RULES OF PROCEDURE

The Scientific Committees on

Consumer Safety (SCCS) and

Health, Environmental and Emerging Risks (SCHEER)

APRIL 2016

The SCCS and the SCHEER adopted these Rules at their joint plenary meeting on 28 April 2016

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I. INTRODUCTION AND BACKGROUND

1. Commission Decision of 7 August 2015 C(2015)5383[1] (hereinafter "the Decision") reorganises the structure of the Commission Scientific Committees and establishes two Scientific Committees: the Scientific Committee on Consumer Safety - SCCS and Scientific Committee on Health, Environmental and Emerging Risks - SCHEER.

2. The Scientific Committees support the European Commission in evidence-based policy making by providing risk assessment and scientific advice on matters related to public health, consumer safety and the environment.

3. In accordance with Article 12(1) of the Decision, common Rules of Procedure are to be adopted by the Committees on proposal by and in agreement with the Commission and they shall cover in particular the subjects listed in Article 12(3) of the Decision.

II. OBJECTIVES OF THE RULES OF PROCEDURE

4. In accordance with Article 12(2) of the Decision, the Rules of Procedure shall ensure that the Committees perform their tasks in compliance with the principles of independence, confidentiality, commitment and transparency, as well as with the Commission rules on expert groups and principles and standards for scientific advice on risk assessment which may be established by the Commission Departments in light of the experience and in view of its policy in this area.

5. In order to achieve these objectives and ensure the effective functioning of the Scientific Committees, these Rules of Procedure regulate the functioning of the Scientific Committees, their working groups, the role and responsibilities of members and experts[2], other activities related to the functioning of the Scientific Committees, as well as the role and responsibilities of the secretariat of the Scientific Committees (hereinafter "the Secretariat").

III. PRINCIPLES

6. The Scientific Committees shall perform their tasks in compliance with the principles of excellence, independence, confidentiality, commitment and transparency, in accordance with Articles 16-19 of the Decision.

a. Excellence

7. The scientific advice must represent the best information and guidance on the assessment of the risks considered that science can provide at the time of adoption of the opinion under the conditions and deadlines

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

imposed. It shall be based on the best data, scientific knowledge and methodology available at the time of preparation of an opinion.

8. The principle of excellence refers to the performance and outcome of the entire process. It refers in particular to the intrinsic scientific quality of the opinion, its adequacy in relation to the aims of the mandate, its clarity, completeness and transparency. It also refers to the effective communication of the contents and conclusions of the opinions and the actual and perceived credibility of the process.

b. Independence

9. The scientific advice must not be influenced by any consideration other than the scientific assessment of the risks in question.

10. This principle implies in particular, independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations.

11. The principle of independence refers to the organisation and results of the process, including in particular the independence criteria and conditions and arrangements for the participation of members and experts.

c. Confidentiality

12. The scientific advice delivered by the Committees is sometimes based on confidential information. Participants and observers of the work of the Scientific Committees shall respect the principle of confidentiality and professional secrecy, and to exercise due diligence in not divulging confidential information acquired as a result of the work of the Scientific Committees, thematic workshops, working groups or other activities related to the application of the Decision and these Rules of Procedure.

d. Commitment

13. The members and experts shall commit themselves to act independently, in the public interest and to contribute actively to the work of the Scientific Committees. They shall set an exemplary conduct in all activities related to the Scientific Committees.

d. Transparency

14. The meaning of the scientific advice, the way conclusions were drawn, the limits of their validity and the relevant uncertainties must be clear and understandable for users, relevant stakeholders and the public. Equally, the organisation and process leading to the scientific advice, as well as their rationale, must be presented in a clear and understandable manner. Openness, dialogue and collaboration with other bodies and third parties should also contribute to transparency.

IV. RULES AND PROCEDURES RELATED TO EXCELLENCE

15. The Rules of Procedure shall be applied in such a way as to ensure that the principles and standards for scientific advice on risks as laid down Annex I are complied with.

16. The application of the principles and standards for scientific advice on risks shall be monitored by the Secretariat in collaboration with the Chair, Vice-Chairs of the Committee and, as appropriate, by the Chair of the working group or the rapporteur, in order to ensure that action is taken, as appropriate, to achieve conformity with the principles and standards in question.

V. RULES AND PROCEDURES RELATED TO INDEPENDENCE

17. Members and experts shall undertake to act independently from any external influence. They shall ensure that they do not directly or indirectly delegate their responsibilities to any other person or allow themselves to be influenced in any way during the execution of their duties.

18. For this purpose, members and experts shall make in writing a Declaration of Interests (see Annex II) at the beginning of their mandate and then annually. *Ad hoc* experts shall make in writing a Declaration of Interests before the meeting to which they are invited.

19. A Declaration of Interests shall not be required in relation to observers, since they do not have voting rights and do not participate in the formulation of recommendations or advice.

20. Members and experts shall be in a position to show beyond question that they can act independently. They are under a continuing duty to declare before undertaking any activity, situation, circumstance or other fact potentially involving an interest, as indicated in Annex II, in order to enable the Scientific Committee and/or the Commission services to identify those interests which might be considered prejudicial to their independence.

21. Declarations of Interests shall be published on the Scientific Committees' website and in the Register of Commission expert groups and other similar entities[3]. They must be complete and updated accordingly with any relevant additional or new information.

22. Members and experts participating in meetings of the Scientific Committees or in a working group, or in any other activity, shall declare at the beginning of each meeting or event any activity, situation, circumstance or other fact potentially involving an interest, as indicated in Annex II, in order to enable the Scientific Committee and/or the Commission services identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda

[3] http://ec.europa.eu/transparency/regexpert/

for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Secretariat and should be noted in the minutes of the meetings.

23. The Secretariat, the Chairs and the Committees shall ensure that the principles of independence of members and experts are complied with at all times. Members shall draw the Committee's and the Secretariat's attention through the Chair to any factual matter that could undermine credibility of Committee's work. The Committee's discussions of the matter shall be recorded.

24. The Secretariat shall draw the Commission services' attention to all cases where it appears that a member or expert might have ceased to fulfil the requirement to act independently from any external influence and address the measures to be taken, included as appropriate, the revocation of his/her appointment.

25. Any member or expert who, in accordance with his/her Declaration of Interests, or according to the opinion of the Scientific Committee, the working group or the Commission services, may not be able to act independently, shall be excluded from the activities considered or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. In such case, the member or expert may not act as a Chair or rapporteur in relation to the specific matter and may not have voting rights. The extent of the concerned individual's participation in the Committee's work shall be decided by the Chair in consultation with the Committee or working group members and in agreement with the Commission services, within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or limited participation.

26. Conclusions and decisions taken in relation to the Declarations of Interests, as well as their rationale, shall be recorded. In the case of declarations made at the meetings, the records shall be part of the minutes.

27. Members or experts contacted by third parties in connection with their participation on a specific question in Committee meetings, a working group or any other activity of the Scientific Committee shall inform the Secretariat and refer the third party to the Secretariat.

28. Members and experts shall inform the Secretariat of any relevant contacts they might have with petitioners, special interest groups, other stakeholders or other Union or international bodies in relation to the fields of work undertaken by the Committees (including Working Groups). The Secretariat, in consultation with the Scientific Committee in question, shall advise on any action to be taken if and when necessary should there be any possibility of a potential conflict of interest.

VI. RULES AND PROCEDURES RELATED TO CONFIDENTIALITY

29. Participants and observers shall not divulge confidential information acquired as result of their work in the Scientific Committee, thematic workshops, working groups, or other activities related to the application of the Decision and these Rules of Procedure. This will include in particular, documents provided by third parties concerning sensitive industrial and commercial matters, and/or for which confidentiality has been requested and agreed by the Commission services in accordance to the applicable provisions.

30. The obligation of the participants and observers not to disclose confidential information shall continue to apply even after their involvement in the work of the Scientific Committees has ceased.

31. Members and experts shall make in writing a Declaration of Confidentiality (see Annex III) at the beginning of their mandate. *Ad hoc* experts and observers shall make in writing the Declaration of Confidentiality before the meeting to which they are invited.

32. With the exception of minority opinions referred to in Article 19(1) of the Decision, individual views, whether expressed orally or in writing by members and experts during deliberations within the Scientific Committee or a working group, shall be confidential.

33. All participants and observers of the work of the Scientific Committees shall comply with Commission's security rules for protecting European Union classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443[4] and 2015/444[5]. Should they fail to comply with those obligations, the Commission may take all appropriate measures.

VII. RULES AND PROCEDURES RELATED TO COMMITMENT

34. Members and experts shall make in writing a Declaration of Commitment (see Annex IV) at the beginning of their mandate. *Ad hoc* experts shall make in writing the Declaration of Commitment before the meeting to which they are invited,

35. Members and experts are expected to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the Committees and the working groups and, when requested, with written comments. They shall take into account that meetings, in general, involve preparatory work and that requested

[4] Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

[5] Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

contributions (e.g. studies, reports or drafting opinions) shall be provided in due time.

36. Members are expected to participate in a fair share of working groups when their expertise is thus required, and act as a rapporteur or Chair of working groups on a rotating basis that fairly divides these tasks among members.

37. Members are expected to represent the Committee in meetings with stakeholders, hearings and workshop on invitation by the Secretariat.

38. In each calendar year, it is expected that members and experts will be in a position to attend at least 70% of the meetings of the relevant Committee and working groups in which they have been invited.

39. The extent to which members and experts have been in a position to participate in the work of their Committee related to the particular work they were assigned to, will be assessed by the Secretariat on a yearly basis. After consultation with the Chair, the Secretariat shall examine the situation with the members and experts who have not been in a position to comply with the participation criteria. They could be dismissed from the working group or from the Committee.

