Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Guidance on the structure and content of SCHEER Opinions and statements

The SCHEER adopted this document by written procedure on 23 February 2017

ABSTRACT

In view of the new organisation of the Scientific Committees, namely the merger of two committees (SCHER and SCENIHR) to form the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), the European Commission asked the SCENIHR first and then the SCHEER to produce a guidance document revising the structure and content of scientific Opinions and statements.

This document aims to provide guidance on how to ensure the high quality of the scientific Opinions and statements in dealing with human health, environmental and emerging risks.

The new structure is proposed as an annex to the guidance. It will be tested by the SCHEER for a period of approximately one year and after that, amended if necessary.

Keywords: template, procedure, structure, SCHEER, Opinion

Opinion to be cited as:

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Guidance on structure and content of SCHEER documents - 23 February 2017

ACKNOWLEDGMENTS

Members of the Working Group from SCENIHR and SCHER (term 2013-2016) are acknowledged for their initial contribution to this Guidance. The members of the Working Group are:

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All Declarations of Working Group members are available at the following webpage:
http://ec.europa.eu/health/scientific_committees/environmental_risks/members_wg_en

http://ec.europa.eu/health/scientific_committees/emerging/members_wg_en

About the Scientific Committees (2016-2021)

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.

They 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 work 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 Committee 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 soil.

- 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

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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.

http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

TABLE OF CONTENTS

1. REQUEST FROM THE EUROPEAN UNION COMMISSION SERVICES

1.1 BACKGROUND

The mission of the Scientific Committees[1] is to provide the Commission services with scientific advice and risk assessment in the areas of public health, consumer safety and environmental risks, including, when relevant, identification of research needs to address critical information gaps, assessment of proposed future research actions and of research results.
Scientific advice and risk assessment provided by the Scientific Committees are provided by means of scientific Opinions.

Point 109 of the Rules of Procedures[2] of the Scientific Committees states the main sections that must be included in the scientific Opinions elaborated by the Scientific Committees. It also mentions that more details about the format of the Opinions may be provided in specific guidance papers prepared by each Scientific Committee.

In light of the new organisation of the Scientific Committees, namely the merger of two committees to form the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), the structure and content of its scientific Opinions and Statements needed to be revised.

1.2 TERMS OF REFERENCE

The Scientific Committees SCENIHR, SCHER and then SCHEER are requested by the Secretariat:

1. to prepare a guidance document on the structure and content of SCHEER scientific Opinions and Statements. The procedure and periodicity for reviewing or updating the guidance documents should be also included. The new structure should be proposed as an annex to the Guidance;

The Scientific Committee on Consumer Safety (SCCS) might be consulted in order to ensure overall consistency between Opinions of Scientific Committees.

[1] Commission Decision C(2015) 5383
http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf

[2] http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

2. CONCLUSIONS

The guidance document proposing a new structure and content of SCHEER scientific Opinions and statements was adopted by the SCHEER by written procedure on 23 February 2017.

The proposed structure and content of the SCHEER Opinions are outlined in the Annex.

This guidance should be publically available to ensure transparency and to enable input from other interested parties.

It will be tested by the SCHEER for a period of approximately one year and after that, amended if necessary.

3. ASSESSMENT

The Scientific Committees, as established by the Commission Decision C(2015) 5383, shall provide the Commission services, on their request, with scientific advice and risk assessment in the fields of public health, consumer safety and environmental risks. The Opinions and scientific advice papers are therefore primarily intended for the Commission services as a basis for their policy making and implementation of the EU legislation.

However, the Opinions and scientific advice papers of the Scientific Committees have become a reference beyond the Commission services, for instance for EU countries authorities, international bodies, non-governmental organisations and other stakeholders.

There is an increasing demand from stakeholders and non-governmental bodies to improve the transparency of risk assessment procedures and also to provide information about how scientific Opinions are elaborated and agreed by the Scientific Committees.

The scientific assessments carried out by Scientific Committees should always be based on scientifically accepted standards of best practice and be transparent with regard to the data, methods and interpretations that are used in the risk assessment process. They should identify weight of evidence and uncertainties and use harmonised terminology, where possible, based on internationally accepted terms.

In order to increase the clarity for non-specialists, it is important to take into consideration the specific needs of the different readers of the Opinions. Indeed, the scientific background of the target audience may condition the language and the level of scientific complexity, at least in some parts of the document (such as the summary and the Opinion section) but this must not affect the scientific soundness of the scientific rationale.

