EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

OPINION

of the Scientific Steering Committee on

Setting the Scientific Frame

for the Inclusion of New Quality of Life Concerns in the Risk Assessment process

Adopted on 10-11 April 2003

as part of its exercise on Harmonisation of Risk Assessment Procedures

Note: A full report is currently under editing and will be published shortly.

OPINION ON
Setting the Scientific Frame
for the Inclusion of New Quality of Life Concerns in the Risk Assessment process

TERMS OF REFERENCE

Background

The Scientific Steering committee adopted the first report on the harmonisation of risk assessment procedures on the 26-27 October 2000. The main recommendation vii in Chapter 10 of this document was to "develop formal means by which issues such as animal welfare, quality of life, socio-economic considerations, and sustainability can be incorporated into the risk assessment process (see Chapter 10)".

Within the Task Force on Harmonisation of Risk assessment Procedures a working group including outside expertise on quality of life issues, such as the impact of risk perception and communication, was established. The report of the working group was made publicly available for comments. The comments received were considered prior to adoption of the report by the Scientific Steering Committee.

Framework

The quality of life concept is multidimensional and covers such aspects as human functional and psychological health. It can also include concerns about animal welfare, environmental impacts, aesthetics, ethics and community identity. In addition to the biological risk assessment, risk perception, communication, benefit estimates, and value identification play an important role in the process of dealing with quality of life aspects.

Within public health policy, quantitative indicators such as physical health and life expectancy play a dominant role in risk assessment. In many cases public crises arose probably because of not considering enough the human quality of life in a broader sense at an early stage in risk assessment and risk management. Two factors trigger the interest of such an enlargement. Most of the innovations

have an endogenous character where humans are causing the benefit and the risk and that ambivalence depending on interest and transparency can lower the confidence in assessment and management. Actions are either performed by individuals or by decision makers for whole populations.

CONCLUSIONS

Consequently there seems to be a need to enlarge the standard biological risk assessment by introducing several new components in the analysis, in particular psychological and social traits. The ultimate goal is to trigger amongst the decision makers a reflection on a change in paradigm, namely to maximise the health or the quality of life instead of merely minimising the risks. One criterion to be considered particularly in the process is the perception that an individual has of the situation. It means that the communication of the scientific analysis changes the way the subject can perceive the risk and then change his or her quality of life. The analysis of the communication and interactions between the relevant groups of the society is thus an important part of the whole strategy.

Such an enlargement of the analysis in principle includes addressing societal and ethical issues. The ones sustaining the questions asked to the risk assessors are of particular importance. Others are found when defining the recommendations. Many parameters can be used for assessing the quality of life. The weights to give to each of them for reaching recommendations are mainly taken on ethical, cultural and political grounds and are under the manager's responsibility. They can be presented as absolute values for example by stating that a parameter should not be above or below a threshold value. Those weights can also be relative between different parameters. One major difficulty is that the weights given to those parameters can differ between individuals and between groups of the population depending on their cultural attitudes and preferences. A framework needs to be developed to allow risks and non-economic, societal benefits to be compared in an understandable and transparent manner. Progress in this area is essential. One key point when reviewing a risk assessment document is to distinguish between the different kinds of data sets, facts and figures, models and theoretical assumptions, values and believes. Further research is needed to characterise the different types of information and arguments in terms of importance and strength of evidence.

