunhofer Institute, and the studies are provided separately. A memo from the Fraunhofer concerning the snail data is also attached, along with three documents from the MS lead (DEPA) commenting on the studies, the memo and the choice of AF.

The specific requests to the SCHER are:

(i) Should the higher-tier data be considered in the EQS derivation process for nickel at this point, before being reviewed for REACH? Notes: (a) The lead MS considers that there are too many outstanding points of discussion/analysis and difficulties with interpretation of the data, especially from the field studies, for the data to be included in the dossier; (b) The Commission is committed to revising the EQS for nickel in the current review, in particular to take into account bioavailability, since the present EQS was acknowledged to be temporary.

(ii) Do the three lines of evidence (the laboratory data, bioavailability correction and cross-species extrapolation and the new higher-tier data) collectively reduce the uncertainty around the HC5 as derived in the EQS dossier to a point where it can be used as the EQS?

(iii) Snail abundance in the meso(micro)cosm studies was analysed by the Fraunhofer Institute according to OECD 53 and guidance from De Jong et al (2008) for summarising and evaluating aquatic micro-and mesocosm studies. A NOEC of 24µg/l was obtained. The dossier lead used an alternative approach and arrived at a NOEC of 6µg/l. The SCHER is asked to provide its opinion on the appropriate statistical analysis and on the interpretation and relevance of the study.

3. OPINION

3.1. Responses to the general requests

1. whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS;

The procedures for the derivation of the EQS values for nickel are in accordance with those prescribed in the TGD-EQS (2010). The SCHER supports the proposed tiered approach which accounts for differences in Ni bioavailability and toxicity in different surface waters. The SCHER notes that an extensive data set that includes 193 chronic laboratory toxicity tests (31 species, 19 families), a 4-month mesocosm

study and a large field data set was available for the derivation of the EQS. This can be considered as the most comprehensive dataset used for deriving an EQS in the context of the WFD. Although the correct procedures have been used, SCHER notes that not all data have been used and/or analysed in the derivation of the EQS and this type of in-depth analysis is needed before a final EQS value can be accepted (see further).

2. whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.

The most critical EQS (in terms of impact on environment/health) is the EQS_{bioavailable} and has been correctly identified.

3.2. Responses to the specific requests on nickel

i) Should the higher-tier data be considered in the EQS derivation process for nickel at this point, before being reviewed for REACH? Notes: (a) The lead MS considers that there are too many outstanding points of discussion/analysis and difficulties with interpretation of the data, especially from the field studies, for the data to be included in the dossier; (b) The Commission is committed to revising the EQS for nickel in the current review, in particular to take into account bioavailability, since the present EQS was acknowledged to be temporary.

The SCHER is of the opinion that the available higher tier data should be considered in the EQS setting for Ni at this point as it might have important consequences on the EQS value. The higher tier data may provide additional information which may allow improved justification or change of the choice for assumptions used in the present document. SCHER notes that the EQS derivation has assumed the same level of uncertainty as that has been assumed in the EU RAR on Ni (2008) despite the fact that additional higher tier data were available for the EQS derivation. These data should be considered in the derivation of the final EQS value.

ii) Do the three lines of evidence (the laboratory data, bioavailability correction and cross-species extrapolation and the new higher-tier data) collectively reduce the uncertainty around the HC5 as derived in the EQS dossier to a point where it can be used as the EQS?.

The SCHER is of the opinion that all information should be considered and a quantitative analysis should be performed to evaluate to what extent this information reduces the uncertainty compared to previously conducted exercises such as the EU RAR on Ni (2008). The data type diversity (laboratory, mesocosm and field data) and the size of the (toxicity) datasets is among the largest available for EQS derivation. Careful examination of all lines of evidence is thus needed (weight of evidence) to establish a final EQS. The SCHER notes that the HC5 derived in the EU RAR and used in the EQS derivation is lower than NOECs from laboratory studies (SSD), the mesocosm study and the effect levels established in the extensive field study. This is also true when a NOEC value of 6 µg/L is used derived from the mesocosm experiment. This quantitative (comparative) uncertainty analysis will possibly allow to determine the size of the assessment factor on the HC5 (ranging from 1 to 5).

iii) Snail abundance in the meso(micro)cosm studies was analysed by the Fraunhofer Institute according to OECD 53 and guidance from De Jong et al (2008) for summarising and evaluating aquatic micro-and mesocosm studies. A NOEC of 24µg/l was obtained. The dossier lead used an alternative approach and arrived at a NOEC of 6µg/l. The SCHER is asked to provide its opinion on the appropriate statistical analysis and on the interpretation and relevance of the study.

The SCHER recognizes that the different types of statistical analysis of the mesocosm data lead to different NOECs (6 and 24 µg Ni /L). Higher variance in the control treatments lead to reduced statistical power of detection which may have affected the value of the derived NOEC. Due to time constraints, the SCHER is not in a position to advise on the most appropriate type of statistical analysis which is needed with this data set, but suggests – as part of the comprehensive (additional) data and uncertainty analysis recommended above - that an in-depth analysis is performed by independent statisticians.

The lead has also reiterated that there has not been an adequate opportunity to thoroughly scrutinise the field study data, and that they appear difficult to interpret. The updated version of the relevant report (110221 Nickel Field Report of 21 February 2011) provided to the SCHER has not been reviewed by the lead, who had received² a version dated September 2009.

As indicated above, the SCHER is of the opinion that all data should be considered in the EQS setting for Ni at this point. The in-depth analysis of the field study may, especially in the context of the WFD, have important consequences on the (comparative) quantitative uncertainty analysis and thus on the EQS value.

² in late November 2010

4. LIST OF ABBREVIATIONS

AA-QS	annual average quality standard
DAR	draft assessment report
EQS	environmental quality standard
MAC-QS	maximum acceptable quality standard
PEC	Predicted Environmental Concentration
TGD-EQS	technical guidance document- environmental quality standard
WFD	Water Framework Directive

5. REFERENCES

SCHER (Scientific Committee on Health and Environmental Risks) (2010), Opinion on Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards, 16 September 2010