Scientific Committee on Health and Environmental Risks

SCHER

Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Scientific Committee on Consumer Safety

SCCS

Making Risk Assessment More Relevant for Risk Management

Scientific Committees adopted this opinion via written procedure in March 2013

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.
They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.
In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

SCCS members

Jürgen Angerer, Ulrike Bernauer, Claire Chambers, Qasim Chaudhry, Gisela Degen, ElsaNielsen, Thomas Platzek, Suresh Chandra Rastogi, Vera Rogiers, Christophe Rousselle, Tore Sanner, Jan van Benthem, Jacqueline van Engelen, Maria Pilar Vinardell, Rosemary Waring, Ian R. White

SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.
It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

SCHER members

Ursula Ackermann-Liebrich, Rolf Altenburger, Herman Autrup, Denis Bard, Stella Canna Michaelidou, Wolfgang Dekant, Pim De Voogt, Arielle Gard, Helmut Greim, Ari Hirvonen, Colin Janssen, Renate Kraetke, Jan Linders, Borut Peterlin, Jose Tarazona, Emanuela Testai, Marco Vighi

SCENIHR

This Committee deals with questions related to emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies. Examples of potential areas of activity include potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards such as noise and electromagnetic fields (from mobile phones, transmitters and electronically controlled home environments), and methodologies for assessing new risks. It may also be invited to address risks related to public health determinants and non-transmissible diseases.

SCENIHR members

Anssi Auvinen, James Bridges, Kenneth Dawson, Wim De Jong, Philippe Hartemann, Arne Hensten, Peter Hoet, Thomas Jung, Mats-Olof Mattsson, Hannu Norppa, Jean-Marie Pagès, Ana Proykova, Eduardo Rodríguez-Farré, Klaus Schulze-Osthoff, Joachim Schüz, Mogens Thomsen, Theo Vermeire

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Executive summary

The ICCG established a joint Working Group including members designated by SCCS, SCHER and SCENIHR for 1) reviewing the current risk assessment (RA) practices, 2) exploring what risk managers and policy makers need from risk assessment, and 3) identifying approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent and easy to interpret and communicate. The motivation for this review has been the perception, that risk assessments as currently carried out do not inform the risk management process as well as they should. The proposed approach focuses on those risk assessments that are not already governed by a formal regulatory framework.

Therefore, the starting point for this review has been an assessment, through a survey, of needs of managers and policymakers recognizing that risk assessment makes little sense unless it is effectively informing the management process. In carrying out this survey, the Scientific Committees have also been sensitive to the continuing need to ensure that while assessment should be informed by the needs of management they should not be biased by them.

The main conclusions and recommendations arising from the Scientific Committees are as follows:

- Two important messages arising from the survey of risk managers and policymakers are that the outputs of risk assessment need to be more policy- and management-relevant and this ought to be facilitated by more dialogue.
- Given that management decisions are often taken against a backdrop of trade-offs between the benefits of interventions for human health and environment and the costs of restrictions for the economy, it follows that to be "management relevant" risk assessments need to inform these cost/benefit analyses.
- A similar problem is encountered in integrated risk assessments where it is often necessary to compare impacts across very different entities, such as humans and ecosystems. Such comparisons can only be achieved by weighting on the basis of people's preferences – and one expression of public preference is economic value – so again, the risk assessment outputs need to be compatible with economic valuation.
- The Scientific Committees concluded that there is considerable confusion on the needs that socio-economic analysis put on risk assessment and that, to be more useful, risk assessments should be expressed in terms of value-relevant impacts on humans and ecosystems rather than in terms of the somewhat technical surrogates often used in the routine risk characterizations.
- To make this change, the Scientific Committees recommend more dialogue between risk assessors and socio-economists. There is often confusion about roles. These should be clarified with proper problem formulations focused on management needs and health, environmental and societal interest. Risk assessors should be expressing likelihood of impact on the basis of evidence; but the impact should be in terms of entities that matter to people. Socio-economists should assess the economic and social consequences of these impacts, of the expected benefits, and of the possible risk management measures. Both assessments should consider the risk manager's needs. The Scientific Committees recommend that risk assessments and socio-economic analyses should be carried out along separate but parallel tracks, with dialogue between them being encouraged and facilitated by appropriate processes especially in the initial problem formulation.

