EUROPEAN COMMISSION

Directorate-General for Health & Consumers

RULES OF PROCEDURE

of the Scientific Committees on

- **Consumer Safety**
- **Health and Environmental Risks**
- **Emerging and Newly Identified Health Risks**

Scientific Committees

on consumer safety
on emerging and newly identified health risks
on health and environmental risks

These Rules of Procedure have been jointly adopted by the Scientific Committees on 18 December 2009, in conformity to Article 12 of Commission Decision 2008/721/EC of 5 September 2008.

TABLE OF CONTENTS

I INTRODUCTION AND BACKGROUND

1. The European Commission established three Scientific Committees by Commission Decision 2004/210/EC, as amended by Commission Decision 2007/263/EC: the Scientific Committee on Consumer Products (SCCP); the Scientific Committee on Health and Environmental Risks (SCHER); and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The experience with the functioning of the three Scientific Committees as an advisory framework showed the need to introduce modifications and improvements in the structure and working procedures of the Committees. As a result Commission Decision 2004/210/EC was replaced by Commission Decision 2008/721/EC (hereinafter "the Decision") of 5 September 2008 that set up a reformed advisory structure of Scientific Committees and Experts (the "Advisory Structure"). This revised Advisory Structure continues to include three Scientific Committees (on Consumer Safety-SCCS, on Health and Environmental Risks-SCHER and on Emerging and Newly Identified Health Risks-SCENIHR) (hereinafter "the Committees") and a Pool of Scientific Advisors on Risk Assessment (hereinafter "the Advisors" and "the Pool").

2. Sound and timely scientific advice is an essential requirement for Commission proposals, decisions and policy relating to consumer safety, public health and the environment. The mission of the Committees and the Advisors of the Pool is to assist the Commission, and through the Commission the other European Institutions, with scientific advice in the fields of consumer safety, public health and the environment.

3. According to the Decision, common Rules of Procedure are adopted by the Committees on proposal by and in agreement with the Commission.

4. The Decision states that the Rules of Procedure shall cover in particular the subject listed in Annex II to the Decision. These Rules of Procedure will be regularly reviewed by the Commission in order to introduce the appropriate adaptations in light of experience through the same procedure applied for their adoption.

II OBJECTIVES OF THE RULES OF PROCEDURE

5. As stated in Article 12(2) of the Decision, these Rules of Procedure shall ensure that the Committees perform their tasks in compliance with the principles of excellence, independence, transparency and confidentiality, as well as with the principles and standards for scientific advice on risk assessment which may be established by the Commission in light of the experience and in view of its policy in this area. Principles and standards for scientific advice on risks are presented in Annex V.

6. The Rules of Procedure provide guidance aimed at ensuring the effective functioning of the Advisory Structure according to the above-mentioned principles by defining the appropriate modalities for the operation of the Committees and the Pool.

7. In order to achieve these objectives and given the experience with the functioning of the Advisory Structure in the past, these Rules of Procedure regulate the functioning of the Scientific Committees, their Working Groups, the Pool of Scientific Advisors, the role of Members, Scientific Advisors and External Experts, the various activities mentioned in the Decision, as well as the role and responsibilities of the Secretariat of the Scientific Committees (hereinafter "the Secretariat") and the Inter-Committee Co-ordination Group.

III PRINCIPLES

8. According to Article 12 of the Decision, Scientific Committees should perform their tasks in compliance with the principles of excellence, independence, transparency, and confidentiality. Chapter 4, Articles 15-17 of the Decision provides further guidance on how the Scientific Committees should comply with the principles of independence, transparency and confidentiality.

a. Excellence

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

10. 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 consultation, 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

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

12. This principle implies in particular the 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.

13. 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, Advisors and Experts.

c. 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.

d. Confidentiality

15. The scientific advice delivered by the Committees is sometimes based on confidential information. The Members of the Scientific Committees, Scientific Advisors, External Experts and trainees are expected to respect the principle of confidentiality and 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 this Decision. All participants and observers of the work of the Committees are to respect the confidentiality during the preparation of the opinion.

IV PRINCIPLES AND STANDARDS FOF SCIENTIFIC ADVICE ON RISKS

16. These Rules of Procedure shall be applied in such a way as to ensure that the principles and standards presented in Annex V are complied with.

17. The application of such principles and standards shall be monitored at the relevant stages of development of an opinion by the Secretariat in collaboration with the Chairs, Vice-Chairs of the Committee and as appropriate by the Rapporteurs and the Chairs of the Working Groups, 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

18. Members of the Scientific Committees, Scientific Advisors on Risk Assessment and External Experts shall undertake to act independently of any external influence. For this purpose, they shall make a declaration of commitment (see Annex I). 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 in the execution of their duties.

19. Members of the Scientific Committees shall also make an annual declaration of interests (see Annex II).

20. Scientific Advisors and External Experts shall make a specific declaration of interest when accepting to participate in any of the activities of the Advisory Structure (see Annex II).

21. Members, Advisors and External Experts shall be in a position to show beyond question that they can act independently. They are under a continuing duty to declare any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the Annex in question, in order to allow the Scientific Committees and/or the Commission to identify those interests which might be considered prejudicial to the independence of the Member, Advisor or External Expert.

22. These declarations of interest shall be made in writing and published on the Commission's website. They must be completed or updated timely with any relevant additional or new information.

23. Members, Scientific Advisors and External Experts participating in meetings of the Scientific Committees or in a Working Group or in any other activity of the Advisory Structure shall declare at each meeting or event any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the relevant Annex in order to allow the Scientific Committees and/or the Commission to identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Commission.

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

25. In particular, the Secretariat shall draw the Commission's attention to all cases where it appears that a Member, Advisor 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 their appointment.

26. Any Member, Advisor or External Expert who, in accordance with their declaration or in the opinion of the Scientific Committee or the Working Group concerned, or the Commission, 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 a case, the Member, Advisor or Expert may not act as Rapporteur or as Chair in relation to the specific matter and may not participate in decision making. The extent of the participation in the Committee's work of the individual concerned shall be decided by the Chair in consultation with the Members of the Committee or Working Group concerned and in agreement with the Commission within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or participation limited to the provision of factual information.

27. Conclusions and decisions taken in relation to the declarations of interest, as well as their rationale, shall be recorded. In the case of declarations presented during meetings, such records will be part of the minutes.

28. Members, Advisors or External Experts who receive documents or information of relevance to the activities of the Scientific Committee or the Working Group concerned from third parties shall ensure that the information is made available promptly to the Secretariat.

29. Members, Advisors or External 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 Advisory Structure shall inform the Secretariat and refer the third party to the Secretariat.