40. When invited to represent a Scientific Committee, members and experts shall ensure that they convey the views of the Scientific Committee, without expressing personal views or interpreting adopted opinions in a way that goes beyond the established position of the Scientific Committee. In such cases, they should inform and consult with the Secretariat in advance. Moreover, they should use the formats, templates and logos provided by the Secretariat in order to make visible the contributions of their presentations to the Committee. Finally, they shall report to the Secretariat in writing and orally at the relevant Committee meeting(s).

41. Members and experts shall not speak on behalf of the Commission unless formally requested by the relevant Commission services to do so.

42. Members and experts shall inform the Secretariat on all issues concerning their external activities directly related to the Committee's work, e.g. relations with the media (interviews, articles, letters, etc.), presentations/speeches, and other communication regarding the work of the Committee.

VIII. RULES AND PROCEDURES RELATED TO TRANSPARENCY

43. The Scientific Committees shall operate in accordance with the high level of transparency, without prejudice to legitimate requests for confidentiality or the need to safeguard the freedom and scientific integrity of the scientific debate and the independence of members and experts vis-à-vis external influence.

44. Requests for access to documents will be handled in accordance with the provisions of Regulation 1049/2001[6] .

45. The following documents of the Scientific Committees shall be published on the Scientific Committees' website without undue delay by the Secretariat, subject to respect of confidentiality requirements as well as protection of personal data:

- draft agendas of plenary meetings of the Committees, and meetings of the Inter-Committee Coordination Group established in accordance with Chapter X point m.
- minutes of plenary meetings and meetings of the Inter-Committee Coordination Group and working groups,
- requests for opinions (mandates),
- preliminary opinions published for public consultation and final opinions, including minority opinions and the names of the participants in the working groups that contributed to the opinion concerned. Minority opinions shall be attributed to the members concerned,
- Declarations of Commitment and Confidentiality of members and experts,
- Declarations of Interest of members and experts who participated in working groups; declarations of interest made in relation to items on the agendas of plenary meetings and working groups shall be published as part of meeting minutes,
- the names of the members of the Scientific Committees and experts, together with their brief CVs,
- Scientific Committee reports clarifying contentious issues as a result of a substantive divergence over scientific issues with other Union bodies (Article 13(3) of the Decision),
- Rules of Procedures,
- stakeholder dialogue activities (consultations on mandates, calls for information, calls for experts, calls for hearings, public consultations on preliminary opinions etc.).

46. For any other document, the Secretariat, in agreement with the relevant Commission services, shall decide about the publication and the dissemination case by case.

47. Names of members and experts appointed to working groups as well as their declarations of interest shall be published after the adoption of the opinion to which they have contributed. Nevertheless, their names may be disclosed earlier if necessary for their participation in hearings or other public events.

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[6] Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43)

48. Availability of preparatory and draft working documents shall be restricted, on a need-to-know basis, to members, experts, the Secretariat and representatives of the Commission services with competence for a specific question. They shall not be given to third parties unless a different decision is taken in specific cases by the Scientific Committee concerned in agreement with the Secretariat, in view of a specific need to involve or inform urgently a third party as part of the process to complete the relevant work.

49. Without prejudice to Article 19 of the Decision, the Commission services shall be responsible for determining the appropriate level of publicity to be given to a scientific opinion and may request the assistance of the Chairs, rapporteurs or other members and experts to ensure the scientific validity of its press releases or related communication actions.

IX. RELATIONS AND DIALOGUE WITH STAKEHOLDERS AND THE PUBLIC

50. The Scientific Committees may require additional information from stakeholders for the completion of a scientific opinion. This may involve in particular invited face to face meetings, consultations, hearings, request for the submission of information etc. To this end, targeted calls for information may be organized by the Secretariat in agreement with the Committee. A deadline for the submission of required information shall be given in agreement with the Commission services. If the required information has not been submitted within the deadline, the Scientific Committees may adopt the opinion on the basis of the available information. No aspect of the stakeholder procedure and its actual application may be invoked as a reason to delay the adoption of, modify or reconsider a scientific opinion.

51. A stakeholder dialogue procedure is laid down in Annex V. The aim of the procedure is to enhance the quality of the scientific opinions. The procedure shall be applied in agreement and co-operation between the Scientific Committee concerned and the Secretariat.

52. The stakeholder dialogue procedure shall apply when and as compatible with the fundamental requirement to ensure the full independence and autonomy of the Scientific Committees in elaborating, determining and deciding the contents and conclusions of their opinions and to preserve the integrity of the process for the establishment of scientific advice. The Secretariat shall suspend the application of the procedure in a particular case if there is any risk to the independence and integrity of the process and shall alert the Commission departments of the nature and extent of such risk.

53. In cases where an opinion is prepared in light of information submitted by a party to a procedure in response to specific regulatory requirements of that procedure (applicants), the Secretariat shall, when appropriate, seek comments of that party on a draft of the opinion, and submit those comments to the Committee before the adoption of the final opinion.

X. FUNCTIONING OF THE SCIENTIFIC COMMITTEES

a. Election of Chairs and Vice-Chairs of the Scientific Committees

54. Each Scientific Committee shall elect from among its members a Chair and two Vice-Chairs.

55. The terms of office of the Chair and Vice-Chairs shall be 5 years, renewable.

56. The names of the Chair and the two Vice-Chairs of each of the Committees shall be made public.

57. The Chair and Vice-Chairs shall be elected by secret ballot and in writing by the members present at the meeting.

58. The election procedure shall be chaired by the Secretariat.

59. The procedure shall be as follows:

- The election of the Chair and of each of the Vice-Chairs shall be held separately. A separate record shall be kept of the election procedure.
- The names of those wishing to stand as candidates shall be notified to the Secretariat before the meeting or be announced at the meeting. Members may present themselves as candidates or be proposed by another member.
- The candidates must, prior to the vote, declare that they are prepared to accept the post of Chair (or Vice-Chair) of the Committee and be prepared to assist the Commission services on matters relating to the coordination of the Scientific Committees, including if necessary participating in coordination meetings organised and chaired by the Commission services.
- The candidate receiving the simple majority of the total number of the members of the Committee shall be elected.
- If none of the candidates receives a simple majority, a second ballot shall be held between the two candidates with the highest individual totals of votes in the first ballot. The candidate obtaining the simple majority of the votes of the members of the Committees shall be elected.
- Candidates may withdraw their candidature at any time during the procedure.

b. Role and replacement of Chairs and Vice-Chairs of the Scientific Committees

60. The Chair of the Scientific Committee, in collaboration with the Secretariat shall be responsible for:

- planning the work of the Committee in agreement with the Secretariat,
- chairing, steering and moderating the discussions at meetings and drawing conclusions,

- keeping a good balance between rapporteurs and the number of dossier allocated,
- advising the Commission services on any selection of additional experts, if needed,
- taking the necessary measures to ensure that the deadline for delivery of the opinion is respected,
- examining the Declarations of Interest, deciding, in consultation with the Committee and in agreement with the Commission services, the relevant conclusions and action in order to ensure the effective application of the independence requirements,
- in collaboration with the Secretariat, monitoring the conformity of the activities of the Committee with all the relevant procedural methodological and substantive requirements, principles and standards established or deriving from the Decision, these Rules of Procedure and the state of the art on risk assessment, and taking, or requesting the Commission services to take as appropriate, the necessary measures,
- representing the Committee.

61. If the Chair is not in a position to fulfil his/her function, he/she shall be replaced by one of the Vice-Chairs or, failing that, another member chosen in common accord by the members.

62. In case of conflict of interest of the Chair with an item on the agenda, he/she shall be replaced by one of the Vice-Chairs or failing that another member chosen in common accord by the members.

63. The Vice-Chairs shall support the Chair in fulfilling his/her responsibilities. The Chair shall consult the Vice-Chairs on a regular basis and as appropriate on emerging issues requiring urgent decisions that could not be postponed for discussion at plenary meetings.

c. Requests for Scientific opinions (mandates)

64. Requests for scientific opinions (mandates) shall be submitted by Commission services to the Secretariat. The terms of reference of the mandate shall be limited to risk assessment.

65. The request shall consist of the background information explaining the European Union interest in relation to the request, the scientific context, and the terms of reference. Required timeline and supporting documents may be indicated.

66. The Commission services may specify in the request for an opinion the consultations, hearings, or collaboration with other scientific bodies deemed necessary for the preparation of the opinion.

67. All mandates shall be reviewed by the Secretariat before submission to a Committee, for conformity with the applicable template, clarity and completeness, relevance in relation to the fields of competence of the

Committee, appropriateness of the terminology and absence of risk management aspects in the questions proposed.

68. The Secretariat shall allocate the mandates to the responsible Scientific Committee having regard to the subject matter of the mandate, the respective on-going mandates of the Committees, the expertise of the members, the need for methodological consistency and a broad, multi-sectorial and multi-disciplinary approach.

69. The Secretariat shall inform the Chair without delay of the allocation of the mandate.

70. The mandate shall be presented to the Committee for adoption by a representative of the requesting Commission service, assisted by the Secretariat, or by the Secretariat on behalf of the requesting Commission service.

71. The Scientific Committee may ask the Commission services to clarify the mandate and/or to supply additional information.

72. Mandates adopted by the Scientific Committee shall be published as soon as possible on the Scientific Committees' website.

73. The Commission services may require the adoption of a joint opinion on mandates not falling exclusively within the fields of competence of a single Committee or which otherwise need to be considered by the two Committees. Requests for joint opinions will be considered by the Inter-Committee Coordination Group and the Secretariat. In this case, the lead Committee may be designated.