- The Scientific Committees also recommend extending this dialogue to all stakeholders in both initial forums and final consultations as a way of clarifying issues and ensuring more ownership. This will be especially important where the issues are complex and the outcomes are likely to be of major socio-economic importance.
- Expressing risk in terms that matter for the regulators will also facilitate communication; but to enhance that the Scientific Committees make recommendations on a system of dialogue that facilitates the exchange of information between risk assessors and risk managers while ensuring the scientific integrity of the risk assessment. The key will be to ensuring transparency in this dialogue. The Opinion focuses on the dialogue between risk assessors and risk managers and recognizes that this is only a limited aspect of the broader area of risk communication.
- Recommendations were also made for improving risk assessment reports, in particular in terms of: including the evaluation of different possible scenarios; making full characterization of the whole populations/ecosystems at risk with attention to particularly sensitive subpopulations/species; including clear expressions of uncertainty; making explicit disclosure of hypotheses used without supporting evidence.
- One step in facilitating the development of better practice could be to arrange training for both assessors and managers based on a common manual. The text in this Opinion could provide a starting point for that.
- Throughout there are important concerns about uncertainty. It impinges on all aspects of risk assessment *and* economic valuations. It needs to be made transparent. However, the Scientific Committees have not made detailed recommendation since that was not part of the terms of reference and is being addressed by other groups.

The Scientific Committees suggested the following next steps:

1. Invite the SANCO Committees to consider the challenges arising from the recommendations in this Opinion on changing the form of risk characterizations that they carry out currently to ones that more explicitly express risks as impacts on human health and ecosystems. This question might then be posed to other committees such as EFSA and ECHA Committees

2. On the basis of this work, organize a meeting with risk managers to identify how the recommendations of the Opinion can be implemented in a way that optimises the benefit of the changes to risk managers while ensuring that risk assessments remain fundamentally science-based procedures.

3. Following further deliberations of the committees hold a workshop with a variety of stakeholders to discuss the implications of the changes proposed in the risk assessment procedures.

1. Background

In accordance with the common Rules of Procedure of SCCS, SCHER and SCENIHR, the ICCG shall assist the Commission to achieve a high level of harmonisation in the risk assessment procedures and shall provide guidance to the Committees on methodological and procedural aspects.

At its meeting of 25 June 2009, the ICCG has considered a proposal, preliminarily discussed and formulated by the SCHER, for a review of risk assessment in view of better adaptation to risk management needs and more effective communication of risk-related issues. The ICCG concluded that a joint working group of the three Committees should be established in order to proceed to such review and produce an opinion, based on an appropriate definition of the terms of reference and of the working procedure.

Current approaches to the assessment of health and environmental risks frequently result in a variety of technical expressions of risks, based on consideration of endpoints, biological responses or other technical parameters that are sometimes only very indirectly related to the protection objectives pursued by risk managers and policy makers. On the other hand, in posing the questions, risk managers do not always provide an appropriate framework, notably by specifying the protection policy objectives in a manner that would allow the risk assessors to deliver outputs that are readily usable and leave no room for misinterpretations.

As a result, interpretation of expressions used in risk assessment reports may be problematic for risk managers and the public, open to misunderstanding and distortion, and difficult to communicate. Moreover, risk assessment reports rarely address in a direct, systematic and transparent way the risk-risk and, where it is possible to express risk and benefits by an appropriate metrics, risk-benefit balance issues which may arise in the specific cases examined.

Finally, risk assessment methods, procedures and expression of results are rarely co-ordinated with the cost-benefit or, more generally, multi-criteria assessment that risk managers and policy makers also need to inform their decisions. A crucial challenge in this process is the possibility (still to be determined) to establish and standardise approaches and methodologies to measure and quantify risks, benefits and costs so that weighing of these parameters in the risk assessment and risk management processes can be done in a comparable and meaningful manner. As a result of the lack of such approaches, comparisons of non-standardised parameters (e.g. potential health benefit versus socio-economic costs) vary considerably depending on the underlying assumptions used thereby limiting the value of these comparisons in policy making.

Risk assessors often fill the gap between the technical parameters resulting from the process (e.g.: a margin of safety) and the risk managers' questions by "interpreting" themselves the risk assessment through more or less conventional expressions for "grading" the risk. When that happens outside a pre-defined and agreed scheme to frame risk expression, misunderstandings and confusion of roles are possible.

2. Terms of Reference

Regarding the procedure, the ICCG is invited to co-ordinate the establishment of a joint Working Group including members designated by SCCS, SCHER and SCENIHR as well as, as appropriate, advisors from the pool and/or external experts in the relevant disciplines.

The Working Group should be given the tasks of:

1. Reviewing the current risk assessment practices;
2. Exploring the needs of risk managers and policy makers;
3. Identifying approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent and easy to interpret and communicate.

In doing so, the Group should evaluate current approaches to quantify and express risks, benefits, and costs, and if possible make recommendations for the development of standardised approaches which would optimise the value of such assessments.

3. Introduction

Evidence-based risk assessment is at the heart of protecting human health and ecosystems from adverse effects arising from exposure to chemicals and other possible stressors. Yet this can be undermined if risk assessors do not understand what risk managers and policy-makers need for effective decisions and action and if risk managers, policymakers and the public do not understand what risk assessment can deliver. These misunderstandings have undoubtedly played a part in high-profile disputes in the past, for example involving bovine spongiform encephalitis (BSE), genetically modified organisms (GMOs), nanotechnology and classification of drugs.

