Opinion of the Scientific Steering Committee on harmonisation of risk assessment procedures (adopted on 26-27 October 2000)

1. BACKGROUND

Scientific risk assessment procedures include consideration of both human health and environmental impacts. These procedures are addressed within the EU and by many national and international bodies (e.g. WHO, FAO, OIE, OECD).

The Scientific Steering Committee of the EC (SSC) welcomes the first Report on the Harmonisation of Risk Assessment Procedures among the Scientific Committees advising the European Commission in the area of human and environmental health. The SSC acknowledges the very substantial work that has been done by its Working Party to produce the Report.

The SSC recognises the potential benefits of the progressive harmonisation of human and environmental risk assessment procedures based on current scientific understanding in terms of:

- enhancing the quality of the risk assessment procedures,

- achieving greater consistency when the same or very similar risk sources are assessed by different Scientific Committees,

- improving transparency and risk communication,

- enabling the EU to demonstrate externally a consistent high quality scientific approach for all risk assessments conducted on its behalf pertaining to the protection of human health and the environment.

The SSC notes that at this stage of the work, it has not been possible to consider the risk assessment activities of scientific committees in Directorates General other than DG SANCO.

2. RECOMMENDATIONS FOR HARMONISATION

The SSC recognises that it is not appropriate, at the present time, to seek to achieve identical methodologies across all Scientific Committees of the EC.

It accepts the principal recommendations of the Report of the Working Party, namely:

2.1 The recommendations are addressed to the Commission. They require an early and on-going dialogue between members of the Scientific Committees and Commission Officials to ensure their effective implementation. The recommendations cover both human health and the environment, and fall into three categories, namely those where:

i. early adoption is appropriate
ii. progressive implementation is considered to be achievable
iii. further investigations and/or discussions are needed

The Scientific Steering Committee is very concerned that the proposed separation of three of its Scientific Committees from its other Scientific Committees will detract from the harmonisation process, particularly in regard to the integration of public health and environmental risk assessment. Means must be found to ensure continuity of collaboration.

Recommendations for early adoption

2.2 Agree that all the Scientific Committees adopt a common glossary of risk terms.

It is also important that committees adopt a common language to describe different degrees of risk. This should consider how these terms will be translated into the different languages of the Member States.

2.3 Identify a common format for expressing the uncertainties in risk characterisation.

2.4 Standardise the format for the presentation of risk assessment findings. It is proposed that in future, unless there are specific reasons why it is not appropriate, the following structure is used by all Scientific Committees:

a. Title
b. Table of contents
c. Terms of Reference (e.g. questions asked of the Committee)
d. Opinion
e. Executive summary
f. Background (where the context of the question formulation is set out and reference is made to the source documents and the data which are provided)
g. Main text providing the scientific arguments which have to lead to the opinion. This should also identify in a transparent way the uncertainties in the risk characterisation
h. Conclusions (from which the essence of the opinion is extracted)
i. Recommendations

   (If so requested by risk managers, these may include priorities for obtaining missing data. Recommendations of risk management nature should be presented by indicating recommended risk management options for the expected level of risk.)

k. References (separately from those listed in section f).

It is noted that where committee are dealing with information provided to it in confidence, access to the full report may be restricted. In such cases, sections a), c), d), and e) may be presented separately.

2.5 Introduce a procedure for regular scientific review of the strategies, methods, and other aspects of the general risk assessment process. Consideration should be given to extending the risk assessment elements of the 5 th Framework Programme and of future Commission Research Programmes to develop and evaluate new methodologies.

It is proposed that an inter-committee Task Force is established which should report regularly to the SSC to promote these aims.

2.6 Establish an agreed transparent framework for interactions between members of Scientific Committees and risk managers. A principal requirement is to establish an effective dialogue to ensure that questions put to the committees by the Commission are clear, unambiguous and relevant to the needs of risk management, that all relevant data sources are defined and provided efficiently, and that time scales and other constraints in providing the risk assessment are identified and agreed. Ground rules for discussions with risk managers need to be defined, while taking account of the necessary independence of Scientific Committee members.