74. Mandates may be submitted to public consultation according to the procedures set out in Annex V. The mandate may be modified on the basis of the public consultation. In either case a proper justification should be provided in the opinion so as to ensure and document the transparency of the process.

75. When the Commission services require the Scientific Committee to adopt a scientific opinion within a specified deadline, the Committee shall take the necessary measures to ensure that the deadline is respected.

d. Hearings and public consultations

76. The Scientific Committees, in agreement with the Commission services, may decide to hold a hearing and/or a public consultation if considered necessary for completing an opinion. The practical aspects of such hearings and consultations shall be decided upon and managed by the Secretariat according to the procedures set in Annex V.

e. Establishment and role of working groups

77. In agreement with Commission services, the Scientific Committees may establish working groups to undertake tasks which are clearly defined and directly linked to the mandates received. In particular, a working

group shall be established when there is a need for external expertise on a particular subject. The working group may be asked to undertake all necessary tasks in relation to preparing and drafting opinions. The Scientific Committees can require that these tasks are completed within a specified period.

78. A working group shall report to the Scientific Committee to whose work it contributes to, providing it with such scientific advice or draft opinions as the Committee has requested within the specified period.

79. Working groups shall comprise of at least one member of the Scientific Committee that established them and may include external or *ad hoc* experts, as well as experts from other Union bodies. Other Commission services and EU agencies can also participate as observers in the working groups' meetings.

80. The working group shall be chaired by a member of the Scientific Committee that established it. The Chair of the working group shall be responsible for organising and steering the work of the working group and reporting to the Committee and to the Secretariat.

81. Members and experts of a working group shall be designated by its Chair in agreement with the Chair of the Scientific Committee and with the Secretariat, following the procedures described in point h. They shall be invited to meetings by the Secretariat.

82. A working group shall endeavour to reach a consensus. In the absence of a consensus, the position of the working group shall be approved by a simple majority of its members. Nevertheless, the Chair of the working group shall inform the Committee of all expressed positions.

83. The names of participants in the working groups shall be comprised in the opinion to which they have contributed.

f. Designation and role of Rapporteurs

84. The Chair of the working group, in agreement with the working group and the Secretariat, may appoint a rapporteur among the members or external experts. For particularly complex questions of a multidisciplinary nature, more than one rapporteur may be appointed. The designation may be revoked. An appointment of the rapporteur shall be followed by a written arrangement between the rapporteur and Commission Departments.

85. Rapporteurs shall be responsible for assembling information, editing and revising draft opinions and ensuring that draft reports, scientific advices and scientific opinions are prepared within a set time period, where appropriate. The rapporteur should ensure that these documents are well structured, written in clear and simple language and are coherent. The rapporteur should also deal, together with the Chair of the working group, with the comments received during the public consultation and prepare the replies, where applicable. The rapporteur shall work in close cooperation with the Chair, the other members of the working group and

the Secretariat. The rapporteur (or the Chair of the working group in case the rapporteur is an expert) shall present the draft opinion to the Committee during a plenary meeting.

86. The work of a rapporteur is concluded when the final opinion is published on the Scientific Committees' website.

g. External, *ad hoc* experts and observers

87. External and *ad hoc* experts possessing particular and relevant scientific knowledge may be invited to contribute to the work of the Scientific Committees and its working groups. This will include in particular the preparation, compilation and presentation of the scientific evidence base which serves as a basis for the opinions of the Scientific Committee.

88. External experts may participate in a working group. They can act as rapporteurs, contribute to preparing and drafting opinions to be submitted to the relevant Committee, but have no voting rights.

89. *'Ad hoc'* experts are experts whose role is limited to testify and give specialist advice on specific issues by providing information and replying to any questions only (in written and oral form). Such experts can be invited to participate in working group meetings and hearings on *ad hoc* basis for limited time. They cannot be appointed as rapporteurs, cannot draft opinions and have no voting rights.

90. The Secretariat, in agreement with the Chair of the relevant Committee and the Chair of the working group, may give observer status to staff of Commission services and Union bodies concerned, and other individuals by direct invitation.

91. Third countries' authorities which are not candidate countries may be granted observer status if their participation in the work of Scientific Committees is in the interest of the Union, in particular in the light of the application of any international agreement, administrative arrangement or Union legislation.

92. Although observers may be permitted by the Chair to take part in the discussion of the group and provide expertise, they shall not have voting rights and shall not participate in the elaboration of opinions.

h. Selection of external experts to participate in working groups

93. External experts designated to participate in working groups may be selected from the reserve list of suitable candidates[7], from the database of experts, or from a specific open call for experts launched by the Secretariat, in that order of priority.

94. A shortlist of suitable candidates shall be established by the Secretariat on the basis of the required fields of expertise needed to complete the assigned tasks as defined by the Scientific Committee.

[7] Established following an open call for expression of interest.

95. The Chair of the Scientific Committee and of a working group, in collaboration with the participants to the working group, as appropriate, shall be consulted by the Secretariat to select the candidates from the shortlist. The selection process shall be properly recorded in order to document the transparency of the process. The final decision remains to the Commission services based on the assessment of the independence of the experts.

i. Meetings (Notice, Agendas, Deadlines, Minutes, Access)

96. The Secretariat shall establish with each Scientific Committee a schedule for the Scientific Committees' plenary meetings for the forthcoming calendar year.

97. As a general rule, the Secretariat shall confirm meetings of the Scientific Committees and working groups at the earliest possible date but no later than ten working days before the date of the meeting and shall give notification of cancellation not less than two working days before the date of the meeting.

98. Meetings of the Scientific Committees and working groups may be called at short notice according to the urgency of the matters.

99. The Secretariat shall prepare the draft agenda of meetings of the Scientific Committees and the working groups and circulate it to members and experts as soon as possible and no later than two weeks before the date of the meeting. The draft agenda of plenary meetings shall be published on the Scientific Committees' website before the meeting takes place.

100. The draft agenda shall include new mandates submitted by the Commission services and shall be accompanied by all appropriate and available supplementary information of relevance to the new mandates submitted. The Secretariat shall provide any additional information as soon as possible to the members.

101. Wherever possible, documents, including reports and draft opinions prepared by chairs, rapporteurs or members, shall be made available to the Secretariat for distribution to the members and experts at the latest one week before the meeting where they will be discussed. Chairs, rapporteurs and members entrusted with the drafting of documents, reports or draft opinions shall ensure that this requirement is complied with.

102. The agenda shall be adopted at the beginning of the meeting taking account of any agreed amendments.

103. Meetings of the Scientific Committees and their working groups shall not be open to the public.

104. Commission services concerned with the topics on the agenda shall be entitled to be present in the meeting. They may assist for the

purposes of clarification or provision of information but shall not seek to influence the outcome of the discussions.

105. The Secretariat of the Scientific Committees shall prepare draft minutes of plenary meetings. The minutes shall contain at least:

- the list of participants and apologies for absence,
- Declarations of Interests by participants concerning their independence including the relevant details, the action taken and its rationale. Information registered in the minutes must be adequate and relevant for the purpose of management of conflict of interest,
- the adopted agenda,
- a summary of discussions, including important minority stand points and agreed actions,
- a record of decisions taken and opinions adopted,
- any vote against or abstentions during voting and the reasons of their vote.

The minutes shall not mention the individual positions of the members during the Committee's deliberations.

106. The draft minutes of the plenary meetings shall be circulated to the members of the Scientific Committees for comments. They should be adopted not later than at the next meeting.

107. Without prejudice to the provisions of Chapter VI, minutes shall be published on the Scientific Committees' website as soon as possible after their adoption. Legitimate requests for commercial confidentiality shall be respected.

108. Correspondence relating to the Committees and their members shall be addressed to the Secretariat, for the attention of the Chair using the functional mailboxes indicated on the website[8].

j. Format and content of scientific opinions

109. The scientific opinion should comprise:

- composition of the working group,
- the background (European Union interests and scientific background),
- the terms of reference providing specific question(s),
- an abstract (where appropriate),
- an executive summary (where appropriate),
- the considerations used by the Committee to reach its conclusions (scientific rationale),

[8] http://ec.europa.eu/health/scientific_committees/contact/index_en.htm

- the conclusion (opinion), setting out the response to the question(s) posed by the Commission services. For complex opinions, the conclusions shall be accompanied by a summary in non-specialised language,
- a bibliography,
- a list of abbreviations,
- a glossary (where appropriate),
- any minority opinions.

More details about the format of the opinions may be provided in specific guidance papers prepared by each Scientific Committee.

110. The Scientific Committees shall adopt scientific opinions at their plenary meetings by a majority of the total number of its members.

111. If necessary, the Scientific Committees may adopt an opinion, previously discussed in a Committee meeting, by written procedure. In this case, the Secretariat shall send to the members of the Scientific Committee the opinion on which it is being consulted with a request for approval by a set deadline. The opinion shall be adopted if the majority of the members of the Scientific Committee have expressed their approval before the deadline. If majority is not reached, the opinion must be put on the agenda of the following meeting of the Scientific Committee or, if the urgency of the matter so requires, an *ad hoc* meeting shall be convened at the earliest date at which the quorum can be assured.

112. In case of urgency, opinions may be adopted by accelerated procedures.

k. Minority opinions

113. The Scientific Committees should strive to reach common conclusions. However, when it is not possible to reach such common conclusions, transparency should be ensured and the opinions of the Scientific Committee shall include any minority opinions together with supporting argumentation. Minority opinions can only be expressed by members and shall be attributed accordingly.

l. Voting Rules

114. The Scientific Committees shall adopt their opinions, rapid advice notes, memoranda and/or position statements by an absolute majority of their members.