The SCHEER shall identify the targeted group(s) for the Opinion at the very beginning of the work. Specialists in the field of the topic described in an Opinion need an exhaustive scientifically elaborated document, while a reading panel without a similar scientific background would appreciate an Opinion addressing the main key points related to the evaluation of the hazard and risk assessment of emerging risks without exhaustive scientific explanations. In the latter case, a more concise report would be much appreciated.

To meet these different needs, the Secretariat will continue to produce fact-sheets, newsletters and web-summaries for the general public, while the Opinions will maintain a high scientific level.

This document aims at providing guidance on how to ensure the high quality of the scientific Opinions in dealing with health, environmental and emerging risks.

The key components of the Opinion (which may address specific or more generic questions) or scientific advice are identified as separate chapters and their content is indicated. Particular attention has been paid to ensure that the format and procedures are flexible enough to be applied in a wide range of scientific Opinions, i.e. risk assessment based on the applicant's dossier and literature review, using a weight of evidence argument.

It is fully recognised that not all chapter headings, or the extent of detailed description within, are appropriate to every Opinion or statement issued. However, whilst the structure proposed allows flexibility to choose headings and content fit for the purpose of individual Opinions and Statements, it is recommended that the information content of both types of output be as complete as possible.

4. ABBREVIATIONS AND GLOSSARY OF TERMS

SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)
ToR	Terms of Reference

ANNEX – Structure and content of SCHEER's scientific Opinions and Statements

NAME OF THE COMMITTEE(S) AUTHOR OF THE OPINION/STATEMENT

The full name should be indicated together with the acronyms (e.g. Scientific Committee on Health, Environmental and Emerging Risks- SCHEER)

TITLE OF THE OPINION/STATEMENT

The title of the Opinion/Statement should be indicated together with the specification whether it is the preliminary or the final version.

Example:

Title: Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Short title: Health effects of sunbeds for cosmetic purposes, *to be used as running title and the main link on the Scientific Committees' website*

Preliminary version/Final version *(in the heading)*

DATE OF THE ADOPTION

The date of the adoption by the Committee should be indicated, together with the specification whether it was at the plenary meeting or via written procedure.

Example:

The SCHEER approved this Opinion at its plenary on (date)/or by written procedure on (date)

ABSTRACT

The abstract should preferably not exceed 200 words and should contain the requestor and the overall conclusion of the Opinion.

KEY WORDS AND CITATION

Example:

Key words: Ultraviolet radiation, UV-tanning devices, Sunbeds, Health effects, Risk assessment, SCHEER

Opinion to be cited as:

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Opinion on (title of the Opinion), date of the adoption by the SCHEER

AKNOWLEDGMENTS

Members of the Working Group and any additional contributors are acknowledged.

Link to the declarations of interest of members of the working group should be provided.

INFORMATION ABOUT THE SCHEER AND LIST OF ITS MEMBERS

A short description of the Scientific Committees and the SCHEER should be provided, together with the list of all SCHEER members.

TABLE OF CONTENTS

SUMMARY

The summary should not exceed 2 pages.

It is a stand-alone part of the Opinion reflecting the full scope of the Opinion; it should not include tables, footnotes, graphs, pictures or references. Clear scientific language should be used.

It should include:

- The requestor and the request;
- The data and methodologies used;
- The assessment and its results, including the weight of evidence;
- The main conclusions and, if appropriate, recommendations expressed by the SCHEER.

If the summary does not contain additional, significant information compared to the abstract, it can be omitted.

1. MANDATE FROM THE EU COMMISSION SERVICES

This part is provided by the requestor Commission service and should include:

1.1 Background

Any information judged useful to better understand the scientific, technical and legislative context of the mandate, as appropriate.

1.2 Terms of Reference (ToR): the request and the questions

This part is provided by the Commission service requesting the Opinion as part of the mandate and is agreed between the requestor and the SCHEER. The ToR provide the frame and the scope of the Opinion.

1.3 Additional information (if appropriate)

This chapter could provide additional background information relevant to the assessment (e.g. previous Opinions or other assessments issued by other bodies/organisations).

2. OPINION or CONCLUSIONS

The Opinion should provide the responses to the question(s) posed by the Commission services in the ToR. It should be written in a language understandable to the requestor but also to scientists in a rigorous scientific language.

The responses shall not address risk management aspects and shall not recommend risk management measures, unless specifically requested.

When appropriate, key scientific information underpinning the assessment should be outlined, including weight of evidence and uncertainties.