30. Members, Advisors and External Experts shall inform the Secretariat of relevant contacts they might have with petitioners, special interest groups, other stakeholders or other Community or international bodies engaged in overlapping activities. The Secretariat shall advise on the action to be taken in consultation with the Scientific Committee concerned as necessary.

31. When invited to represent a Scientific Committee, Members and Advisors 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 attribution of their presentations to the Committee.

32. They shall not speak on behalf of the Commission unless officially requested by the Commission itself to do so.

VI RULES AND PROCEDURES RELATED TO TRANSPARENCY

33. The Scientific Committees shall operate in accordance with the need for a 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 External Experts vis-à-vis external influence.

34. Requests for access to documents will be handled in accordance with the provisions of Regulation n° 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, p.43). When considering the exceptions listed in Art. 4 of 1049/2001 account shall be taken of the need to preserve the integrity and the independence of the scientific advice which supports the decision making process of the Community.

35. The following documents of the Scientific Committees are published on the Commission's website, subject to respect of confidentiality requirements as well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data:

    - Draft agendas of plenary meetings of the Committees, and meetings of the Inter-Committee Co-ordination Group (ICCG);
    - Agendas of Working Groups.
    - Minutes of plenary meetings and meetings of the Inter-Committee Co-ordination Group and Working Groups;
    - Requests for opinions;

- Final opinions and pre-consultation opinions published for public consultation;
- Declarations by Members, and of Advisors and Experts participating in ongoing work of their commitment to act independently of any external influence;
- Annual declarations of interest made by members of the Scientific Committees and specific declarations of interests made by Advisors associated in accordance with Article 6(1) of Decision 2008/721/EC as well as by Members, Advisors and External Experts who participated in Working Groups;
- Declarations of interest made in relation to items on the agendas of plenary meetings will be published as part of the meeting minutes;
- The names of the Members of the Scientific Committees together with their brief CVs;
- Scientific Committee reports clarifying contentious issues as a result of a substantive divergence over scientific issues with other Community bodies (Art. 14(3) of Commission Decision 2008/721/EC);
- Rules of procedures; and
- Stakeholder dialogue activities (mandate consultations, calls for information, calls for Experts, calls for hearings, public consultations on pre-consultation opinions etc.).

36. Names of Members, Advisors and External Experts appointed to Working Groups as well as their declarations of interest shall be published after the adoption of an opinion to which they have contributed. Nevertheless, their names may be disclosed earlier if necessary for their participation in hearings or other public events.

37. Availability of preparatory and draft working documents shall be restricted, on a need-to-know basis, to Members, Advisors, External Experts, the Commission's Secretariat and representatives of the Commission's 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 Commission, in view of a specific need to involve or inform urgently a third party as part of the process to complete the relevant work.

38. Without prejudice to Art 16 of Decision 2008/721/EC, the Commission 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 Advisors to ensure the scientific validity of its press releases or related communication actions.

VII RULES AND PROCEDURES RELATED TO CONFIDENTIALITY

39. Members, Advisors and External Experts shall make a written declaration of confidentiality (see Annex III). They shall not divulge confidential information acquired as result of their work on the Scientific Committee concerned, or one of the Working Groups. 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 in accordance with the applicable provisions.

40. The obligation not to disclose confidential information shall continue to apply even after the participation of Members, Advisors and External Experts in the work of the Scientific Committees has ceased.

41. With the exception of minority opinions referred to in Article 16 of Decision 2008/721/EC, individual views, whether expressed orally or in writing by Members, Associated Members and External Experts during deliberations within the Scientific Committee or a Working Group shall be confidential.

VIII RELATIONS AND DIALOGUE WITH STAKEHOLDERS AND THE PUBLIC

42. 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, requests for the submission of information etc. To this end, targeted calls for information may be organised by the Secretariat in agreement with the Committees. A deadline for the submission of required information shall be given in agreement with the Commission. 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. This procedure and its actual application may not be invoked as a reason to delay the adoption of, or to modify or reconsider a scientific opinion.

43. A stakeholder dialogue procedure is established in Annex IV of these Rules. This procedure applies to the activities of the Scientific Committees. The aim of such a procedure is to enhance the quality of the scientific opinions. The procedure will be applied in agreement with and co-operation between the Scientific Committee concerned and the Secretariat.

44. 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 to the nature and extent of such risk. 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.

45. In cases where an opinion is prepared in light of information submitted by a stakeholder in response to specific regulatory requirements, the Secretariat will, when appropriate, seek comments from the applicant on a draft of the opinion, and submit those comments to the Committee before the adoption of the opinion.

IX FUNCTIONING OF THE SCIENTIFIC COMMITTEES AND THE INTER-COMMITTEE CO-ORDINATION GROUP

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

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

47. The terms of office of the Chair and Vice-Chairs shall be three years; this is renewable.

48. A separate record shall be kept of the election procedure. The names of the Chair and the two Vice-Chairs of each of the Committees shall be made public.

49. The Chair and Vice-Chairs shall be elected by secret ballot and in writing.

50. The election procedure shall be chaired by the Commission.

51. The procedure shall be as follows:

- The election of the Chair and of each of the Vice-Chairs shall be held separately.
- The Secretariat shall be notified of those wishing to stand as candidates before the meeting, or their names 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 concerned and be prepared to assist the Commission on matters relating to the co-ordination of the three Scientific Committees, including if necessary participating in co-ordination meetings organised and chaired by the Commission.
- The candidate receiving the majority of the votes from the Members of the Committees shall be elected.
- If none of the candidates receives an absolute majority, a second ballot shall be held between the two candidates with the highest individual totals of votes in the first ballot. The procedure shall be repeated until one candidate obtains the majority of the votes of the Members of the Committee.
- Candidates may withdraw their candidature at any time during the procedure.
- Where there is, or remains a single candidate, that candidate shall be elected provided that they receive the majority of votes cast.

b. Role and replacement of Chairs and Vice-Chairs

52. The Chair in collaboration with the Secretariat will 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.
- Examining the declarations of interest, and deciding, in consultation with the Committee and in agreement with the Commission, the relevant conclusions and necessary 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 Commission Decision 2008/721/EC, these Rules of Procedure and the state of the art on Risk Assessment, and taking, or requesting the Commission to take as appropriate, the necessary measures.
- Representing the Committee.

53. If the Chair is not in a position to fulfil their function, they shall be replaced by one of the Vice-Chairs or, failing that, another Member chosen in common accord of the Members.

54. In case of conflict of interest of the Chair with an item on the agenda, they shall be replaced by one of the Vice-Chairs or failing that, another Member chosen in common accord by the Members.

55. The Vice-Chairs will support the Chair in fulfilling their responsibilities. The Chair will 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)

56. Requests for scientific opinions shall be submitted by the Secretariat to the relevant Scientific Committee. The request shall consist of the terms of reference, the Community interest and the scientific background. The mandate shall be presented to the Committee by a representative of the requesting service, assisted by the Secretariat, or by the Secretariat on behalf of the requesting service.