115. Meetings are considered in force when the absolute majority of the members of the Committee concerned are present.

116. Members who have resigned or whose membership has been terminated shall not be taken into account for the calculation of the majority required.

m. Coordination of the Scientific Committees. The Inter-Committee Co-ordination Group

117. Chairs and Vice-Chairs of the Scientific Committees and the Secretariat shall assist the Commission services on matters relating to the coordination of the Scientific Committees. They form the Inter-Committee-coordination group that shall assist the Commission services in achieving a high level of harmonisation in the risk assessment procedures both between the Committees themselves and between the Committees and other European Union or international bodies charged with risk assessments in their domains.

118. Participation of the Chair or Vice-Chairs of one Committee in plenary meetings of the other Committee is encouraged.

119. The Inter-Committee-coordination group shall achieve its objectives by means of periodic meetings or exchange of documentation as appropriate to the matter at hand. Meetings shall be convened and chaired by the Secretariat.

120. The Inter-Committee Co-ordination Group may also provide support to the Commission services on matters and activities related to the EU and international dialogue on risk assessment, collaboration with other scientific bodies, establishment of networks, organisation of thematic workshops and scientific conferences, general advice on research programmes, and priorities.

121. Co-ordination shall cover, notably, the following areas:

- Joint opinions

The Inter-Committee Co-ordination Group shall advise the Secretariat on the allocation of the joint opinions to the responsible Committee (the lead Committee) and to designate members of the associated Committee.

- Diverging scientific opinions

When the Secretariat is informed of divergence or risk of divergence between opinions of the Scientific Committees or of one of the Scientific Committee and an international or Union body, the Inter-Committee Co-ordination Group shall advise the Secretariat on the appropriate course of action and the optimum use of the Scientific Committees to avoid or resolve the divergence. In particular, the Chairs shall make a preliminary assessment of the nature of the divergence, advice on the need for a joint meeting with the parties concerned and on the Committee(s) and members to be involved.

- Coherence and improvement in structure and content of opinions

The Inter-Committee Co-ordination Group shall provide regular feedback and advice on the structure and content of scientific opinions of the Committees, with a view to improving coherence, consistency and

clarity. Advice shall include in particular the establishment and updating of a risk assessment vocabulary for use in scientific opinions and recommendations for improvement based on retrospective review of the adopted opinions.

- Providing a single point of reference on matters of common concern

The Inter-Committee Coordination Group shall agree on a common position in cases where the Committees should be represented by a single view.

- Methodological approaches in the area of risk assessment

The Inter-Committee Co-ordination Group shall advise the Secretariat on the need for and the approach to establishing risk assessment methodologies of common interest to the work of the Committees.

- Exchange of information on the activities of the Committees

The Inter-Committee Co-ordination Group shall be invited to share information concerning activities undertaken by their own Committee and to raise organisational or scientific problems requiring a harmonised approach.

122. Minutes of each meeting of the Inter-Committee Co-ordination Group shall be published on the Scientific Committees' website.

n. Risk-related issues raised by the Scientific Committees

123. The Scientific Committees shall draw attention of the Commission services to a specific or emerging problem falling within their remit, which they consider may pose an actual or potential risk to consumer safety, public health or the environment by adopting and addressing to the Commission services memoranda or position statements.

124. The Secretariat shall inform the Commission services interested of the intention to adopt a memorandum or position statement and facilitate the dialogue between the services in question and the Committee on the relevant subject.

125. The Secretariat, in consultation with the Commission services, shall arrange to publish on the Scientific Committees' website such memoranda and position statements and inform the Committee accordingly.

o. Rapid advice and Accelerated Procedure

126. In case of urgent needs, the Commission services may request the Scientific Committees to provide rapid advice on the state of scientific knowledge concerning specific risks. The rapid advice is intended to support the Commission services with scientific information in case of crisis, sudden events or developments or urgent need to react to public concerns or requests from other institutions. This procedure is not

intended to produce full risk assessment reports. Normally, it shall apply in cases where the advice is needed within at the latest a few days.

127. The rapid advice may take the form of:

- informative "Rapid Advice Notes on Specific Risk Issues" issued by the Secretariat, in the most urgent cases, prepared in accordance with the procedure laid down below or in accordance with a specific procedure (e.g. Guidance on Rapid Risk Assessment for serious cross-border chemicals threats, including environmental and biological threats not related to communicable diseases[9]),

- an opinion adopted by the relevant Committee through an accelerated procedure launched by the Secretariat in agreement with the Chair.

128. In the case of informative "Rapid Advice Notes on Specific Risk Issues", when requesting rapid advice, the Secretariat shall contact by the fastest means the Chair(s) and, if necessary, the Vice-Chairs for identifying the relevant expertise in the Committees and Working Groups, the appropriate sources of information on the subject matter and the scoping and formulation of the issue in question. On the basis of the indications obtained, the Secretariat shall collect from the appropriate members and experts the information needed and will summarize it in collaboration with the relevant Chairs and Vice-Chairs as appropriate. The names of contributors to the rapid advice will be acknowledged in the note.

129. In the case of accelerated procedure to adopt an opinion, the Secretariat shall request, whenever possible in agreement with the Chair of the Scientific Committee, a member, an expert and/or a working group to draw up a draft opinion and submit it to the Secretariat within a set deadline.

130. If the Chair and Secretariat consider that the nature and urgency of the matter require an emergency meeting, the Secretariat shall endeavour to organise a meeting at short notice. The Secretariat shall put the draft opinion on the agenda of the next meeting of the Scientific Committee. In the event that the circumstances do not require or allow holding a meeting, a draft opinion may be adopted by written procedure.

XI. CO-OPERATION WITH OTHER SCIENTIFIC BODIES

a. Diverging opinions

131. Each Scientific Committee shall assist the Commission services and contribute in identifying, resolving or clarifying at an early stage potential or actual divergence between their scientific opinions and the scientific opinions of Union, national or international bodies carrying out

[9] Article 9 of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

similar tasks, on general or specific risk assessment issues. Each Scientific Committee shall assist and contribute in identifying needs and possibilities for coordination of work and collaboration, in particular the need for a joint opinion and/or a joint working group or exchange of experts as members of a working group.

132. When a substantive divergence is identified with a Union risk assessment body, the Scientific Committee concerned shall, on the request of the Commission services, cooperate with the body concerned. To this end, the Commission services may convene a meeting between the Scientific Committee and the scientific organs of the bodies concerned. The Scientific Committee shall designate a rapporteur.

133. When it is not possible to resolve divergent opinions, a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data shall be submitted to the Secretariat. This document shall be made public.

134. In order to help identifying, preventing or managing divergences over scientific opinions, the Secretariat shall seek to agree with Union bodies involved in risk assessment appropriate arrangements which may take the form of common guidelines.

b. Co-operation with other EU, national, international and non-EU bodies

135. The Scientific Committees shall assist the Commission services in establishing and maintaining collaboration relationships with other relevant Union, national or international bodies.

136. In particular, the Scientific Committees shall assist the Commission services on scientific technical matters requiring coordination and cooperation with other Union bodies charged with risk assessment, notably with the European Food Safety Authority (EFSA), European Chemicals Agency (ECHA), European Centre for Disease Prevention and Control (ECDC), and European Medicines Agency (EMA).

137. In order to ensure that this cooperation is effective:

- the Commission services may organise meetings of the Secretariat and members of the Scientific Committees with the Secretariat and Members of other Union risk assessment bodies;
- the Scientific Committees may ask for the assistance of members of the Scientific Committees or panels of other Union bodies as external experts if the question submitted has a bearing on the field of competence of one or more of the Scientific Committees and overlaps with the competence of other Union risk assessment bodies.

138. The Commission services may request and organise joint work of the Scientific Committees with the relevant Union, national or international bodies including bodies outside the European Union.

139. The Commission services may in particular request the Scientific Committees to produce joint opinions with other Union bodies, upon agreement with such bodies. In such a case, the relevant mandate submitted by the Secretariat shall specify the sharing of tasks and responsibilities and the arrangements for the organisation of the work and adoption of the joint opinion.

140. Requests for collaboration from other scientific bodies shall be addressed to the Chairs through the Secretariat. Depending on the subject and nature of the request, they shall be considered by the Inter-Committee Coordination Group or the relevant Committee. The Secretariat shall define and manage the practical aspects and take the appropriate contacts.

141. The Secretariat may establish appropriate arrangements, which may take the form of common guidelines, with other EU bodies involved in risk assessment on sharing scientific data. These guidelines shall be agreed by bodies participating in the exchange mechanism and approved by the Inter-Committee Coordination Group.

XII. ROLE OF THE SECRETARIAT

142. The Secretariat shall be responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Scientific Committees, to monitor compliance with the Rules of Procedure, particularly in relation to the requirements for excellence, independence, commitment, confidentiality and transparency, to ensure communication on the Committees' activities, the appropriate stakeholder dialogue, publication of the opinions and other relevant documents. Moreover, the Secretariat shall provide support to the Committees and organise and apply quality control of the opinions as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned. Specific duties shall include in particular:

a) ensuring best use of resources and the planning to meet priorities and time limits,

b) ensuring that requests for opinions comply with the relevant requirements,

c) allocating the mandate to the relevant Committee(s) and, where appropriate, in collaboration with the requesting Commission service, organising scientific meetings, hearings, consultations, collaboration with other bodies,

d) avoidance of overlapping or inconsistent opinions between Scientific Committees and other Union risk assessment bodies,

e) co-ordinating the administrative, scientific and technical work carried out within and between the Committees and their respective working groups, in consultation with the Chairs and Vice-Chairs where appropriate,

f) providing information on the legislative/policy aspects of the questions with the help of the relevant and interested Commission services and ensuring that relevant background information is made available to the Scientific Committee and working groups.

g) assisting in identifying the appropriate experts to be invited in working groups,

h) coordinating communication between the Committees and Commission services in relation to Committees' activities, including feedback from the Commission services on the adopted opinions,

i) assisting the Chairs of the Committees and their working groups in the preparation of the draft opinions in particular by monitoring, assessing and reporting to the Committees, before adoption, the quality of draft opinions, in particular in relation to correspondence with the mandate, completeness, clarity and coherence, editorial standards, as well as conformity to the principles of excellence, independence and transparency and the other relevant principles and standards referred to in these Rules of Procedure,

j) assuring the scientific and technical coordination of the activities of the Scientific Committees in relation to the activities of other Union and international bodies involved in scientific risk assessment,

k) deciding, in agreement with the interested Commission services, about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops,

l) monitoring compliance of members and experts with participation criteria and informing the Commission services as appropriate,

m) providing administrative support in relation to calculation of a special allowance for members and experts, in accordance with the rules laid down in the Decision.