Answers to the questions in the ToR should only be drawn from conclusions which are based on data and reasoning all duly explained and described in the assessment part.

For complex Opinions, the Opinion shall be accompanied by a summary in layman's terms to be published on the Scientific Committees' website.

3. MINORITY OPINIONS

Transparency should be ensured and the Opinions of the Scientific Committee shall include any minority Opinions, together with scientific supporting argumentation. Minority Opinions can only be expressed by members and shall be attributed accordingly.

4. DATA AND METHODOLOGIES

The elaboration of a scientific Opinion is the result of critical evaluation (weight of evidence) of data/evidence and expert judgement. It is therefore essential that both the data/evidence and the expert judgement are properly presented, explained and documented in each Opinion.

4.1 Data/Evidence

The decision on the type of evidence (e.g. individual data, summary data or expert knowledge) to be used in each step of the assessment is taken on the basis of evidence availability, regulatory framework (e.g. dossiers) or established approach (e.g. Scientific Committees Guidance documents).

Data can be derived from several sources: (peer-reviewed) scientific journal publications, reports of governmental, non-governmental, international bodies and organisations, confidential reports. The sources of all data considered must be described.

When a literature review is performed, the search key words and the period covered in the search should be provided.

4.2 Methodologies

The methodology used to acquire, process and integrate the data should be explained and described within the assessment (e.g. systematic literature review).

The specific criteria (quantity, quality, strength, relevance, etc.) used for critically selecting and evaluating data and scientific information and attributing a weight to the various lines of evidence in order to determine the existence of risks, and characterise them and to draw conclusions, shall be clearly explained; as well as the decision to include them, exclude them or partially take them into account by attributing to them a certain weight. (i.e. 'SCHEER Memorandum on the use of the scientific literature for human health risks assessment purposes - weighing of evidence and expression of uncertainties'[3]).

The steps and methodologies followed in the assessment should be described or cited in order to enhance transparency.

When the assessment methods follow an established approach (e.g. in the case of regulated products), it may be sufficient to refer to other documents where

[3] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_s_001.pdf

details are provided (e.g. guidance documents/guidelines, previous assessments, accepted referenced models). Deviation from such methods must be documented and the rationale for doing so explained.

The accepted methodology for the assessment consisting of hazard identification, hazard characterisation, exposure assessment and risk characterisation is expected to be followed, as appropriate. It is not always necessary to perform all four steps; in certain cases only part of the full risk assessment may be requested.

5. ASSESSMENT

This chapter may be the most variable across SCHEER Opinions due to differences in the ToR and type of assessment carried out (e.g. type and number of substances, medical devices, risks etc.).

This part includes the scientific rationale, findings from the scientific papers and their interpretation and conclusions.

Expert judgement should be properly explained and documented so as to clearly demonstrate the contribution of evidence and of expert judgement in the Opinion and its conclusions.

The outcome of the individual steps of the assessment should be clearly documented. The final output should be the logical and transparent result of integrating these steps.

In quantitative assessments (deterministic and probabilistic), results are based, at least partly, on calculations or mathematical models. In qualitative assessments, results are expressed in a narrative way. In both cases, transparency requires that every element of the reasoning and/or calculation, and/or mathematical modelling, should be communicated and justified.

Each section of the assessment should have a conclusion, as appropriate, which should logically draw from data and reasoning explained and described in the section.

At the end of the assessment chapter, an overall conclusion should sum up the main findings of the assessment as derived from conclusions of previous sections.

Uncertainty and variability should be described and quantified to the extent possible at the most appropriate place(s) in the assessment, following the SCHEER Memorandum (see footnote 3).

This section should include, as appropriate:

- scientific background summarising the state of art in the research or reasons for an update
- Gaps in knowledge
- Section concerning different parts of the assessment, with a summary at the end of each part
- Overall conclusion

6. RECOMMENDATIONS FOR FUTURE WORK

Recommendations for future work may be provided, if applicable.

7. REFERENCES

All publications that are used and/or cited in the scientific output should be reported. In the case of systematic literature reviews, it may be appropriate to list the references either in a technical report or in an annex to the scientific output.

8. GLOSSARY OF TERMS, UNITS

A glossary of technical terms should be provided, or refer to an accessible glossary.

9. LIST OF ABBREVIATIONS

ANNEXES (if appropriate)

An annex may contain data and analyses that are considered too detailed to be included in the main text of the document or a stand-alone document that offers additional information to the main document.