

Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

Request from the SCHEER secretariat for

Testing the WoE approach as formulated in the 'Memorandum on weight of evidence and uncertainties – Revision 2018'

1. Background

According to the Commission Decision C(2015) 5383¹, the mission of the Scientific Committees 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.

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

According to the Rules of procedure², “the development of a scientific opinion ought to be the result of the critical evaluation of data/evidence and expert judgement. It is therefore essential that both the evidence and the expert judgement are properly presented, explained, and documented in each opinion. The specific criteria (quantity, quality, strength, relevance, etc.) for critically evaluating data and scientific information that have led to decisions on whether to include or exclude them, or partially take them into account by attributing to them a certain weight, shall be clearly explained. Their application in the specific case considered shall also be documented and explained in the opinion. The criteria used for attributing a weight to the various streams of evidence in order to determine the existence of risks, and characterise them, and to draw conclusions, as well the application of those criteria should also be explained. In a similar manner, the expert judgement should be properly explained and documented to clearly demonstrate the contribution of evidence and of expert judgement in the opinion and its conclusions.”

On 26 June 2018 the SCHEER adopted 'Memorandum on weight of evidence and uncertainties - Revision 2018'³ with the aim to provide greater transparency in its risk assessments, to be an aid to consistency between opinions, to be helpful to stakeholders and to be in line with the provisions stipulated in the Rules of Procedure.

2. Terms of reference

The SCHEER is required by the Secretariat to start applying the WoE approach as described in the 'Memorandum on weight of evidence and uncertainties - Revision 2018' taking into consideration the new methodology that has been described in this document.

Concretely, the SCHEER is required to:

1. Identify and discuss the difficulties and problems, benefits, solutions and methodological needs related to the implementation of 6-step approach described in the Memorandum (problem formulation, identification, collection and selection of the possible sources of evidence, assessment and weighing of individual lines of evidence, integration of lines of evidence, description of uncertainties, conclusion and reporting) in SCHEER scientific assessments/Opinions;

¹ http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf

² https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf

³ https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_014.pdf

2. In order to achieve the first request, the SCHEER should start applying in a consistent way the methodology described in the Memorandum in all new opinions (case-studies) aimed at testing the approach;
3. Elaborate a list of problems/difficulties encountered during this exercise and to describe the benefits and possible solutions to adapt the approach to the specificity of each scientific Opinion requested to the SCHEER;
4. Write a report (as outcome of this exercise) which will become an annex of each new Opinion the SCHEER will be requested to formulate starting with 2019. A summary of this report, adapted to the specificity of each risk assessment performed by the SCHEER, will be included as Chapter 'DATA AND METHODOLOGIES' in each Opinion.

In order to answer this request, the SCHEER should appoint a WG, which will work together with the specific WGs appointed to elaborate specific Opinions.