57. The terms of reference of the mandate shall be confined to risk assessment.

58. All mandates will be reviewed by the Secretariat in advance of submission to a Committee for conformity with the applicable template, clarity and completeness, pertinence in relation to the fields of competence of the Committee, appropriateness of the terminology and absence of risk management aspects in the questions proposed.

59. Mandates may be put to public consultation according to the procedures set out in Annex IV of these Rules. The mandate may or may not 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.

60. Questions submitted to the Scientific Committee shall be published as soon as possible on the Commission's website.

61. Where necessary, the Commission may require the Scientific Committee to adopt a scientific opinion within a specified deadline. The Scientific Committee shall take the necessary measures to ensure that the deadline is respected.

62. The Scientific Committee may ask the Commission to clarify a question and/or to supply additional information.

63. The Commission may require the adoption by more than one Committee of a joint opinion on questions which do not fall exclusively within the fields of competence of a single Committee or which otherwise need to be considered by more than one Committee. Requests for joint opinions will be considered by the Inter-Committee Co-ordination Group. A joint opinion may also be adopted by more than one Scientific Committee on the initiative of the Inter-Committee Co-ordination Group, when the Co-ordination Group concludes that a mandate from the Commission is better fulfilled in this way. The Inter-Committee Co-ordination Group may designate a lead Committee.

64. The Commission may define in the request for an opinion the consultations, hearings, or collaboration with other scientific bodies it deems necessary for the preparation of the opinion.

65. A Committee, in agreement with the Commission, may decide to hold a hearing and/or a 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.

d. Designation and role of Rapporteurs

66. The Scientific Committee may designate Rapporteurs from among Members, Advisors or External Experts.

67. The designation may be revoked.

68. Rapporteurs shall be responsible for assembling information, editing and revising draft opinions and ensuring that draft reports and scientific opinions are prepared within a set time period, where appropriate. The Rapporteur should also ensure that draft opinions are well structured, written in clear and simple language and are coherent. The Rapporteur shall work in close co-operation with the Secretariat.

69. The work of a Rapporteur is terminated when the Scientific Committee publishes the opinion.

e. Establishment and role of Working Groups

70. The Scientific Committees may establish Working Groups to undertake tasks which are clearly defined and directly linked to the question submitted by the Commission. In particular, the Working Group may be asked to undertake all

necessary preparatory tasks in relation to a draft opinion. The Scientific Committees may require these tasks be completed within a set period.

71. Working Groups shall comprise at least one Member of the Scientific Committee that convened them and may include Advisors and External Experts, as well as Experts from other Community bodies. Working Groups shall be chaired by a Member of the Scientific Committee that convened it, or an Advisor associated to the Committee, designated by the Scientific Committee.

72. Members, Advisors and External Experts of a Working Group shall be designated by its Chair in agreement with the Chair of the Scientific Committee and in collaboration with the Secretariat in accordance with the procedure described in paragraphs 82-5 below. They shall be invited to meetings by the Secretariat. If an Expert is invited but is not available, the Secretariat may, in agreement with the Chair, invite another suitable Expert.

73. A Working Group shall endeavour to reach a consensus. In the absence of a consensus, the position of the Working Group shall be that approved by a simple majority of its Members. Nevertheless, the Chair of the Working Group and the Rapporteur shall inform the Committee of all the positions expressed.

74. The Working Group shall report to the Scientific Committee to whose work it contributes, providing it with such reports or draft opinions as the Committee has requested.

75. When a common Working Group is created in accordance with article 7(4) of Decision 2008/721/EC, it shall report to the Scientific Committee designated as the lead Committee under the co-ordination procedure set out in these Rules of Procedure.

76. The list of participants in the Working Groups shall be attached to the opinion to which they have contributed.

f. Association of Scientific Advisors

77. Each Scientific Committee may associate on its own initiative up to five Scientific Advisors from the Pool to contribute to the Committee's work on specific issues or disciplines. The proposal to associate an Advisor should be presented to the Committee by the Chair based on a short list of Advisors from the Pool prepared by the Secretariat who best fit the required fields of expertise for the issue at hand. The process and selection should be recorded and attached to the minutes of the plenary meeting of the Scientific Committee.

78. Scientific Advisors shall be associated for contributing to the preparation of a scientific opinion, rapid advice, and memorandum or position statement.

79. The decision to associate an Advisor shall specify the issue and/or the discipline on which the Advisor is requested to contribute, as well as the opinion, rapid advice, memorandum or position statement in the preparation of which they will participate.

80. The Chair, in collaboration with the Secretariat, shall take care of organising the relevant work and discussions in such a way as to facilitate the participation of the associated Advisors.

81. The Advisors associated shall participate in the activities and deliberations concerning the subjects considered with the same functions, responsibilities, and rights as the Members of the Committee concerned. In particular, they shall vote on the adoption of the opinions, rapid advice, memoranda and position statements to which they have contributed.

g. Selection of Advisors and External Experts to participate in Working Groups

82. External Experts designated to participate in Working Groups may be selected from the Pool or the database of Experts.

83. A short list of suitable candidates will be established by the Secretariat on the basis of the required fields of expertise defined by the Scientific Committee.

84. The Chair and the Working Group Chair in collaboration with the Working Group as appropriate will select suitable candidates from the short list. The selection process should be properly recorded in order to document the transparency of the process.

85. If no suitable candidates are identified in the Pool and the database for a particular issue/area of expertise, the Scientific Committee in agreement with the Secretariat may solicit additional expertise by conducting a specific call for Experts or through another systematic method as appropriate. In that case, the selection process should be recorded.

h. Meetings (notice, agendas, deadlines, minutes, access)

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

87. As a general rule, the Secretariat will 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.

88. Meetings of the Scientific Committees or Working Groups may be called at short notice according to the urgency of the matters to be discussed.

89. The Secretariat shall prepare the draft agenda of the meeting of the Scientific Committee or the Working Group concerned and circulate it to the Members no later than two weeks before the date of the meeting, if possible. The draft agenda of plenary meetings shall be published on the Commission's website before the meeting takes place.

90. The draft agenda shall include questions submitted by the Commission and shall be accompanied by all appropriate and available supplementary

information of relevance to the questions submitted. The Secretariat shall provide any additional information as soon as possible to the Members.

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

92. Wherever possible, documents including reports and draft opinions prepared by a Rapporteur or External Expert shall be made available to the Secretariat for distribution to the Members, Associated Members and External Experts one week before the meeting where they will be discussed. Rapporteurs and Members entrusted with the drafting of documents, reports or draft opinions shall ensure that this requirement is complied with.