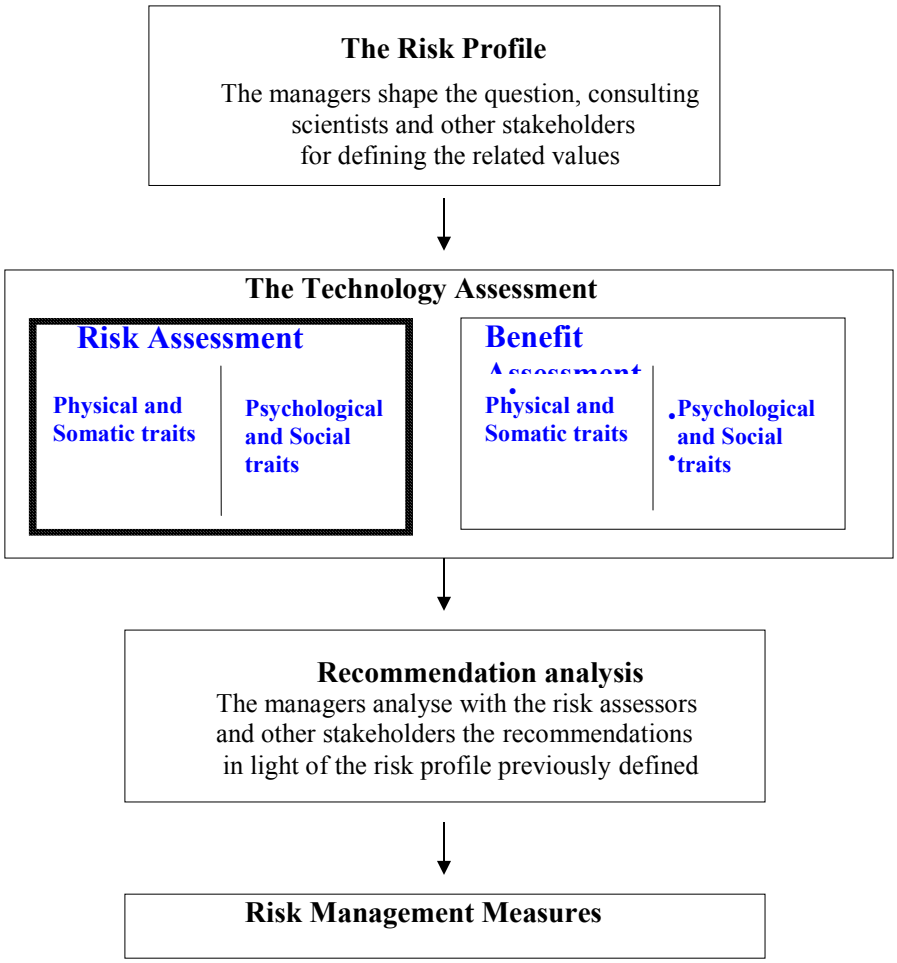
Considering quality of life aspects requires special emphasis on communication of risks and also consumer benefits, transparency, clarity and reasonableness. Bad or poor communication can easily lead to largely irreversible non-facts perception and public crisis. Professional risk communication tools are essential in all cases and must in particular facilitate the individual decisions. Despite recognising this need, they are still not well developed and implemented. They also show that the generally accepted strict and absolute separation between scientific assessment and management does not fully work in reality due to societal prerequisites for scientific assessments as well as uncertainties and biases in the expert judgement processes.

Although these managerial issues are outside the mandate of scientific committees, they influence the work of the assessors when the managers frame the questions. They have also an influence on the way managers use the recommendations proposed by the assessors. One objective of the proposed actions is to elaborate on these links and to develop transparent tools for a systematic strategy. Furthermore it is well understood, that more and different arguments than those expressed here have to be included when developing such a strategy. Nevertheless it is considered legitimate to express the thoughts of the scientists involved in preparing this opinion.

Therefore, it is – as one element in the process - proposed to complement the standard risk assessment by including new quality of life parameters from the beginning and particularly psychological and social traits. It needs to be considered whether the assessment of those traits should constitute an additional dimension to the assessment as it is performed today or if it should be conducted in a separate, regular and interactive process.

The following simplified scheme, which does not include interactions and feedback, is to summarise the broader issues to be addressed and show the position of scientific assessment within the process (Figure 1).

Figure 1 :Possible framing of the quality of life traits in the Risk Analysis Process



RECOMMENDATIONS

Scientific Risk Assessment

The scientific part of quality of life parameters, and in particular psychological and social traits, should be considered as elements of the scientific risk assessment.

The links between that assessment and other criteria (e.g. ethical and political) need to be transparently addressed.

The quality of life assessment should cover the physical impact of the risk factors as well as the perceived impact wherever it is possible. It could also include the foreseen perceived impacts of managerial decisions.

It will need to be decided where the psychological and social trait analysis fits on the overall risk analysis: in parallel, prior or possibly after the classical risk assessment. In any case the scientific panels should meet to interact and prepare a comparative report at the end of the assessment process. Experts from disciplines not involved today, and in particular those from human and social sciences, should be involved in the risk assessment process. It is recommended to invite a group of experts from those disciplines to analyse further the questions elaborated in the report and to prepare a targeted guidance providing the details for the introduction of the identified quality of life criteria and tools in the risk assessments of the scientific committees.

Framework for the Risk Assessment

It is proposed to consider a consistent and transparent approach, which could include three steps (see Figure 1 also):

1- Risk assessors, risk managers and other stakeholders would jointly elaborate the risk profile, identify the criteria to be used, the specific issues to be addressed and the major concerns stated. This will give the opportunity to the risk managers to define the different criteria that will be used for taking their decisions (societal, economical, ethical, political…). In light of those criteria, the risk assessors will be able to decide the objective tools and models that will be the more appropriate to help the decisions to be taken afterwards.

2- The assessments of risks should be performed to answer on the ground of the set of criteria elaborated in the first step. It should be clear that some other aspects could also be assessed, and in particular the social and economic benefits, but they are probably not to be included at least in the short term in the framework of the risk assessment.

3- The strength, limits and uncertainties of the assessment could be analysed jointly by the managers, the other stakeholders, and the assessors, in order to discuss with transparency the selection of management tools of societal and economic consequences.

Such a process will be particularly important at the beginning of the evaluation for defining a comprehensive risk profile and at the end to help to better characterise the risk and to propose measures to the community to handle the risk cycle with utmost acceptability to all groups concerned.