2.7 Establish effective induction programme(s) for new members of Scientific Committees and regular workshops at which key issues can be discussed. Facilitate a high level training programme(s) to meet the increasing requirement for expertise in risk assessment. This would require the support of Commission' services.

2.8 Develop guidelines for carrying out quantitative risk assessments and for assessing their validity.

Areas where progressive implementation is achievable

2.9 Develop a resource within the Commission for the ready provision of data required for risk assessment purposes. It is also recommended that the Commission services play a key role in the development of databases which will enable better predictions to be made of potential adverse effects and to aid consistency in developing risk assessments. It is recognised that issues of confidentiality of data will need to be overcome to achieve this. The access to all relevant data will also aid the reduction of animal use for risk assessment purposes.

2.10 A priority should be to agree a stepwise procedure for assessing exposures. This procedure should provide the tool for integrated exposure assessment including all relevant exposure sources and pathways and keep the specific needs of the different Scientific Committees as separate elements. Develop common exposure model scenarios and ensure procedures for their validation. Consideration should be given to drawing on data from existing banks of appropriate samples of aquatic, terrestrial, atmospheric, and human origin to enable validation of such models. The models should also be validated where practicable by direct experimentation.

2.11 Assessment of environmental effects is demanded for an increasing range of risk sources. Common guidelines for the assessment of these environmental impacts need to be developed. This should include as far as appropriate an integrated risk assessment strategy (i.e. examination of human and environmental risk assessments together).

2.12 Introduce requirements for monitoring and surveillance for an increasing range of risk sources for which:

- there is significant uncertainty in the risk assessment, in particular where there is an absence of data in humans and / or environmental species of concern, **and/or**

- a wide exposure of the public and / or of the environment is anticipated, **and/or**

- there is considerable uncertainty regarding actual levels of exposure, **and/or**

- the risk source is novel, i.e. there is no previous experience of risk sources of this nature.

It is recommended that DG SANCO should co-ordinate this activity. This is important not only from a scientific point of view but also to provide public reassurance.

2.13 A review should be conducted by the Scientific Steering Committee within an agreed time scale to ensure that implementation of the above (2.1 to 2.12) has been effective.

Areas for further development

2.14 There are several areas where further work is needed, for example:

a) the introduction of a "thresholds of toxicological concern" approach as a means of reducing unnecessary testing and determining priorities for risk assessment;

b) means by which issues such as animal welfare, quality of life and sustainability can be taken into account in the risk assessment process;

c) involvement of stakeholders on the issue of suitable means to setting the risk assessment findings in the context of other risks and/or of benefits. These discussions should also consider criteria for "acceptable" risk and whether "action" levels for various risk sources should be identified as part of the overall risk analysis process.

3. IMPLEMENTATION

The SSC understands that the details of the Report are not yet fully finalised. Once it is completed, the Committee recommends that its findings are published and disseminated widely, both in print and electronic forms.

The SSC stresses the need to be made aware promptly of new scientific data in the field of risk assessment and related areas in order to incorporate these into the work of the SSC and other Scientific Committees. It should be realised that conflicting interests may exist for scientists and policy makers to share scientific data, as they emerge, with the Scientific Committees, and a mechanism should be implemented to secure the flow of scientific information wherever appropriate. The SSC recommends that the Task Force (see recommendation 2.5) should include this within its remit, along with the investigation of opportunities for harmonisation of risk assessment procedures both across the EC Scientific Committees and with scientific committees of other national and international bodies. Funding should be made available to facilitate this. Discussions should be initiated with Member States to identify areas where specific progress can be made.

- First report on the harmonisation of risk assessment procedures - Part 1 : The Report of the Scientific Steering Committee's Working Group on Harmonisation of Risk Assessment Procedures in the Scientific Committees advising the European Commission in the area of human and environmental health - 26-27 October 2000 (published on the internet 20.12.2000) (642 KB)
- First report on the harmonisation of risk assessment procedures - Part 2 : Appendices - 26-27 October 2000 (published on the internet on 20.12.2000) (1121 KB)