93. Meetings of the Scientific Committees or their Working Groups shall not be open to the public.

94. Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present at the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions.

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

- The list of participants and apologies for absence;
- Declaration of interests by participants concerning their independence including the relevant details, the action taken and its rationale;
- The adopted agenda;
- A summary of discussions, including important minority stand points and agreed actions;
- A record of decisions taken and opinions adopted; and
- Any abstentions during voting.

96. The draft minutes shall be circulated to Members of the Scientific Committees and, where applicable, to associated Advisors, for comments. They should be adopted not later than the next meeting.

97. Without prejudice to the provisions of paragraph 36 above, minutes shall be published on the Commission's website as soon as possible after their adoption.

98. Legitimate requests for commercial confidentiality shall be respected.

i. Co-ordination of the Scientific Committees – the Inter-Committee Co-ordination Group

99. The Secretariat shall allocate the requests to the Scientific Committee responsible with regard to the subject matter of the request, the respective mandates of the Committees, the expertise of the Members, the need for methodological consistency and a broad, multi-sector and multi-disciplinary approach.

100. The Secretariat shall inform the Chairs without delay of the allocation of the request. Chairs will inform the Secretariat of any concern that might require inter-committee co-ordination.

101. In cases where a request falls within the remit of more than one Committee, the allocation is decided in consultation with the Inter-Committee Co-ordination Group.

102. The Inter-Committee Co-ordination Group shall be composed of the Chairs and Vice-Chairs and the Secretariat. It shall assist the Commission on matters relating to the co-ordination of the three Scientific Committees. In particular, it shall assist the Commission in achieving a high level of harmonisation in the risk assessment procedures both between the Committees themselves, and between the Committees and Community or international bodies charged with risk assessments in their domains.

103. The Inter-Committee Co-ordination Group shall achieve its objectives by means of periodic meetings or exchange of documentation as appropriate to the matter in hand. Meetings shall be convened and chaired by the Commission. The Inter-Committee Co-ordination Group shall provide guidance to the Committees on methodological and procedural aspects, in the form of guidance notes. When deliberating on methodological guidance the Inter-Committee Co-ordination Group shall be chaired by one of the Chairs or Vice-Chairs designated by the Group.

104. The Inter-Committee Co-ordination Group shall also provide support to the Commission 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.

105. The Inter-Committee Co-ordination Group shall endeavour to reach consensus on its conclusions and decisions

106. Co-ordination will cover, notably, the following areas:

- ***Questions which are common to more than one Committee***

  The Chairs, in consultation with the Vice-Chairs as appropriate, shall advise the Secretariat of the:

  - Committee to be designated as responsible for the opinion (the lead Committee) on behalf of the Committees concerned;
  - Committee(s) to be associated with the establishment of an opinion;
  - Need for a Working Group to be established by the lead Committee and the designation of Members of the associated Committee(s); and
  - Procedure for the collaboration between the Committees involved and for the adoption of the opinion by the lead Committee or, in the case of joint opinions, by all the Committees involved.

- ***Diverging scientific opinions***

When the Secretariat is informed of divergence or risk of divergence between the opinions of the Scientific Committees or of one of the Committees and an international or Community body, the Chairs, in consultation with the Vice-Chairs as appropriate, will 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, and advise 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 Chairs, in consultation with the Vice-Chairs as appropriate, shall provide regular feedback and advice on the structure and content of scientific opinions of the three 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 Chairs, in consultation with the Vice-Chairs as appropriate, 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 Chairs, in consultation with the Vice-Chairs as appropriate, 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 Chairs of the Scientific Committees shall be invited to share information concerning activities undertaken by their own Committee and to raise organisational or scientific problems requiring a harmonised approach.

107. Minutes of each meeting of the Inter-Committee Co-ordination Group shall be published on the Commission’s website.

j. Risk-related issues raised by the Scientific Committees

108. The Scientific Committees shall draw the Commission's attention 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 memoranda or position statements.

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

110. The Commission in consultation with the Scientific Committees will arrange to publish on the Internet such memoranda and position statements, and inform the relevant Committee(s) accordingly.

k. Format and content of scientific opinions

111. The scientific opinion comprises:

- An abstract (where appropriate);
- An executive summary (where appropriate);
- The background (Community interests and scientific background);
- The terms of reference giving the specific question(s);
- The considerations used by the Committee concerned to reach its conclusions (scientific rationale);
- The conclusion (opinion), setting out the response to the question(s) posed by the Commission. For complex opinions, the conclusions shall be accompanied by a summary in non-specialised/technical language;
- A bibliography;
- A list of abbreviations (where appropriate);
- A glossary (where appropriate);
- Any minority opinions; and
- The composition of the Working Group.

112. The Scientific Committees shall adopt their scientific opinions at their plenary meetings.

113. The Scientific Committee may adopt an opinion, previously discussed in a Committee meeting, using the written procedure.

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

115. Legitimate requests for commercial confidentiality are to be respected.

l. Minority opinions

116. 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 Committees shall include any minority opinions together with the supporting arguments and reasons. Minority opinions can only be expressed by Members or associated Advisors and shall be attributed accordingly.

m. Rapid advice and accelerated procedure

117. In urgent cases, the Commission 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 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 will apply in cases where the advice is needed within a timeframe of a few days.

118. When requesting rapid advice, the Secretariat will contact by the fastest means possible, the Chair(s) and, if necessary, the Vice-Chairs for identifying the relevant expertise in the Scientific Committees and the Pool, 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 will collect from the appropriate Members, Advisors and Experts the information needed and will summarise it in collaboration with the relevant Chairs and Vice-Chairs as appropriate.

119. The rapid advice may take either 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 mentioned above, or an opinion adopted by the relevant Committee through an accelerated procedure launched by the Secretariat in agreement with the Chair.

120. In the latter case, the Secretariat shall request, whenever possible in agreement with the Chair of the relevant Scientific Committee, a Member, an Advisor and/or an External Expert or a Working Group to draw up a draft opinion and submit it to the Secretariat within a set deadline.

121. 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 concerned.

122. In the event that the circumstances do not require or allow a meeting to be held, a draft opinion may be adopted by written procedure. In this case, the Secretariat shall send the draft opinion to the Members of the relevant Scientific Committee with a request for approval by a set deadline. The draft opinion shall be adopted if the majority of the Members of the Scientific Committee have expressed their approval before the deadline. If a majority is not reached, the draft opinion must be put on the agenda of the following meeting of the Scientific Committee or, if the urgency of the matter so requires, of an ad hoc meeting to be convened at the earliest date at which the quorum can be assured.

n. Voting rules

123. The Scientific Committees shall adopt their opinions, rapid advice, and memoranda and /or position statements by a majority of the total number of the Experts who have been appointed by the Commission as Members of the Committee concerned combined with the number of Associated Members who have contributed to the document under consideration.

