EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Updated Opinion of the Scientific Steering Committee on Harmonisation of Risk Assessment Procedures

Adopted on 10-11 April 2003

Note: A full Second Report on the Harmonisation of Risk Assessment Procedures is currently under editing and will be published shortly.

1. BACKGROUND

Scientific risk assessment procedures include consideration of the possible effects of chemical, physical and biological agents and processes on human, animal and plant health and on the environment. These procedures are conducted within the EU and by many national and international bodies (e.g. WHO, FAO, OIE, OECD).

The Scientific Steering Committee (SSC) welcomes the second Report on the Harmonisation of Risk Assessment Procedures among the Scientific Committees advising the European Commission in the area of human, animal and plant health and on the environment. The SSC acknowledges the very substantial work that has been done by its Task Force to produce the Report.

The SSC recognises the potential benefits of the progressive harmonisation of human, animal and plant health 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 and animal health and the environment.

A particular concern is to ensure a harmonised approach to risk assessment between scientific advisory committees of the Commission and those of the increasing number of the EU Agencies eg EFSA and the proposed chemicals Agency. Harmonisation with Scientific Advisory Committees of other international and national bodies is also viewed as highly desirable.

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 however it regards progress towards harmonisation as highly desirable.

The SSC acknowledges that, for various technical reasons, the Task Force was not able to address all the current issues of risk assessment where harmonisation may be desirable. Other issues should be considered elsewhere.

The SSC accepts the principal recommendations of the First and Second Reports on Harmonisation of Risk Assessment Procedures. It notes that these are not set out in order of priority. The recomendations are:

Measures that can be implemented immediately

a) Develop the cooperation between the scientific committees and Commission services and EU Agencies, particularly EFSA and DG RESEARCH. Other bodies involved with risk assessment are listed in the appendix to the Second Report. Harmonisation between these bodies is highly desirable. As a first step, put in place a coordination procedure for situations where the same stressors is dealt with by more than one committee/panel.

b) Adopt an agreed glossary of terms involved (identified in the First Report).

c) Request that each of the scientific advisory bodies test the risk characterisation framework in pilot studies and report back with any suggestions for improvements etc.

d) Adopt the common format for the presentation of opinions (as set out in chapter 9 of the Second Report)

e) Introduce a familiarisation programme for new committee members (see first report). Hold annual seminars/workshops for committee members and risk managers to discuss strategies, methodology and other aspects of the risk assessment process (see first report)

Further Work But Probable Implementation Within In The Short Term

f) Establish a procedure to ensure dialogue between risk assessors, risk managers and other appropriate stakeholders.

g) The Scientific Assessment process:
- Introduce probabilistic risk assessments initially as a pilot scheme,
- Establish a strategy for the adoption of integrated risk assessment (see chapter 6 of the Second Report)
- Develop a common EU data base of risk assessments of chemical, biological and physical stressors. This data base should include risk assessment conducted on human and animal health and the environment across Commission services and EU Agencies as well as those carried out for national and other international bodies.

h) Formalisation of approaches for dealing with key variables:
- Adopt a strategy for the identification of sensitive groups of the human, and animal and plant population and allowance to the ecosystems (see chapter 6 of the second report)
- Introduce a step wise process in the assessment of exposures which includes consideration of multiple stressors (chemical, biological and physical). This

requires in terms of enviromental contaminants particularly the establishment of a set of generic European scenarios for instance in terms of environmental contaminants (industrial and municipal discharges, waste disposal, soil.)

i) Development and communication of opinions:
- Selection of a short list of descriptive terms for the expression of levels and likelihood of risk. Request translation services to identify the most robust of these other translated (see First Report).
- Agree a format for the presentation of uncertainties in each risk assessment (see chapter 9 of the Second Report).
- Establish a framework for risk comparisons/bench marking (see chapter 9 of the Second Report).

j) Additional criteria that should be considered:
- Set up a coordination group to explore and prepare the introduction of quality of life parameters into the risk assessment process.
- Decide whether or not to adopt thresholds of toxicological and ecotoxicological concerns in a step wise scheme of risk assessment.

k) Review:
- Develop a strategy for situations in which monitoring/surveillance should be implemented (see first Report)
- The parameters for good evaluation should be agreed and implemented (see chapter 9 of the Second Report)
- A transparent process for the periodic review of the risk assessment of stressors should be established.

Measures For The Long Term

l) Introduction of quality of life parameters into the risk assessment process (see chapter 8 in the Second Report)

m) Introduction of sustainability criteria into the risk assessment process (see chapter 7 in the Second Report)

n) A systematic approach to involve the appropriate stakeholders in the risk profiling stage (see chapter 8 and 10 in the Second Report)

o) Develop a methodology for a harmonised risk benefit analysis.

p) Revision of the conceptual models for non-human and ecosystem risk assessment (see chapter 6 the Second Report)

Multidisciplinary Research Priorities to facilitate harmonisation

A number of research priorities in specific areas are identified in the individual chapters and appendices of the Second Report:

Implementation

In view of the importance of harmonisation the SSC strongly recommends that the European Commission's Health and Consumer Protection Directorate General takes the initiative and coordinates the actions set out in these recommendations. It recognises that this will require active discussions with a number of other DG's and independent Agencies (such as EFSA) in the EU and other international and national bodies.