XIII. TRAINEES

143. In order to contribute to capacity building in the area of risk assessment, trainees may be admitted to the meetings of the Scientific Committees, in agreement with the Secretariat.

XIV. REPRESENTATION OF THE SCIENTIFIC COMMITTEES

144. The Secretariat may invite the Chairs and Vice-Chairs to represent the Scientific Committees in external events, contacts, missions, etc., as appropriate. Chairs of working groups and rapporteurs may be designated by the Secretariat to make presentations of the opinions to which they have contributed. Other members and experts may be invited by the Secretariat to attend events, meetings, etc. in relation to the work of the Scientific Committee’s, but shall not speak on behalf of the Committees, unless explicitly requested to do so by the Secretariat.

XV. THEMATIC WORKSHOPS, SCIENTIFIC MEETINGS, NETWORKS

145. Thematic workshops shall be organised by the Secretariat:

- at the request of the Commission services, or
- at the own initiative of a Committee, in agreement with the Commission services.

146. The objective of such workshops may be to present an opinion, review data and scientific knowledge on particular risks or broad risk assessment issues. These workshops may involve members and experts, including experts from Union, national or international bodies carrying out similar tasks.

147. Workshops at the initiative of a Scientific Committee shall be organised by the Secretariat subject to consultation of the interested Commission services, availability of funds and adequate planning.

XVI. TRAVEL EXPENSES AND SPECIAL ALLOWANCE FOR MEMBERS AND EXPERTS, CHAIRS AND RAPPORTEURS

148. Travel and subsistence expenses incurred by members and experts in connection with Scientific Committee meetings and other activities are reimbursed in accordance with the provisions in force at the Commission.

149. Members and experts are entitled to a special allowance for their activities related to the work of the Committee and working groups as set out in Article 15 of the Decision.

150. Special allowance directly linked to attendance of meetings of Committees and working groups or agreed external meetings shall be based on the attendance list. Participation through audio or video link shall be highly encouraged and authorised by the Secretariat.

151. Special allowance for Chairs of the Committees and of the working groups shall be proportionate to the extra workload requested from them consisting in preparatory and follow-up work before and after the plenary and working group meetings and the coordination work carried out with the Secretariat, members and rapporteurs.

152. Special allowance for rapporteurs shall be proportionate to the extra workload requested from them, in accordance with the modalities laid down in the Decision. Payment of the special allowance shall be made after adoption of the final opinion by the relevant Scientific Committee.

153. The amount of special allowance paid to members and experts shall be published if it exceeds EUR 15 000 for the task performed, in accordance with the Rules of Application of the Financial Regulation.[10]

[10] Article 287(5) and (6) of the Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

ANNEX I - PRINCIPLES AND STANDARDS FOR SCIENTIFIC ADVICE ON RISKS

A. PROCESS

1. Transparency of processes

Both the processes applied and the opinions themselves must have a high degree of transparency.

As far as the process is concerned, this requirement applies in particular to the way in which the relevant expertise is identified and organised, including the procedures for the identification and selection of experts in the Committees and working groups, the procedures for the identification and acquisition of the relevant data and information, the weight of evidence, the role of the different actors intervening in the process, the consultations held and the decision making procedures.

2. Access to the best experts

The Committees should strive to involve or to consult the most qualified experts on the issue considered, while ensuring compliance with independence requirements. Experts should be selected taking also into account pluralism of views and multi-disciplinarily and, as far as possible, geographical origin distribution and gender balance.

3. Proactive search for scientific collaboration

As far as reasonably feasible and appropriate in light of the objectives of the consultation and time constraints, consultation and collaboration with other scientific organisations dealing with the subject addressed by a Committee should be proactively sought. In particular, risk assessments available on the subject addressed should be looked for and the results duly considered.

4. Effective organisation and planning

Planning and organisation of work should be realistic and proportionate to the scope and objectives of the request for an opinion. In this respect, the Chair of the Scientific Committee and the Chair of the working group are critical to identify and remedy, together with the Secretariat, problem situations (non - availability of experts for meetings, delays in delivering drafts, etc.) that may be detrimental to the quality and timely delivery of outputs.

5. Collegiality and pluralism

The process should be organised and managed in such a way as to enable the full involvement and contribution of all participants. The role of the Chair of the Scientific Committee in facilitating the process is critical. The opinion should properly reflect the contributions of the participants. In the case where consensus is not reached, different positions of experts in the working groups shall be reported to the relevant Committee while minority positions of Committee members shall be attributed and included in the opinion together

with supporting argumentations.

6. Effective dialogue

Dialogue with stakeholders will be organised in such a way that the input received can contribute to the quality, clarity and completeness of the opinion. To the extent possible, the Committees shall provide clarification as to why a particular scientific contribution was or was not considered and taken on board in a manner that appropriately documents the transparency of the process.

B. METHODS

7. Definition of objectives and scope

The scope and objectives of the risk assessment should be clearly defined in the mandate, in collaboration between the requesting Commission service and the Committee.

8. Transparency of opinions

Transparency should be ensured on all aspects of an opinion, including data and methods used and calculations and assumptions made, in such a way that the risk assessment performed and its conclusions are understandable and reproducible.

9. Use of best data

The risk assessment should be based on the best reasonably obtainable data and information at the time of the consultation. Limitations related to the data used, in particular due to time or other practical constraints, must be explained. Strategies and procedures for identifying and acquiring data and information shall be documented and sources of data shall be clearly identified in the opinion.

10. Best practice methodological approach

Risk assessment methods and procedures applied shall correspond to best international practices and accepted standards. In cases where a Committee considers it appropriate to use novel or non-validated methodological approaches in the development of an opinion, the Committee shall ensure that it clearly documents and explains the reasons/benefits for using such a method as well as its potential limitations.

Specific guidelines on the methodological approach to be used, (e.g. how to weight evidence, or assess uncertainties), may be elaborated by the Committee in the form of memoranda or notes of guidance that shall take into consideration best practices used for risk assessment.

11. Clarity on weight of evidence

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.

12. Qualitative and quantitative assessment

Risk assessment should be, as far as relevant and scientifically and practically possible, quantitative. When qualitative assessment is made, the narrative assessment should provide an unequivocal description and characterisation, of the nature, extent, probability, and magnitude of the risk.

In particular, ranges (or bounds) and scenario/sensitivity analyses may be used as rather simple ways to provide information about the uncertainty of the measured risks.

13. Systematic identification and assessment of uncertainties and variability

The uncertainties related to the various aspects and stages of the risk assessment shall be, as far as possible, systematically identified, analysed and documented.

Uncertainties, limitations, and assumptions, as well as their relative importance and their influence on the results of the assessment, shall be treated and expressed as far as possible quantitatively. Equally, all relevant sources of variability as well as their influence of the assessment of risks shall be identified, analysed, documented, treated and expressed, as far as possible, quantitatively.

Use of point estimates as well as factors used for accounting for uncertainties should be explained and justified and the influence of the assumptions made assessed and explained.

14. Use of confidential data compatible with clarity

While respecting the applicable confidentiality requirements, the opinions should provide sufficient information on the data on which they are based in order to allow understanding the rationale of their conclusions.

15. Avoidance of risk management statements

Both the questions posed in a mandate and the replies provided in the opinion,

shall not address risk management aspects. The opinions shall not recommend risk management measures.

Nevertheless, if so requested in a mandate, an opinion may assess (including comparatively) the effectiveness of specified measures in terms of risk reduction.

16. Avoidance of considerations not related to health, safety and environmental risk aspects

Risk assessment opinions should not address or be influenced by economic, social, ethical aspects or other aspects different from human health, safety and environmental risks.

Nevertheless, if so requested, an opinion may address risk-risk and risk-benefit aspects when the benefits in question are related to health, safety or the environment.

17. Expression of risks

Risks should be expressed quantitatively as far as scientifically and practically feasible, account taken of the data and knowledge available. Uncertainty and variability of the risk estimate should be presented contextually. Expression of risks includes its nature, scope and distribution, probability, and magnitude.

Framing risks, if appropriate, in particular referring to notions of acceptability of certain risks using terms like "acceptable risk", "normal risk", "serious risk", "safe" etc. should be avoided and preference should be given to descriptive terms deriving from the results of the risk assessment (i.e. versus the margin of safety, probability and severity of effects etc.). Notions of ranking or acceptability of risks should only be introduced based on an approach and criteria that have been previously agreed with the risk managers.

18. Setting risks in the appropriate context

As far as relevant, a scientific opinion should help readers to put the results of the assessment in the appropriate perspective, notably when the scope of the opinion is limited and does not enable a comprehensive view of the risks (e.g. in case of assessments not taking into account multiple sources, cumulative or synergistic effects etc.).

19. Clarity on limitations due to the state of scientific knowledge and data availability

When relevant, scientific opinions should explain the limitations related to the state of scientific knowledge and/or the data and information available, and the influence of such limitations on their conclusions.