124. On all other issues, each Committee shall act by a majority vote of the Experts who have been appointed by the Commission as Members of the Committee.

125. Meetings are considered valid when the majority of the Experts who have been appointed by the Commission as Members of the Committee concerned are present.

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

o. Information of the Secretariat

127. Members, Advisors, External Experts should inform the Secretariat on all issues concerning their activities related to the Committee work, for example:

- Communication with Members/Experts regarding the work of the Committees;
- Relations with the media (interviews, articles, letters etc.); and
- Presentations/speeches regarding the work of the Committee.

X CO-OPERATION WITH OTHER SCIENTIFIC BODIES

a. Diverging opinions

128. Each Scientific Committee shall assist the Commission and contribute towards identifying, resolving or clarifying at an early stage potential or actual divergence between their scientific opinions and the scientific opinions of Community, national and international bodies carrying out similar tasks, on general or specific risk assessment issues. Similarly, they will assist and contribute towards identifying needs and possibilities for co-ordination 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.

129. When a substantive divergence is identified with a Community body, the Scientific Committee concerned shall, on the request of the Commission, cooperate with the body concerned. To this end the Commission may convene a meeting between the Scientific Committee and the scientific organs of the bodies concerned. The Scientific Committee shall designate a Rapporteur.

130. 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 Commission. This document shall be made public.

131. In order to help identifying, preventing or managing divergences over scientific opinions, the Secretariat will seek to agree with EU Agencies involved in risk assessment appropriate arrangements which may take the form of common guidelines. Once agreed by the interested bodies and

approved by the Inter-Committee Coordination Group (ICCG), such guidelines shall be considered to be part of these Rules of Procedure.

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

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

133. In particular, the Scientific Committees shall assist the Commission on scientific technical matters requiring co-ordination and co-operation with other Community bodies charged with risk assessment, notably with the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), The European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMEA).

134. In order to ensure that this co-operation is effective:

- The Commission may organise meetings of the Chairs of the Scientific Committees and the Chairs of other Community risk assessment bodies.
- The Scientific Committees may ask for the assistance of Members of the Scientific Committees or Panels of other Community 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 Community risk assessment bodies.

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

136. The Commission may in particular request that the Scientific Committees produce joint opinions with other Community 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.

137. 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 Co-ordination Group or the relevant Committee. After the principle decision has been made by the Co-ordination Group or the relevant Committee, the Secretariat shall define and manage the practical aspects and make the appropriate contacts.

138. 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. Once agreed by bodies participating in the exchange mechanism and approved by the ICCG, such guidelines shall be considered to be part of these Rules of Procedure.

XI SCIENTIFIC ADVISORS ON RISK ASSESSMENT

139. In addition to the their involvement in the activities of the Scientific Committees as provided for by the Commission Decision 2008/721/EC and these Rules of Procedure, Scientific Advisors of the Pool may be invited by the Commission to participate in scientific meetings or to provide the Commission Services with ad hoc information on specific issues.

140. Invitations and requests will be sent by the Secretariat. They can be addressed to individual Advisors or to groups of Advisors depending on needs.

XII ROLE OF THE SECRETARIAT

141. In addition to the specific tasks referred to in these Rules of Procedure, the Secretariat shall be responsible for providing the necessary scientific and administrative support 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, transparency and confidentiality, to ensure communication on the Committees' activities and the appropriate stakeholder dialogue, including organisation of hearings, and publication of the opinions and other public 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:

142. Ensuring the best use of resources and planning to meet priorities and time limits.

143. Ensuring that requests for opinions comply with the requirements on mandates.

144. Identifying the need for collaboration or for a joint opinion and preparing the request accordingly.

145. Identifying, in collaboration with the requesting service, and including in the mandates the requirements concerning scientific meetings, hearings, consultations, and collaboration with other bodies.

146. Ensuring avoidance of overlapping or inconsistent opinions.

147. Preparing the work of the Committees and their respective Working Groups, in consultation with the Chairs.

148. Providing information on the legislative/policy aspects of the questions.

149. Ensuring that relevant background information is made available to the Scientific Committees and Working Groups.

150. Assisting in identifying the appropriate Advisors and Experts to be invited to participate in Working Groups.

151. Organising the appropriate dialogue between the Committees and the requesting services at the various stages, including feedback from the services on the adopted opinions. The Secretariat shall agree with the requesting services procedures for ensuring that the dialogue with the Scientific Committees takes place on a systematic basis. The Secretariat shall inform the Scientific Committees of the arrangements made and systematically monitor their application.

152. Assisting the Chairs of the Committees and their Working Groups in the preparation of the draft opinions. This involves monitoring, assessing and reporting on the quality of draft opinions before adoption to the Committees, particularly in relation to correspondence with the mandate, completeness, clarity and coherence and editorial standards. Draft opinions should conform to the principles of excellence, independence and transparency and the other relevant principles and standards referred to in these Rules of Procedure or set up by the Inter-Committee Co-ordination Group.

153. Co-ordinating the administrative, scientific and technical work carried out within and between the Committees and their respective Working Groups.

154. Assuring the scientific and technical co-ordination of the activities of the Scientific Committees in relation to the activities of other Community and international bodies involved in scientific risk assessment.

155. Deciding, in agreement with the interested Commission Services, about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops.

156. Monitoring compliance of the Members with participation criteria and informing the Commission as appropriate.

XIII EXTERNAL EXPERTS

157. External Experts possessing particular and relevant scientific knowledge may be invited to contribute to the work of the Scientific Committees or the Working Groups. This will include in particular the preparation, compilation and presentation of the scientific evidence base which serves as a basis for the opinion of the Scientific Committee.

158. To that end, the Secretariat will make use as far as possible of the Pool of Scientific Advisors and a database in which Experts may register in view of their possible involvement in Working Groups.

XIV PUBLICATION OF THE OPINIONS AND OTHER DOCUMENTS

159. All documents mentioned under paragraph 35, particularly the adopted scientific opinions, shall be published on the Internet without undue delay by the Secretariat

160. For any other document, the Secretariat in agreement with the interested services, shall decide about the publication and dissemination on a case–by-case basis.

XV REPRESENTATION OF THE SCIENTIFIC ADVISORY STRUCTURE

161. 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 requested by the Secretariat to make presentations of the opinions to which they have contributed. Other Members, Advisors and Experts may be invited by the Secretariat to attend events, meetings etc. in relation to the work of the Scientific Advisory Structure activities, but shall not speak on behalf of the Committees, unless explicitly requested to do so on specific issues by the Secretariat.

