ANNEX I

DECLARATION OF COMMITTMENT

Scientific Committee
on
Consumer Safety
Health and Environmental Risks
Emerging and Newly Identified Risks

Name:

Position: Member of the Committee ☐

Advisor ☐

External expert ☐

1- Commitment

While contributing to Scientific Committees activities, I undersigned shall:

- act independently in the public interest and to make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence;
- attend meetings regularly and contribute actively to the work of the Scientific Committees;
- Respect the Commission internal security policy and measure made available to me;
- Always set an exemplary conduct in all activities linked to Scientific Committees;
- Comply with Scientific Committees' rules on Declarations of interest and independence;
- As far as applicable, comply with the rules on expert's reimbursement of travel expenses and payment of allowances and indemnities in place in the Commission;

- Read and understand the way personal data are processed as detailed in point 2 of the present Declaration;

- Ensure appropriate use of scientific publications provided by the Scientific Committees and respect copyrights as explained in point 3 of the present Declaration;

- When communicating with media, stakeholders or the general public on a matter that falls within the Scientific Committees' remit always contact the Scientific Committees' Secretariat.

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

2- Personal data processing & respect of privacy

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

3- Copyrights and library working tools provided by Scientific Committees

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

The undersigned will be allowed to make limited use of journals and scientific publications, but shall not:

- Distribute copies of articles and journals to third parties;
- Use articles or journals for commercial purposes;
- Use the materials for other purposes than the Scientific Committees' assignment

Done at Date

Signature : …….

ANNEX II

GUIDANCE TO DECLARATION OF INTERESTS

INTRODUCTION

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

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

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

4. 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, organizations or states.

5. 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.

6. These rules of procedure cover the Declaration of Interest to be filled in by the Members before the start of their mandate, 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 SC members) and the Advisors associated to a Scientific Committee.

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

8. The SDoI is linked to a specific subject matter and enables to assess whether a conflict of interest exists in the context of the specific activity. It is to be filled in before the start of the work of every Working Group. It is to be completed by the Advisors associated to a Scientific Committee. It should be completed by all members of the WG. 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 SC members when they are asked to participate to special events on behalf of the SC (e.g. hearings at the EP, meetings with stakeholders, etc).

9. Declarations of Interest are declared by an expert as an indication of where conflicts of interest could arise and do not require from the author to assess whether there is actually a conflict. The assessment of whether there is a potential conflict is performed by the peers (i.e. the Chair and the other members of the SC) and by the Secretariat.

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 recognizes that high quality and up-to-date scientific expertise is by nature based on prior experience, connection to the scientific world and involvement in current research. Therefore, having an interest does not necessarily mean having a conflict of interest.

1. Ownership of shares or other 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 interests3 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 in a Management Body or equivalent structure.

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

3. Membership in another Scientific Advisory Body

The person concerned is participating or has participated in the works of a Scientific Advisory Body with 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 his depended collaborators provides technical or scientific advice or services

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

in domains of relevance for the work of the Scientific Committee.

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 SC need be taken into account. These can be copyrights, patents, trademarks et cetera.

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

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

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

CONSEQUENCES OF NOT DECLARING an Interest

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

PUBLICATION

The **ADoIs and SDoIs** will be made public in accordance with the provisions on transparency foreseen by Decision 2008/721/EC. They will be posted on the web-site of the Scientific Committees www.ec-scientific-committees.eu

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

Scientific Committee on

Consumer Safety

Health and Environmental Risks

Emerging and Newly Identified Health Risks

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

Name:

Position: Member of the Scientific Committee …….

Title:

Profession:

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

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

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

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

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

Done at …….Date:

Signature:

ANNEX III

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

1. I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of the work of the Scientific Committees, or one of its Working groups, 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 disclose such information even after my participation in the work of the scientific committees has ceased.

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

The above implies that the undersigned:

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

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

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

Done at Date

Signature: ……..

ANNEX IV

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 independency.

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;
- 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. These procedures must therefore, not be seen as, and must not be used to interfere with the internal work of the Committees, claiming a right or trying to be involved in such work or exerting pressure on Committees' members. The overall aim of these procedures is to contribute to ensure the highest quality of the scientific opinions adopted by the Committees. In case of any evidence of significant risks for the independence of the committees due to the application of these procedures, the Commission will discontinue their application in part or in total as appropriate.