C. COMMUNICATION

20. Clarity of Opinions

Risk assessment opinions should be drafted in a clear and understandable way and include a self-standing executive summary providing sufficient information on the issue and its background, the process, the uncertainties, the conclusions and their meaning and limitations.

The conclusions should address the issues and questions of the mandate and correspond to its scope and objectives. They should provide a clear characterisation of the risks accompanied by narrative presenting the relevant qualifications.

21. Harmonised and clear terminology

Terms used should be, as far as possible consistent with harmonised and generally accepted terminology. When necessary in order to prevent misunderstandings, a glossary or definitions should be introduced. Particular care should be taken in order to ensure consistency of the terminology used across opinions of the Scientific Committees.

22. Internal coherence of opinions

The conclusions must be based on and be consistent with the data, calculations and developments presented or referred to in the other parts of the text.

23. Completeness of opinions

The opinions should include all the information necessary for the understanding and, as far as possible, reproducibility of processes and results. All the important steps, assumptions, calculations made should be documented.

ANNEX II - GUIDANCE TO DECLARATION OF INTERESTS AND DoI FORM

INTRODUCTION

1. This guidance relates to the implementation of the provisions on independence and transparency of Commission Decision C(2015) 5383 (the Decision)

2. It aims at giving clear indications on how to declare any interest that could affect the ability of the expert to act in the public interest.

3. According to the Decision, the responsibility for declaring all relevant interests is placed on the individuals completing their declaration.

4. Experts are nominated to the Scientific Committees of the European Commission as independent experts, strictly in their personal capacity and not as representatives of public or private bodies, organizations or states.

5. An "interest" declared is not automatically considered to create a conflict of interest[11]. It is well understood that, in general, individuals who are involved in a particular process have an inherent professional interest in the subject and in being involved in the process as such. In particular, interests of an intellectual nature are considered as essential to safeguard the quality and overall objectivity of the scientific work.

6. This Guidance covers the Declaration of Interests to be filled in by the Members of the Scientific Committees before the start of their mandate and every subsequent year of their mandate (the Annual Declaration of Interests ADoI) and the Specific Declaration of Interests (SDoI), required from all experts participating in Working Groups.

7. The ADoI is a written declaration which has a broad scope and describes all the interests that could conceivably give rise to a conflict in the general operation of the Scientific Committee. This declaration has to be done on an annual basis, at the beginning of the year.

8. The SDoI is linked to a specific subject matter and enables to assess whether a conflict of interest exists in the context of the specific activity (Opinion to be produced by the Working Group). It is to be filled in before the start of the work of every Working Group by all members of the WG. It should be updated whenever a new relevant interest occurs and at least annually. In addition, ad hoc SDoIs may be requested from Working Group experts who are not SC members when they are asked to participate to special events on behalf of the SC (e.g. hearings at the EP, meetings with stakeholders, etc).

9. Declarations of Interest are declared by an expert as an indication of where

[11] 'Conflict of interest' means any situation where an expert has an interest that may compromise or be reasonably perceived to compromise the expert's capacity to act independently and in the public interest when providing advice to the Commission in relation to the subject of the work performed by the group or sub-group in question.' Commission Communication on Horizontal rules of expert groups XXXX

conflicts of interest could arise and do not require from the author to assess whether there is actually a conflict. The assessment of whether there is a potential conflict is performed by the Secretariat and peers, in consultation with the Chair and the other members of the Scientific Committees where appropriate.

WHAT TO DECLARE?

Members of the Scientific Committees and external experts shall declare current and activities in the past 5 years (as specified under "other definitions" below) in the ADoI and SDoI (same form). The Commission recognizes that high quality and up-to-date scientific expertise is by nature based on prior experience, connection to the scientific world and involvement in current research. Therefore, having an interest does not necessarily mean having a conflict of interest.

1. Ownership of shares or other financial investments.

Any financial interests in a company or other entity operating in a business that can be affected directly by the opinions of the Scientific Committee. This includes holding of any form of equity, bonds, partnership interests[12] in the capital of a company and which amounts to more than 10 000 EUR per legal entity or entitling to a voting right of 5% or more in such entity? The holding of financial interests connected with a pension scheme or other complex investment funds would not be considered a financial interest, provided that the individual has no influence on its financial management.

2. Membership in a Management Body or equivalent structure.

Any participation in the internal decision-making of a company, trade association or other private entity such as a non-profit organisation dealing with issues related to the field of activity of the Committee or Working Group .(e.g. board membership, directorship).

3. Membership in another Scientific Advisory Body

The person concerned is participating or has participated in the works of a Scientific Advisory Body with an interest in the field of activity of the Committee or Working Group with a right to vote on the outputs of that entity.

4. Employment

All forms of employment, part-time and full-time, either paid or unpaid, in any organisation having activities with an interest in the field of activity of the Committee or Working Group.

5. Consultancy/Advice and Legal Representation

[12] When declaring financial interests e.g. stock and shares, only the kind, company name need to be stated.

Any paid or unpaid, past, present or future activity in which the expert or his depended collaborators provides technical or scientific advice or services in domains of relevance for the work of the Scientific Committee or Working Group.

6. Research

Any current or future influence on the definition of research priorities, the drafting of research programmes or the selection of research projects and current funding of research (also to the research entity to which the expert belongs) in relation to matter or work financed by a private or public entity with an interest in the field of activity of the Committee or Working Group, including grants, rents, sponsorships and fellowships.

7. Intellectual property rights (IPR)

Rights granted to creators and owners of works that are the result of human intellectual creativity that bring personal financial benefit to the expert. Only the IPR falling within the remit of the work of the Scientific Committes need be taken into account. These can be copyrights, patents, trademarks et cetera.

8. Public statements and positions

Any expert opinion or testimony in the field of activity of the Committee or Working Group for a legal entity or other body as part of regulatory, legislative or judicial process. Any office or other position, paid or unpaid, where the expert represented an interest or defended an opinion in the field of activity of the Committee or Working Group.

9. Other membership or affiliation

Any membership or affiliation other than the above which can be perceived with an interest in the field of activity of the Scientific Committees.

10. Interests of close family members

Known interests as described under points 1 to 8 held by family members and relatives (spouse, parents, children, brothers and sisters) or other persons under the care of the members of the household of the expert. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) does not need to be specified.

11. Other

Any interest other than the above which can be perceived as a potential source of conflict in an activity included in a Committee's remit.

<u>Other definitions</u>

Current means ongoing activities.

Past period means activities that are no longer ongoing and which have been completed in the preceding <u>five</u> years.

Name of entity or organization means name, location and nature of all organisations (private, public, etc.) that relate to a Committee's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.

Subject matter is to be interpreted as means the domain in which the activity was or is carried out. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institutions should equally be declared.

CONSEQUENCES OF NOT DECLARING AN INTEREST

Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a *prima facie* breach of trust towards the Commission. As a consequence, the Commission will take any actions deemed necessary, including the dismissal of the concerned persons from the Committee or Working Group.

PUBLICATION

The **ADoIs and SDoIs** will be made public in accordance with the provisions on transparency foreseen by the Decision. They will be posted on the web-site of the Scientific Committees[13]. A link from the Register of expert groups to this website will also be provided.

COMPLIANCE WITH PROVISIONS ON PERSONAL DATA PROTECTION

The Commission shall process DoIs pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data.

[13] http://ec.europa.eu/health/scientific_committees/index_en.htm

DECLARATION OF INTERESTS

Scientific Committee on
☐ **Consumer Safety**
☐ **Health, Environmental and Emerging Risks**

Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest

Name:

Position: Member/ external expert of the Scientific Committee (please delete the non-applicable position)

Title:

Profession:

[please copy rows as needed for subsequent or parallel activities of the same nature]

Nature of Activities	Period	Organisation	Subject matter
I. Ownership or other investments, including shares	MM/YYYY – MM/YYYY	Companies or organisations in which the financial interest is placed	[Relevant field of activity]

Nature of Activities	Period	Organisation	Subject matter
II. Member of a Managing Body or equivalent structure	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	Function of expert: Function of institution: [Describe e.g. role of yourself and of the institution] Link to website of institution:
III. Member of a Scientific Advisory Body	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	Member of Scientific Committee, sub-committees, working group on … Function of expert: Function of body: Link to website of body:
IV. Employment	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe professional activities in relation to activities of the SCs]
V. Consultancy/Advisory	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe role]
VI. Research funding	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe research]
VII. Intellectual property	MM/YYYY – MM/YYYY		
VIII. Public statements and opinions	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe activity, function, website]

Nature of Activities	Period	Organisation	Subject matter
IX. Other membership or affiliation	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe activity, function, website]
X. Other	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, …	[Describe activity, function, website]
XI. Interests of close family members	MM/YYYY – MM/YYYY		[Describe activity, function]

I hereby declare on my honour that I have read both the Guidance Document on Declarations of Interests and the Rules and Procedure related to Independence (section V of the Rules of Procedure). I also declare that the information disclosed in this form is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the Secretariat of the Scientific Committees and complete a new DOI form including the changes.

I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) N° 45/2001.

Date…….Signature:

****

Your DOI form shall be made publicly available on the website of the Scientific Committee and on the Register of Commission Expert Groups and Other Similar Entities, as long as you are appointed as member or expert of the Scientific Committees in a personal capacity. Technical measures will be taken to indicate search engines that your DOI form should not appear in search results.