XVI PARTICIPATION CRITERIA AND TERMINATION OF MEMBERSHIP

162. The minimum participation criteria are fixed as follows:

163. In each calendar year, it is expected that Members will be in a position to attend at least 70 per cent of the meetings of the relevant Committee and Working Groups to which they have been invited.

164. Members are expected to be in a position to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the Committees and their Working Groups and, when requested, provide written comments.

165. The extent to which Members have been in a position to participate in the work of their Committee will be assessed by the Secretariat on a yearly basis. After consultation with the Chair, the Secretariat shall examine the situation with the Members who have not been in a position to comply with the participation criteria and inform the Commission in view of possible decisions in accordance with Article 5(2) of the Commission Decision 2008/721/EC.

XVII THEMATIC WORKSHOPS, SCIENTIFIC MEETINGS, NETWORKS

166. Thematic workshops shall be organised by the Secretariat:

167. At the request of the Commission itself; or

168. Initiated by a Committee, in agreement with the Commission.

169. The objective of such workshops may be to review data and scientific knowledge on particular risks or broad risk assessment issues. These workshops may involve Members, Advisors, and External Experts, including Experts from Community, national or international bodies carrying out similar tasks.

170. Workshops initiated by a Scientific Committee will be organised by the Secretariat subject to consultation of the interested Commission services, availability of funds and adequate planning.

XVIII TRAINEES

171. In order to contribute to capacity building in the area of risk assessment, trainees may attend the meetings of the Scientific Committees in agreement with the Commission.

172. The request for a trainee to attend a meeting must be presented to the Committee in writing by a Member or by the Secretariat. The request shall present in particular the curriculum, objectives and duration of the traineeship as well as the proposed practical arrangements. Each Committee shall not admit more than two trainees at the same time. The trainees will be invited to meetings as observers by the Secretariat. They will access the Commission premises as invited visitors for the duration of the meetings in which they are invited. Trainees shall sign a confidentiality declaration and a declaration of interest.

XIX MISSION EXPENSES AND INDEMNITIES OF MEMBERS, ADVISORS AND EXTERNAL EXPERTS

173. Travel and subsistence expenses incurred by Members, Advisors and External Experts in connection with Scientific Committee meetings and activities are reimbursed in accordance with Commission's rules.

174. Members of Scientific Committees, Advisors and External Experts are entitled to a special indemnity for attendance at meetings as set out in Annex III of Commission Decision 2008/721/EC as modified by Decision 2009/566/EC of 27 July 2009.

175. Indemnity payments are directly linked to presence as documented by the attendance list which is signed by participants in the meetings of Committees and Working Groups, or agreed external meetings and certified as correct by the meeting secretary. In exceptional cases, participation through audio or video link may be authorised by the Secretariat.

176. Rapporteurs shall be entitled to an indemnity as set out in Annex III of Commission Decision 2008/721/EC as modified by Decision 2009/566/EC of 27 July 2009. A written agreement between the Rapporteur and Commission services will be established when the Rapporteur is nominated. Payment of the indemnity will be made after adoption of the specific opinion by the relevant Scientific Committee.

ANNEX I – DECLARATION OF COMMITMENT

Scientific Committees
on
[Consumer Safety
Health and Environmental Risks
Emerging and Newly Identified Health Risks]

DECLARATION of COMMITMENT

Name:

Position: Member of the Committee ☐

Advisor ☐

External expert ☐

I undertake to:

1. 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.

2. Attend meetings regularly.

Done at on

Signature: …….

ANNEX II – GUIDANCE ON DECLARATION OF INTERESTS AND DECLARATION FORM

GUIDANCE ON DECLARATION OF INTERESTS

A. INTRODUCTION

This guidance relates to the implementation of the provisions on independence and transparency of Commission Decision 2008/721/EC.

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.

According to Decision 2008/721/EC, the responsibility for declaring all relevant interests is placed on the individuals completing their declaration.

Experts are nominated to the Advisory Structure of the European Commission as independent Experts, strictly in their personal capacity and not as representatives of public or private bodies, organisations or states.

An "interest" declared is not automatically considered to create a conflict of interest. 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.

These Rules of Procedure cover the Annual Declaration of Interests (ADoI), required from all Members of the Scientific Committees and the Specific Declaration of Interests (SDoI), required from all Advisors and Experts participating in Working Groups (including the relevant Scientific Committee Members) and the Advisors associated to a Scientific Committee.

The ADoI 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.

The SDoI is linked to a specific subject matter and allows assessment of whether a conflict of interest could exist in the context of the specific activity. It is to be filled in at the start of the work of every Working Group, and is to be completed by the Advisors associated to a Scientific Committee. It should be completed by all Members of the Working Group except participating Members of the Scientific Committee who already declared the same interest in the ADoI. It should be updated whenever a new relevant interest occurs which is not yet specified in the actual SDoI or ADoI. In addition, ad hoc SDoIs may be requested from Working Group Experts who are not Scientific Committee Members when they are asked to participate to special events on behalf of the relevant Scientific Committee (e.g. hearings at the European Parliament, meetings with stakeholders, etc.).

Declarations of Interest are addressed by an expert to their peers and the

Secretariat as an indication of where conflicts of interest could arise and do not require from the author to assess whether there is a conflict. The assessment of whether there is a potential conflict is performed by the peers (i.e. the Chair and the other Members of the Scientific Committee) and the Secretariat.

B. WHAT TO DECLARE?

Members of the Scientific Committees, Advisors as well as External Experts shall declare current and past activities (as specified under "other definitions" below) in the ADoI and SDoI (same form). The Commission recognises 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 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[1] in the capital of a company. 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 of 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 scope of work of the Committee (e.g. board membership, directorship).

3. Membership of another Scientific Advisory Body

The person concerned is participating or has participated in the works of a Scientific Advisory Body 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 falling within the scope of the work of a Scientific Committee.

5. Consultancy/Advice

Any paid or unpaid, past, present or future activity in which the Expert or their collaborators provide technical or scientific advice, or services in domains of relevance for the work of the Scientific Committee.

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[1] When declaring financial interests e.g. stock and shares, only the type of company needs to be stated.

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 in relation to matter or work financed by a private or public entity, 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 Committee need be taken into account. These can be copyrights, patents, and trademarks etc.

8. Other membership or affiliation

Any membership or affiliation other than the above which can be perceived as an interest in the field of activity of a Committee.

9. Interests of close family members

Known interests as described under points A.II 1-8, held by family members and relatives (e.g. 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 and the relationship (e.g. wife) need not be specified.

10. 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.

C. DEFINITIONS

Current means ongoing activities.

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

Name of entity or organisation 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 meaning 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.

D. 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 action deemed necessary, including the dismissal of the person(s) concerned from the Advisory Structure.

