



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

**GUIDANCE FOR THE EXPRESSION OF OPINIONS AND OTHER
OUTPUTS OF SCIENTIFIC ADVISORY COMMITTEES**

Adopted by the Scientific Steering Committee (SSC)

as part of its exercise on

Harmonisation of Risk Assessment Procedures

I PREAMBLE

The advice given to the European Commission by its scientific committees can have a great influence on both consumers and the industry in member and non-member states. In its statement of 26 May 2000 on *Advice to the Commission from its scientific committees*, the Scientific Steering Committee (which includes among its membership, the chairman of the eight scientific committees) considered it important that the organisation and working procedures behind the scientific advice are transparent. These are briefly presented in the statement.

To enhance the transparency of the scientific advice, it is important that the various Scientific Committees as much as possible adopt harmonised working procedures. The purpose of the current document is to recommend how opinions should be set out and the relationship between opinions and reports. As the guidance proposed here extends beyond the current frame of scientific advice at the level of Commission Services, the remainder of the text refers to “scientific advisory committees (SACs)” rather than to scientific committees.

Key issues in the conduct of a risk assessment by the scientific advisory committees are:

- The increasing need for transparency throughout the process;
- Ensuring a very high and consistent scientific standard;
- Clarity both for scientists and other stakeholders about the outcomes of the risk assessment, both at the time of issuing an opinion and subsequently;
- A harmonised approach between different scientific advisory committees to avoid apparent ambiguities in assessments and to facilitate joint working between committees where practicable;
- Reducing unnecessary duplication of work both between EU scientific committees and with other national and international scientific committees;
- Enabling RAs carried out by one scientific committee to be readily utilisable by others.

The Scientific Steering Committee realises that these recommendations, when implemented, may have a greater impact on some Scientific Advisory Committees (SAC's) than others. However, harmonisation can only be achieved by modifications in the details of the way the SAC's currently function. The recommendations should be seen as a framework for a harmonised approach, rather than a set of rules. It is recognised that some aspects of the work of the committees are not amenable to this framework.

It is appreciated that adoption of these proposals would change to some extent the relationship between a committee and its working groups responsible for generating reports.

II. PROPOSAL

The principal proposed changes from current practice are as follows:

A) The roles of Scientific Advisory Committee and Working Groups

SAC's should continue to have the responsibility for establishing, where necessary, a Working Group (WG) to address a specific issue. The SAC should set the WGs terms of reference and the chairman of the WG should be appointed from among the SAC members. The terms of reference for a working group may not necessarily be identical to the questions asked of the SAC. It is recognised that some WGs comprise only members of the main Committees, whereas other comprise mainly external experts. Inevitably the balance of internal to external members will influence the interactions between the WG and the SAC.

To ensure that the scientific report meets the needs of the SAC it is important that agreement is reached at an early stage between the committee and the particular WG responsible for developing the report on:

- Source data to be utilised
- Structure of report
- Time Scale.

B) Relationship between the Opinion and the Report

The Opinion and the Scientific Report, although closely related, should be produced on the assumption that for some purposes they may be used as stand alone documents. SAC's may draw on information not covered in the report in reaching their Opinion. Opinions should, however, be based on the Scientific Report. In drafting both documents it should be assumed that, for various purposes, the Opinion and the Report might be utilised separately. Opinions should typically be quite short (1-5 pages). It is recommended that where possible the opinion and the report be published simultaneously. However, this may not be practicable, particularly if publication of the Opinion is deemed to be urgent. It is essential that scientific reports be of high quality, based on the best available scientific data. Risk assessment is becoming a recognised academic discipline in its own right. High quality reports, in addition to being valuable for a specific purpose, also serve to raise the status of the discipline.

Recommendations should not normally be included in the final Scientific Report. They should, however, be a specific sub-heading of the Opinion.

It is proposed that SACs should not alter the content of these reports, (and would therefore not have the responsibility for editing them) although as part of the peer review process they should be encouraged to propose improvements to the authors of any report. In making this proposal the Scientific Steering Committee notes that it is expected to be an increasingly common practice for these Reports to be commissioned (and paid for) by Commission Services / European Agencies which require specific risk assessments.

The Scientific Report should, wherever it could be of value to those outside the relevant committee, be prepared on the assumption that it will be published in an appropriate form. Reports published on the Internet following review and acceptance by an SAC may be considered to be peer reviewed. However, it is acknowledged that in many cases the format may differ from the procedure used by existing scientific journals. It is recommended that the principal authors names are included in the Report. This measure is consistent with encouraging a high scientific standard and making participation in working groups more attractive to non-members of the SAC's in that it would provide much more tangible professional recognition of the authors for the work they carry out. It will also aid transparency and help to reduce duplication of effort by different committees. A crucial element of the Opinion is that it should be written in a form that is unambiguous and can be understood readily by the appropriate stakeholders.

C) Sources and confidentiality of information

Whether a full literature search was conducted or whether the working group only used the literature provided by Commission Services should be identified. In future this identification should include whether or not individual stakeholders were invited to submit information. All sources of information that are used must be cited along with the rationale for excluding from consideration particular data sources.

Individual committees draw, to a variable extent, on information provided by manufacturers 'in confidence'. This situation has a substantial impact on the detail that can be cited in the Scientific Report and the Opinion and the transparency of the process. The committee/working group should identify the way that confidential material has been used to reach its conclusions/opinion. It should be made clear in the report what weight has been given to any unpublished data that is used and the basis for this.

D) Expression of alternative opinions

From time-to-time genuine significant differences arise in committees on the interpretation of scientific data. Where these differences cannot be resolved by extensive discussion they should be expressed in an alternative opinion to

ensure transparency. It is also important for risk managers to appreciate that on a particular risk assessment there are differences of view.

The alternative opinion should be noted in the text of the opinion and the detailed scientific argument attached as an appendix. Normally it is recommended that the authors of the alternative opinions are not identified specifically unless they require so. In instances of serious disagreement it may be appropriate to hold a formal vote of the SAC and to publish the results of this.

III REVISED RECOMMENDED STRUCTURE

The revised recommended structure is as follows:

- A) For the Opinion (ie: committee's position)
 - a) Title
 - b) Terms of Reference and statement on sources of information available
 - c) Brief background
 - d) Summary of key issues
 - e) Conclusions and recommendations
 - f) Key words
 - g) References including cross references to other relevant opinions by SACs
 - h) Appendix (to include declarations of interest if relevant, alternative opinions, statement on sources of information available, etc.)

- B) For the Scientific Report
 - a) Title
 - b) Table of Contents
 - c) Summary abstract
 - d) Purpose of the report and background to the issue(s)
 - e) Scientific discussion of the issue(s) following, where appropriate: a statement of sources of information available, hazard identification, hazard characterisation, exposure assessment, risk characterisation, other scientific considerations. (It is recognised that some aspects of the work of the SACs cannot be fitted into this framework).
 - f) Scientific interpretation (but not recommendations)
 - g) Key words
 - h) References
 - i) Appendix (to include declarations of interest if relevant, alternative opinions).