ANNEX III – DECLARATION CONCERNING CONFIDENTIALITY

DECLARATION CONCERNING CONFIDENTIALITY

Scientific Committee on

☐ **Consumer Safety**

☐ **Health, Environmental and Emerging Risks**

Name:

Position: Member of the Committee ☐

External expert ☐

Ad hoc expert ☐

I hereby declare that:

1. I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of the work of the Scientific Committees, or one of its working groups. I shall also respect the confidential nature of the scientific opinions expressed by members or experts of the Committee during discussions in Committee or in working groups. I undertake not to disclose such information even after my participation in the work of the Scientific Committees has ceased. I am aware the Commission's security rules for protecting European Union classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443[14] and 2015/444.[15]

2. Should the undersigned receive confidential information or restricted information in the course and context of her/his duties for the Scientific Committees, it shall be treated under conditions of strict confidentiality, be used exclusively for the purpose for which it was made available to him/her and it shall not be divulged to any third party.

The above implies that the undersigned:

- will not divulge, publish or otherwise make available to any third party information received from Scientific Committees, without prior written consent of the Scientific Committees, also not after completion of the event or assignment involved in with the Scientific Committees. The duty of confidentiality exists vis-à-vis any third party, including employees, employers or affiliates or the general public;

- will not use information received from the Scientific Committees for a personal benefit or that of any third party;

[14] Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

[15] Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

- will ensure safe storage of the confidential information and restricted information, applying appropriate security measures if the information is managed electronically and not retain the information for longer than needed for the completion of the assignment or event with the Scientific Committees.

Done at: Date:

Signature: ……

ANNEX IV – DECLARATION OF COMMITTMENT

Scientific Committee
on

☐ **Consumer Safety**

☐ **Health, Environmental and Emerging Risks**

Name:

Position: Member of the Committee ☐

External expert ☐

1- Commitment

While contributing to Scientific Committees activities, I undersigned shall:

- Act independently in the public interest and to make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence;
- Attend meetings regularly and contribute actively to the work of the Scientific Committees;
- Respect the Commission internal security policy and measure made available to me;
- Always set an exemplary conduct in all activities linked to Scientific Committees;
- Comply with Scientific Committees' rules on Declarations of Interest and Independence;
- Comply with the rules on reimbursement of travel expenses and payment of special allowance in place in the Commission;
- Acknowledge the rules on protection of personal data as detailed in point 2 of the present Declaration;
- Ensure appropriate use of scientific publications provided by the Scientific Committees and respect copyrights as explained in point 3 of the present Declaration;
- When communicating with media, stakeholders or the general public on a matter that falls within the Scientific Committees' remit, always contact the Scientific Committees' Secretariat.

Duration: The validity of the present Declaration is limited to the term of Scientific Committees from the date of signature, unless the expert or member informs the Scientific Committees' Secretariat on the termination of her/his activities within Scientific Committees.

2- Personal data processing & respect of privacy

- Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data applies to Scientific Committees' activities. The present Declaration constitutes a legal act in the sense of Article 23 of the aforementioned Regulation and the undersigned is considered to be a processor of personal data on behalf of Scientific Committees in the sense of Article 2(e) of the Regulation. As a processor of personal data, the undersigned is subject to the following obligations:
- To process the data received in the context of the assignment with Scientific Committees solely for the purpose for which it was transmitted;
- To act only on instruction of Scientific Committees' Secretariat, in its capacity of controller with regard to any personal data processing in the context of the assignment with Scientific Committees;
- To ensure the confidentiality and security of personal data processing in the sense of Articles 21 and 22 of the Regulation, without prejudice to the obligations regarding confidentiality and security laid down in the national data protection legislation of the EU Member State, in which the undersigned is having her/his residence;
- To follow specific instructions of Scientific Committees' Secretariat in the case of transfer of personal data to any third party, therefore observing appropriate security safeguards to avoid unauthorised processing and disclosure.

3- Copyrights and library working tools provided by Scientific Committees

In case the undersigned is involved in the preparation of scientific outputs, she/he may receive from Scientific Committees' Secretariat scientific publications and journals protected by copyrights as hand-outs or via e-mail.

The undersigned will be allowed to make limited use of journals and scientific publications while engaged in Scientific Committee's activities, as laid down in Decision, but shall not:

- Distribute copies of articles and journals to third parties;
- Use articles or journals for commercial purposes;
- Use the materials for other purposes than related to the tasks of the Scientific Committees' as laid down in the Decision C(2015)5383.

Done at Date

Signature: ……

ANNEX V- STAKEHOLDER DIALOGUE PROCEDURES

1. Introduction

These procedures are intended to enable structured, balanced, ordered and manageable engagement with stakeholders in the process of elaboration of scientific opinions by the Scientific Committees, SCHER and SCCS, whilst ensuring the effectiveness of the process and compliance with the principle of independency and transparency.

These procedures are not intended to be used for each opinion and will be applied taking into account the expected added value in each specific case and the need for sound management of the limited resources available.

Stakeholder interaction will particularly be encouraged on issues that are:

- relevant to several Member States,
- of potentially high importance for human health and/or environmental protection,
- not closely related to a particular product of company,
- not previously addressed by any Scientific Committee.

While these procedures are part of the Commission's efforts to engage with stakeholders in a spirit of openness and accountability, it should be clear that the work of the Scientific Committees is, and must remain, independent of any influence. These procedures must therefore, not be seen as, and must not be used to interfere with the internal work of the Committees, claiming a right or trying to be involved in such work or exerting pressure on Committees' members. The overall aim of these procedures is to contribute to ensure the highest quality of the scientific opinions adopted by the Committees. In case of any evidence of significant risks for the independence of the Committees due to the application of these procedures, the Commission will discontinue their application in part or in total, as appropriate.

The procedures apply to the following stages:

- suggestions for new topics which the Commission services may consider to submit to a Scientific Committee,
- finalisation of mandates,
- calls for data and information,
- scientific input during the preparation of the opinion,
- public consultations on a preliminary opinion,
- scientific comments on existing opinions.

Stakeholders may subscribe to an IT alert system which will enable them to receive an alert each time a new item is published and a consultation is

launched[16].

Only submissions sent to the appropriate functional mailbox SANTE-C2-SCIENTIFIC-COMMITTEES@ec.europa.eu and complying with all the other conditions mentioned below will be considered. In all other cases, the Committees will not be in a position to consider the submission.

2. Suggestions to the Commission services for new Opinions of the Scientific Committees

In order to maximise the potential of the Scientific Committees, the motivated and documented suggestions[17] for new topics to be assessed by the Scientific Committees may be submitted to the Secretariat, provided the suggested topics do not fall under the competence of European Union bodies like, in particular, ECHA, EMA, ECDC or EFSA. The suggestions will therefore be considered under the following conditions:

- the issue is related to competences of the EU in the health and environmental areas,
- the issue falls under the competence of one of the Committees, both in terms of nature and specific content,
- the background, interest, importance for the EU and the Commission in particular are demonstrated with solid arguments,
- the issue concerns scientific risk assessment, not risk management or policy matters, and the questions proposed concern scientific issues,
- the importance of the issue in terms of health and environmental risks is documented,
- the issue is clearly and completely defined. In particular, the questions for the Committee are clearly formulated,
- the issue and the questions are formulated in neutral terms, without explicitly or implicitly suggesting a particular answer or asking for the endorsement of a predefined thesis or hypothesis,
- the suggestion does not aim at obtaining reconsideration of a recent opinion on which consultations have been closed (unless important published scientific results and the urgency of the matter require such reconsideration),
- adequate data and scientific knowledge (published literature etc.) exist and are provided, enabling the Committee to develop an opinion.

If the above conditions are met, the Secretariat, in collaboration with the other interested Commission services, will examine the suggestion, taking into account the degree of relevance, importance and priority of the issue (in general and in relation to Commission priorities and policy orientations), as well

[16] http://ec.europa.eu/health/scientific_committees/rss/all_latest_updates_en.rss

17 Suggestions for possible topics should be submitted by e-mail to the following address: SANTE-C2-SCIENTIFIC-COMMITTEES@ec.europa.eu. The name, title, organization, postal address, telephone number and e-mail address of the sender should appear in the text or the cover note of the submissions. "Suggestion of new Opinion" in the subject line of the e-mail should be included.

as any practical limitation in light of possible difficulties and other priorities.

If the Commission services decide to take the proposal on board, the suggested questions might be revised and/or amended by the interested departments.

The Commission services will decide upon the appropriate Committee which will deal with the mandate.

The proponent will be informed of the decision and its motivations.

This procedure does not create any right for stakeholders to have the proposed issues accepted by the Commission services and examined by the Scientific Committees.

3. Finalisation of new mandates

All new mandates are published at the following internet address: http://ec.europa.eu/health/scientific_committees/all_mandates/index_en.htm

For issues of broader significance or wider public interest, the Secretariat, when so agreed by the requesting Commission service, may submit draft mandates to public consultation. In selecting mandates for a public consultation, the Commission departments will take into account the expected added value of such consultation for the completeness and clarity of the questions as well as the need to ensure sound management of the limited resources available. The draft mandates could still be refined in light of the comments received. In such a case, a final version of the mandate will replace the draft one.

Comments on the draft mandates shall be submitted in general within 20 working days from the date of publication, unless a shorter period is fixed due to the urgency of the matter[18]. After such a period, in general, the Secretariat shall not be in a position to ensure consideration or follow up further comments.

The comments and proposals will be considered provided that they meet the following conditions:

- they are expressed in a clear way, related to the questions in the mandate and the relevant scientific matters and shall not relate to policy and risk management issues,
- any modification requested must be motivated by documented scientific considerations and must be related to the aims, background and subject matter of the mandate,
- any modification must be presented in a neutral way and be related to risk assessment, not risk management,
- the reasons, relevance and importance of the issues raised must be clearly explained,
- in case the comments involve an extension of the scope of the mandate,

18 This condition would not strictly apply for emerging risks for which only limited data is usually available. The condition would be to provide the available elements allowing for the identification of an emerging risk or safety issue.

adequate data and scientific knowledge exist and is provided to enable the Committee to advise on the suggestion and the Commission services to decide.