E. PUBLICATION

The ADoIs and SDoIs will be made public in accordance with the provisions on transparency foreseen by Decision 2008/721/EC.

F. 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 Community institutions and bodies and on the free movement of such data.

DECLARATION OF INTERESTS

(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:

SCCS, SCHER, SCENIHR involvement: Chair – Scientific Committee (SC), Member – Working Group (WG) on …

Title:

Profession:

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

Nature of Activities	**Period**	**Organisation**	**Subject matter**
1. Ownership of shares or other investments	MM/YYYY – MM/YYYY	Companies or organisations in which the financial interest is placed	*[Relevant field of activity]*
2. Membership 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:

Nature of Activities	Period	Organisation	Subject matter
3. Membership of another 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:
4. Employment	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private …	*[Describe professional activities in relation to activities of the SCs]*
5. Consultancy/Advice	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private …	*[Describe role]*
6. Research	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private …	*[Describe research]*
7. Intellectual property rights (IPR)	MM/YYYY – MM/YYYY		
8. Other membership or affiliation	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private …	*[Describe activity, function, website]*
9. Interests of close family members	MM/YYYY – MM/YYYY		*[Describe activity, function]*

Nature of Activities	Period	Organisation	Subject matter
10. Other	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private …	*[Describe activity, function, website]*

I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Rules and Procedures related to Independence (section V of the Rules of Procedure) and that the above Declaration of Interests is complete.

Date: DD/MM/20XX

Signature:

SIGNED

ANNEX III – DECLARATION CONCERNING CONFIDENTIALITY

DECLARATION CONCERNING CONFIDENTIALITY
Scientific Committee
on
[Consumer Safety
Health and Environmental Risks
Emerging and Newly Identified Risks]

Name:

Position: Member of the Committee ☐

Advisor ☐

External Expert ☐

I hereby declare that 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 Committee, or one of its Working Groups, when informed that it is confidential. I shall also respect the confidential nature of the scientific opinions expressed by Members of the Committee Advisors or External Experts 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.

Done at on

Signature: ……..

ANNEX IV – STAKEHOLDER DIALOGUE PROCEDURES

STAKEHOLDER DIALOGUE PROCEDURES

COMMISSION SCIENTIFIC COMMITTEES SCCS, SCHER AND SCENIHR

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 Commission Scientific Committees SCHER, SCCS and SCENIHR, whilst ensuring the effectiveness of the process and compliance with the principle of independence.

These procedures will be implemented as part of the Rules of Procedure of the said Committees. It needs to be emphasised that the procedures described 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; and
- Not previously addressed by any of the three Scientific Committees.

While these procedures contribute to the implementation of the principle of transparency and 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 Commission Scientific Committees is, and must remain, independent of any influence. Therefore these procedures must not be used to claim a right to interfere with, or try to become involved in, the internal work of the Committees; nor should they be used to exert pressure on Members of the Scientific Committees. 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 may consider submitting to a Scientific Committee (Section 2);
- Finalisation of new mandates (Section 3);
- Calls for information (Section 4);
- Scientific input during the preparation of the opinion:

- Hearings (Section 5a)
- Public consultations on a pre-consultation opinion (Section 5b)

- Revision of existing opinions (Section 6).

Only submissions sent to the appropriate functional mail box and complying with all the other conditions mentioned below will be considered. In all other cases, the Commission will not be in a position to consider the submission.

2. SUGGESTIONS TO THE COMMISSION FOR NEW TOPICS FOR THE SCIENTIFIC COMMITTEES

SCHER, SCCS and SCENIHR have been established to advise the Commission. According to their legal basis, they develop and adopt opinions upon Commission's request. DG Health and Consumers is in charge of managing these three Scientific Committees.

In order to maximise the potential of the Scientific Committees, the Commission will welcome motivated and documented suggestions[2] for new topics for the Scientific Committees, provided the suggested topics do not fall under the competence of European agencies, in particular, ECHA, EMEA or EFSA. The suggestions will therefore be considered under the following conditions:

- The issue is related to competences of the EU in 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, and 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;

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[2] Suggestions for possible topics should be submitted:
by surface mail to the following address: European Commission, DG SANCO C7-Risk Assessment, B-1049 Brussels
or, preferably, by e-mail to the following address: Sanco-C7-risk-assessment@ec.europa.eu
In order to be considered, 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.
When submitting suggestions for topics in electronic form, "Suggestion of new topic" in the subject line of the e-mail should be included.

- 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); and
- 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, DG Health and Consumers, in collaboration with the other interested Commission services, will examine the suggestion in view of a decision on the possible follow- up, 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 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 services.

The Commission 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 and examined by the Scientific Committees.

3. FINALISATION OF NEW MANDATES

All new mandates will be published at the following Internet address: http://ec.europa.eu/health/ph_risk/committees/committees_en.htm

For issues of broader significance or wider public interest, DG Health and Consumers, when so agreed by the requesting Commission service, will submit "working" mandates to public consultation. In selecting mandates for a public consultation, the Commission services 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 working mandates could still be refined in light of the comments received. In such a case, a final version of the mandate will replace the "working" one.

The Commission will welcome comments on the working mandates 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[3]. After such a period, in general, the Commission shall not be in a position to ensure consideration or follow up further comments.

[3] This condition would not strictly apply for emerging risks 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.

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

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.
- In the case of additional issues and questions being proposed, see the conditions mentioned in the paragraph "Suggestions to the Commission for new topics for the Scientific Committees" above.
- 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 cases where the comments involve an extension of the scope of the mandate, adequate data and scientific knowledge exist and is provided to enable the Committee to offer advice on the suggestion and the Commission to decide.

If the above conditions are met, the Commission services concerned will examine the comments in view of a decision on the possible follow up, 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 Commission service requesting the opinion decides in agreement with DG Health and Consumers to take the proposal on board, questions might be revised and/or amended.

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

The results of the consultation will be summarised on the website of DG Health and Consumers mentioned above.

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

This procedure will not apply in case of urgent matters and accelerated consultation procedure.

4. CALL FOR INFORMATION

Reports 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 as specified in the Call is available to the Scientific Committee for its assessment.

In general, only submissions directly related to the Call and complying with its specifications will be considered[4]. Any document referred to shall be attached to the email in an appropriate electronic form. All relevant material specified in the scope of the Call should be attached to the submission of the contribution.

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

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

- It is submitted after the deadline set out in the call; or
- It does not correspond to the scope and format specified in the call and in these guidelines.

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

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

a. Organisation of hearings

Technical hearings with individuals, petitioners or other stakeholder representatives may be organised:

- On the initiative of the Scientific Committees, if they consider it necessary for the completion of a scientific opinion;
- 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 Commission services will assess the request in collaboration with the Scientific Committee and decide upon the action to be taken. The precise

[4] 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.).

organisation of the hearing will be decided on a case-by-case basis. The requesting party will be informed of the conclusions.

