EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

September 2007

(Stakeholderfinal)

Pilot Dialogue Procedures

Commission Scientific Committees

SCHER, SCCP 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, SCCP and SCENIHR, whilst ensuring the effectiveness of the process and compliance with the principle of independency.

These procedures will be implemented initially on a pilot basis for a period of one year, starting on 15 September 2007. In fact, the Commission and its Scientific Committees wish to gain more experience in order to find the most effective means to interact with its stakeholders in an even handed and open way. 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 preliminary report
- scientific comments on existing opinions

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, SCCP 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 Consumer Protection 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[1] 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[2];

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[1] 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.

[2] It should be noted that during 2008, the vast majority of the current tasks of SCHER related to risk assessment of chemicals will be handed over to the European Chemical Agency (ECHA) established under the REACH regulation. The Commission will not follow up suggestions concerning topics on which EFSA has worked, or which fall under ECHA's mandate. This will also apply in case of revisions of old opinions.

- the background, interest, importance for the EU and the Commission in particular are demonstrated with solid arguments;
- the issue concerns scientific risk assessment, not risk management or policy matters and the questions proposed concern scientific issues;
- the importance of the issue in terms of health and environmental risks is documented;
- the issue is clearly and completely defined. In particular the questions for the Committee are clearly formulated;
- the issue and the questions are formulated in neutral terms, without explicitly or implicitly suggesting a particular answer or asking for the endorsement of a predefined thesis or hypothesis;
- the suggestion does not aim at obtaining reconsideration of a recent opinion on which consultations have been closed (unless important published scientific results and the urgency of the matter require such reconsideration);
- adequate data and scientific knowledge (published literature etc) exist and are provided[3], enabling the Committee to develop an opinion.

If the above conditions are met, DG Health and Consumer Protection, 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/ph_risk/committees/committees_en.htm

For issues of broader significance or wider public interest, DG Health and Consumer Protection, 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[4]. 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 Consumer Protection 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 Consumer Protection mentioned above.

[4] 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 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[5]. 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] 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)

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;

- 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 preliminary reports)

In those cases, the following procedures will be followed:

- DG Health and Consumer Protection 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 Consumer Protection 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 draft opinions

The Scientific Committees may decide to submit a draft 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 report 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 may consider including 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 report.

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 are 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.