If the above conditions are met, the Commission services concerned will examine the comments, taking into account the degree of relevance, importance and priority of the matter (in general and in relation to Commission priorities and policy orientations), and the practical implications on the Commission and Scientific Committee priorities and resources.

If the proposal is accepted, questions may be revised and/or amended, as deemed necessary by the Commission services.

The Commission services may decide on a case-by-case basis to meet with the proponents in order to discuss the comments presented if they are of particular interest.

The results of the consultation will be summarized on the Scientific Committees' website.

This procedure does not entail any right for stakeholders to have their proposals accepted.

4. Call for information

Opinions prepared by the Scientific Committees deal exclusively with scientific risk assessment aspects. The objective of a Call for information is to ensure that all relevant scientific information is available to the Scientific Committee for its assessment.

In general, only submissions directly related to the Call and complying with its specifications may be considered[19]. Any document shall be submitted as indicated in the Call.

No research of referenced documents or websites will be carried out. The name, title, organization, postal address, telephone number and e-mail address of the sender should appear in the text of the e-mail.

It should be noted that a submission shall not be considered if:

- it is submitted after the deadline set out in the call,
- it does not correspond to the scope and format specified in the call and in these procedures.

An automatic system to acknowledge receipt is foreseen but no further individual reply will be made.

19 Format of submission: in order to facilitate the assessment of contributions, the following structure should be used:
1) Scientific Journal Articles: Last name of first author, publication year, short name of journal topic
2) Other submissions: Please use the same structure but replace journal name by specifying the sort of publication (e.g. report, book chapter etc.)

Confidential data:

- the submission of confidential data should be accompanied by appropriate documentation to justify the confidentiality requirement,
- a statement confirming/permitting that the data may be considered in the risk assessment carried out by the scientific committee and that at least a summary of the data provided may be presented in the opinion.

5. Scientific input during the preparation of the opinion

5.1. Organisation of hearings

Technical hearings with stakeholder representatives, applicants, or other third parties may be organised:

- at the initiative of the Scientific Committees, if they consider it necessary for the completion of a scientific opinion,
- at the initiative of the Commission services in agreement with the Scientific Committees;
- upon request of a stakeholder who makes a valid *prima facie* case. A relevant element is the ability to offer relevant scientific data and analysis not otherwise available to the Committee. Requests shall be accompanied by a clear scientific justification for the hearings and be supported by credible scientific documentation. The Secretariat will assess the request in cooperation with the Commission services and the Scientific Committee. The precise organisation of the hearing will be decided on a case-by-case basis. The requesting party will be informed of the conclusions.

The relevant Committee will decide who will represent the Committee at the hearing.

The persons attending the hearings should be scientists with appropriate expertise in the field who can present and understand the scientific arguments.

The Secretariat and the Chair shall ensure that the persons attending such hearings limit their presentations to scientific matters related to the subject (for example, to provide additional scientific evidence, discuss interpretation of data or clarify data). Invitees shall under no circumstances engage in public relations or lobbing activities.

The members of the Scientific Committees shall not take any decisions during hearings.

In conformity with the generally applicable obligation to respect confidentiality in all the aspects of the work of the Scientific Committees, members and experts shall exercise care during hearings to avoid giving information to competitors or other interested parties regarding specific products where this information is not public.

Open public hearings might also be organised at the initiative of the Scientific Committees or the Commission services (with the agreement of the Scientific Committee concerned). The objectives of such hearings will be to gather

specific comments, suggestions, explanations or contributions on the scientific basis of a particular preliminary opinion.

Open hearings can be organised as stand-alone independent events or in conjunction or with the other data/information gathering activities of the Scientific Committees (call for information, public consultation on preliminary opinion, commenting period).

In those cases, the following procedures will be followed:

- the Secretariat will publish on the website the information about the public hearing together with the invitation to interested parties to register,
- registration will be open for a minimum period of 30 days,
- when registering, potential participants will be asked to provide full professional details, to specify the subject they wish to address in the hearing and to submit a 1-2 page technical justification for their request,
- approval for participation to the hearing will be decided by the Commission services on the basis of the following criteria:
  - interested participants should be scientists or technical experts with appropriate expertise in the field who are able to present and understand the scientific arguments,
  - interested participants have clearly identified the subject matter they would wish to contribute to and have provided sufficient technical justification,
- all registered participants will be informed at least two weeks before the hearing,
- the Secretariat will publish on the Committees' website the final programme of the hearing together with the participants' names,
- during the hearing, the Secretariat and the Chair shall ensure that participants limit their presentations to scientific matters related to the specific matters indicated in their registration,
- invitees shall under no circumstances engage in public relations or lobbing activities,
- the members of the Scientific Committees shall not take any decisions during hearings,
- during hearings, members and experts shall avoid giving information to competitors or other interested parties regarding specific products if this information is not public.

5.2. Public consultation and commenting period on preliminary opinions

Public consultation

The Scientific Committees may decide to submit a preliminary opinion to a public consultation in case the Committee and the Commission services consider that it would enhance the quality of the work.

The objective of public consultations is to gather specific comments and

suggestions on the scientific basis of the opinion, as well as any other relevant scientific information regarding the questions addressed, in order to allow the Scientific Committees to focus on issues which need to be further analysed.

This consultation process shall not deal with policy or risk management needs and measures. In addition, this particular consultation procedure should not be confused with other consultations launched by the Commission services regarding policy or regulatory matters, for which a different scope, as well as rules and procedures apply.

Public consultation shall be open for a minimum period of 4 weeks.

In general, only submissions directly referring to the content of the preliminary opinion and relating to the issues that the report addresses will be considered. Furthermore, only studies and data which are published or accepted for publication in peer reviewed scientific reports or journals will be taken into consideration.

Any document referred to shall be attached as indicated in the call. No researching of referenced documents or websites will be carried out.

A submission will not under any circumstances be considered if:

- it is submitted after the deadline set out in the call,
- it is presented in any other form than the template provided,
- it exceeds the maximum length indicated for each section, or contains comments which do not correspond to the indicated title of that particular section,
- it contains information on individual cases or any other material not included in published reports,
- it contains complaints against institutions, personal accusations, irrelevant or offensive statements or material. Complaints should be made according to the existing procedures,
- it is related to policy or risk management aspects.

An automatic system to acknowledge receipt is foreseen and no further individual reply will be made.

The Commission services may decide, on a case-by-case basis, to publish the submissions corresponding to the criteria of the consultation, unless the author has explicitly opposed publication of his or her contribution.

The Scientific Committee will consider all the relevant submissions related to the scope of the public consultation and will decide if and in how each of the contributions should be taken into account in the formulation of the final opinion.

The Scientific Committee shall include a section on the results of the consultation, summarising in general terms the main issues arising from the consultation and how they are addressed in the opinion. A separate document listing all the contributions received and the responses of the Scientific Committee may be produced.

Commenting period

In other cases, such as those described in point 53 of the rules of Procedure, the Scientific Committees may decide to submit a preliminary opinion to a commenting period to seek comments from the applicant and other interested parties before the finalisation of the opinion.

The objective of this consultation is to gather specific comments and suggestions on the scientific basis of the opinion, as well as any other relevant scientific information regarding the questions addressed, in order to allow the Scientific Committees to focus on issues which need to be further analysed.

The commenting period shall be open for a minimum period of 4 weeks.

In general, only submissions directly referring to the content of the preliminary opinion and relating to the issues that the report addresses will be considered. Furthermore, only studies and data which are published or accepted for publication in peer reviewed scientific reports or journals will be taken into consideration.

Any document referred to shall be attached as indicated in the call. No researching of referenced documents or websites will be carried out.

As a general rule, comments received are not published, due to the confidentiality nature of the comments and information provided.

No aspect of the public consultation or commenting period procedures and their actual application may be invoked as a reason to delay the adoption of, modify or reconsider a scientific opinion.

5.3. Revision of existing opinions

As a rule, the opinions of the Scientific Committees on a particular subject will be considered closed and not subject to revision for a period of 3 years.

After that period and in order to keep the Scientific Committee opinions up-to-date with new scientific knowledge, the Scientific Committees may, at their own initiative, at the request of the Commission services or at the request of stakeholders, consider it appropriate to revise an existing opinion in light of new evidence.

The revision of an existing opinion will be initiated on the basis of the following criteria:

- new data or information is provided in response to the explicit needs expressed by the Scientific Committees in an existing opinion,
- substantial new evidence was made available in the public domain that, in the view of the Scientific Committee or the Commission services, is worth evaluating with a view to update an existing opinion,
- stakeholders, international organisations, third countries, submit adequate data indicating a possible change in the level of safety for human health and the environment for a particular stressor subject of an existing opinion,

– Member States notifying safeguard clauses with supporting evidence showing previously unidentified hazard properties, exposure situations, or potential risks associated with a stressor subject of an existing opinion.

On rare occasions and depending on accentuating circumstances concerning new evidence available and the concomitant potential risks to humans and the environment, the Commission services, in agreement with the Scientific Committees, may request the revision of an existing opinion before the 3 year period since the publication of the final existing opinion.

6. Functional mailboxes and practical guidance

Two types of functional mailboxes will serve the communication needs of the Scientific Committees: permanent mailboxes and specific mailboxes of limited duration.

The permanent mailbox will serve as a general communication tool for each Scientific Committee allowing stakeholders and interested parties to communicate with the Scientific Committee and the Secretariat.

The temporary specific mail boxes will be of limited duration and will serve a specific purpose such as data/information collection, public consultations, open public hearings etc.