- On the initiative of the Commission services in agreement with the Scientific Committees.

The relevant Committee will decide who will represent the Committee at the hearing. As a general rule, only Members of the Committees will be involved in such hearings.

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 when invited to such hearings, individuals, petitioners or other stakeholders 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 make 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, Associated Members and External 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.

On occasion, open public hearings might be organised on the initiative of the Scientific Committees or the Commission (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 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 pre-consultation opinion).

In those cases, the following procedures will be followed:

- DG Health and Consumers will publish the intention to organise a public hearing on behalf of the Scientific Committee on a particular subject, the specific items on which the Scientific Committee would wish to receive contributions and an invitation to interested parties to register;
- Registration will be open for a 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 in the hearing will be decided 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; and

- Interested participants have clearly identified the subject matter they wish to contribute to and have provided sufficient technical justification;

- All registered participants will be informed at least two weeks before the hearing;
- DG Health and Consumers will publish 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; and
- During hearings, Members, Associated Members and External Experts shall avoid giving information to competitors or other interested parties regarding specific products if this information is not public.

b. Public consultation on pre-consultation opinions

The Scientific Committees may decide to submit a pre-consultation opinion to a public consultation in case the Committee and the Commission 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 regarding policy or regulatory matters, for which a different scope, as well as rules and procedures apply.

In general, only submissions directly referring to the content of the pre-consultation 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 scientific reports or journals will be taken into consideration.

Any document referred to shall be attached as indicated in the template in an appropriate electronic form. All relevant material should be attached to the contribution. No researching of referenced documents or websites will be carried out.

It should be noted that 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; or
- It is related to policy or risk management aspects.

Follow up to submissions

An automatic system to acknowledge receipt of submission 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 their contribution.

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

Depending on the results of the consultation, 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 as well as an Annex to the opinion listing the contributions received.

It is not intended to provide any separate document on the consultation, the participation in it or a summary of the submission received.

6. 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 three years.

After that period and in order to keep the Scientific Committee opinions up-to-date with new scientific knowledge, the Scientific Committees may, on 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 new evidence meeting one or more of the following criteria:

- New data or information is provided in response to the explicit needs expressed by the Scientific Committees in the existing opinion;
- Substantial new evidence was made available in the public domain that, in the view of the Scientific Committee or the Commission or of stakeholders, is worth evaluating with a view to update an existing opinion;

- Stakeholders, international organisations, or 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; or
- 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 (in agreement with the Scientific Committees) may initiate the revision of an existing opinion before the three year period since the publication of the final existing opinion. In this case, the decision to revise the existing opinion will be based on the above criteria and the evaluation of the accentuating circumstances necessitating a revision.

7. FUNCTIONAL MAILBOXES AND PRACTICAL GUIDANCE

Two types of functional mail boxes will serve the communication needs of the Scientific Committees; a permanent mail box and specific mail boxes of limited duration.

The permanent mail box will serve as a general communication tool for each Scientific Committee allowing stakeholders and interested parties to communicate with the Scientific Committee secretariat on a number of items identified in the present document such as suggestions for new topics, comments on the mandates, inquiries on status of work in progress, general information on conferences and scientific events of potential interest to the Scientific Committees or organised by the Scientific Committees, general comments, etc.

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

ANNEX V – PRINCIPLES AND STANDARDS FOR SCIENTIFIC ADVICE ON RISKS

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 processes are 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, the composition of Working Groups (without prejudice to the need to protect the independence of Working Group Members during the preliminary work from external pressures and influences), the procedures for the identification and acquisition of the relevant data and information, 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. When selecting Experts objectives such as multi-disciplinary expertise and a wide range of views taken into account.

3. Pro-active search for collaboration

As far as reasonably feasible and appropriate in light of the objectives of a consultation and the time constraints, consultation of, and possibly collaboration with other scientific organisations dealing with the subject in question should be pro-actively sought. In particular, dialogue and collaboration with risk assessment bodies which have produced risk assessment on the subject addressed by a Committee should be looked for and the results of their risk assessment duly considered.

4. Effective organisation and planning

Planning and organisation of work should be realistic and proportionate to the scope and objectives of the consultation. In this respect, the roles of the Chair of the Scientific Committee and the Chair of the Working Group are critical to identify and remedy (together with the Secretariat and the Commission) problem situations (non-availability of Experts for meetings, delays in delivering drafts, etc.) that may be detrimental to the timely delivery of outputs.

5. Collegiality and pluralism

The process should be organised and managed in such a way as to allow for the full involvement and contribution of all the 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 cases where consensus is not reached, minority positions of Committee Members shall be recorded and explained in the opinion.

6. Effective dialogue

Dialogue with stakeholders will be organised in such a way that the input received can be properly addressed as far as relevant in order to contribute to the quality, clarity and completeness of the opinion. In so far as possible, the opinions should address the science-based, technical points raised by the contributions and provide clarification as to why a particular point made was or was not considered and/or 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 and documented at the beginning of the work, in collaboration with the requesting service and the Committee.

8. Transparency of opinions

Transparency should be ensured on all the 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.

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 shall be clearly explained. Such criteria lead to decisions on whether to include, exclude or partially take data and information into account by attributing a certain weight to them. The application of these criteria in the specific case considered shall also be documented and explained in the opinion.

The criteria used, and their application, for attributing a weight to the various streams of evidence in order to determine the existence of risks, characterise them, and to draw conclusions should also be explained.

In a similar manner, the expert judgement should be properly explained and documented so as to clearly demonstrate the contribution of evidence and of expert judgement in the opinion and its conclusions.

12. Qualitative and quantitative assessment

As far as relevant, and scientifically and practically possible, risk assessment should be quantitative and consistent with the available data and knowledge. When a qualitative assessment is made, the narrative of the 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 relevant 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 quantitatively, where possible. Equally, all relevant sources of variability as well as their influence of the assessment of risks shall be identified, analysed, documented, treated and expressed quantitatively.

The 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. Those aspects are to be addressed, as appropriate to the Impact Assessment Procedure. 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. Quantitative expression of risks

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

18. Appropriate criteria for framing risks

Framing of risks, in particular alluding 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, if appropriate, 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.

19. 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 allow for a comprehensive view of the risks (e.g. in case of assessments not taking into account multiple sources, cumulative or synergistic effects etc.).

20. 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

21. 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.

22. Harmonised and clear terminology

Terms used should be consistent with harmonised and generally accepted terminology, wherever possible. In order to prevent misunderstandings, definitions should be introduced when necessary. Particular care should be taken in order to ensure consistency of the terminology used across opinions of the three Committees.

23. 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.

24. 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.