The procedures apply to the following stages:

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

Only submissions sent to the appropriate functional mail box (published on the website of the Commission: *http://ec.europa.eu/health/scientific_committees/policy/index_en.htm)*, 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[4] for new topics for the Scientific Committees, provided the suggested topics do not fall under the competence of European agencies like 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 the health and environmental areas;
- the issue falls under the competence of one of the Committees, both in terms of nature and specific content;
- the background, interest, importance for the EU and the Commission in particular are demonstrated with solid arguments;
- the issue concerns scientific risk assessment, not risk management or policy

4 Suggestions for possible topics should be submitted:
by surface mail to the following address: European Commission, DG SANTE C2-Scientific Committees, L-2920 Luxembourg
or, preferably, by e-mail to the following address: Sante-C2-scientific-committees@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.

matters and the questions proposed concern scientific issues;

- the importance of the issue in terms of health and environmental risks is documented;
- the issue is clearly and completely defined. In particular the questions for the Committee are clearly formulated;
- the issue and the questions are formulated in neutral terms, without explicitly or implicitly suggesting a particular answer or asking for the endorsement of a predefined thesis or hypothesis;
- the suggestion does not aim at obtaining reconsideration of a recent opinion on which consultations have been closed (unless important published scientific results and the urgency of the matter require such reconsideration);
- adequate data and scientific knowledge (published literature etc) exist and are provided[5], 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 are published at the following Internet address: http://ec.europa.eu/health/scientific_committees/all_mandates/index_en.htm

For issues of broader significance or wider public interest, 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[6]. After such a period, in general, the Commission shall not be in a position to ensure consideration or follow up further comments.

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 case additional issues and questions are proposed, see the conditions mentioned in the paragraph "Suggestions for new topics" 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 case 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 advise 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 the comments presented if they are of particular interest.

The results of the consultation will be summarized on the web site of DG Health and Consumers mentioned above.

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

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

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[7]. Any document referred to shall be attached to the e-mail 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, organization, postal address, telephone number and e-mail address of the sender should appear in the text of the e-mail.

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

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

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

Confidential data:

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

5. Scientific input during the preparation of the opinion

5.1. Organisation of hearings

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

- at the initiative of the Scientific Committees, if they consider it necessary for the completion of a scientific opinion;

7 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)

– 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 organisation of the hearing will be decided on a case-by-case basis. The requesting party will be informed of the conclusions.
– at 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 take any decisions during hearings.

In conformity with the generally applicable obligation to respect confidentiality in all the aspects of the work of the Scientific Committees, Members, 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 at 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 to 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;
  - interested participants have clearly identified the subject matter they would wish to contribute to and have provided sufficient technical justification;
- all registered participants will be informed at least two weeks before the hearing;
- 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;
- 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.

5.2. 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;
- it is related to policy or risk management aspects.

Follow up to submissions

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

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

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

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.

5.3. Revision of existing opinions

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

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

The revision of an existing opinion will be initiated on the basis of 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, third countries, submit adequate data indicating a possible change in the level of safety for human health and the environment for a particular stressor subject of an existing opinion;
- Member States notifying safeguard clauses with supporting evidence showing previously unidentified hazard properties, exposure situations, or potential risks associated with a stressor subject of an existing opinion.

  On rare occasions and depending on accentuating circumstances concerning new evidence available and the concomitant potential risks to humans and the environment, the Commission (in agreement with the Scientific Committees) may initiate the revision of an existing opinion before the 3 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.

6. 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

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. Experts should be selected taking also into account the objective ensuring pluralism of views and multi-disciplinarily.

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 the case 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. To the extent 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 at the beginning of the work, in collaboration between the requesting service and the Committee, and documented.

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 that have lead to decisions on whether to include them, exclude them or partially take them into account by attributing to them a certain weight shall be clearly explained. Their application in the specific case considered shall also be documented and explained in the opinion.

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

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

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

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

13. Systematic Identification and Assessment of Uncertainties and Variability

The relevant uncertainties related to the various aspects and stages of the risk assessment shall be, as far as possible, systematically identified, analysed and documented. As far as possible, 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. Equally, all relevant sources of variability as well as their influence of the assessment of risks shall be identified, analysed, documented and treated and expressed, as far as possible, quantitatively.

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

14. Use of confidential data compatible with clarity

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

15. Avoidance of risk management statements

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

shall not address risk management aspects. The opinions shall not recommend risk management measures. Nevertheless, if so requested in a mandate, an opinion may assess (including comparatively) the effectiveness of specified measures in terms of risk reduction.

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

Risk assessment opinions should not address or be influenced by economic, social, ethical aspects or other aspects different from human health, safety and environmental risks. Those aspects are to be addressed, as appropriate in 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, account taken of the data and knowledge available. Uncertainty and variability of the risk estimate should be presented contextually. Expression of risks includes its nature, scope and distribution, probability, and magnitude.

18. Appropriate Criteria for Framing Risks

Framing of risks, if appropriate, 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 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, as far as possible consistent with harmonised and generally accepted terminology. When necessary in order to prevent misunderstandings, definitions should be introduced. 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 perts 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.