The aim of this review has been to explore to what extent the risk assessments inform the management process and vice-versa, and also provide a good basis for risk communication to all stakeholders, especially the general public. It should be noted that from the very broad area of risk communication, only the dialogue among risk assessors, socio-economic experts and risk managers/policymakers is covered in this opinion. The distinguishing feature of the approach of this report is that it has been led by the needs of managers and policymakers in recognition that risk assessment makes little sense unless it is effectively informing the management process. At the same time, care needs to be taken that the important separation between risk assessment and risk management is not breached. The report takes the view that the needs of risk management (including socio-economic analysis) should properly inform but not bias what is measured in risk assessment.

Hence, the review has involved wide-ranging consultations with EU level risk managers and policymakers. The opinion, according to the mandates of the SANCO Committees, focuses on risk management at the EU level; the specific needs of national, regional and local risk managers, which may use the opinions in their specific domains, are not specifically addressed as this requires more specific case-by-case considerations. The results are described in Section 4. They serve to inform the rest of the report and its conclusions and recommendations.

An overview of the current practices in risk assessment and socio-economic analysis is presented in Sections 5 and 6 respectively. The interactions between these two activities are explored in Section 7. Management interventions involve restrictions which come with costs as well as benefits. Hence risk assessments also need to inform the balancing of these costs and benefits. Consequently, the work has involved a study on issues and challenges at the important interface between risk assessment and socioeconomic analysis. The focus has been on REACH since there

are urgent pressures for implementation, but more general principles have also been addressed.

A recurrent concern is that the risk assessments required by the legal instruments are focussed too strictly, for example on a stressor by stressor approach and/or on the separate consideration of humans and ecosystems. Yet in the real world stressors act in combination and have differential effects on human health and ecological processes. Judgements have to be made about the comparability of different impacts on various targets. This review has taken the position that the weightings, reflecting these judgements, should express public preferences and values and this means that there are important connections with the cost-benefit approaches.

Sections 8 through 12 summarise the issues and make some recommendations.

4. Dialogue with Risk Managers

A major motivation of this review has been to ensure that risk assessments carried out by Commission scientific committees have been meeting the needs of risk managers. It is self-evident that risk assessments make little sense unless they are informing risk management; yet one of the possible unintended consequences of the separation of assessment and management functions is the possibility of divergences and mismatches.

This was investigated by a series of consultations with Commission risk managers at various levels in three "customer" DGs. The exercise involved one "round-table discussion" with 8 managers at desk-officer level and 10 one-on-one interviews with high-level risk managers (heads of unit, directors, and director-generals). All were structured around questionnaires.

The number of managers participating in these dialogues by definition was limited, so there was no attempt at any quantitative, statistical analysis of responses. The aim of this chapter is to identify and elaborate upon a number of the recurring themes.

A further element of consultation was the public consultation that followed the compilation of the first draft opinion. This consisted of an opportunity for written feedback (during which 21 comments were received) and an open hearing (attended by around 50 people). All this feedback informed the final refinement of the Opinion – and should be considered as a broadening of the initial consultation.

4.1 The separation of risk assessment and risk management

All recognized the importance of the separation of responsibilities and functions between assessors and managers. The science should not be influenced by values and political issues; and management decisions almost always involve more than the science-based conclusions, even in those circumstances where the scientific conclusions can be expressed with some certainty. There was recognition that in a complex world there can be many ways of expressing impacts in terms of endpoints, levels of organization and types of system. Yet management goals may be more precise and set in terms of particular policy and legal contexts. The needs of risk management should therefore inform the way that the risk assessment is carried out. On the other hand, the needs of risk management will not always be compatible with what can be achieved through science.

These differences in perceptions and responsibilities argue for a better dialogue between assessors and managers that should inform the framing of the questions raised by the initial mandate and then iteratively through subsequent refinements. It was suggested that this could lead to more clarity and a more cost-effective process.

The challenge, then, is to develop a dialogue in which assessment is informed but not influenced by management, at least in terms of how the assessments are carried out and what conclusions are drawn from them.

There was also a recommendation to explore ways of facilitating the better understanding of the risk assessment process by risk managers especially at "desk officer" level. A manual was suggested. This should be the subject of a separate exercise.

4.2 Making opinions policy relevant

It follows from the previous section that risk assessment should relate to the protection goals that are of importance for management. One aspect of this is making risk assessment relevant for socio-economic assessments. None thought that risk assessments should involve cost-benefit assessments *per se* since that would clearly breach the assessment/management divide. However, to be relevant in this respect requires that risks are expressed in terms of impacts on entities that matter to people; from a human-health perspective, this means using criteria such as changes in morbidity and mortality and from an ecological point of view, criteria such as changes in ecosystem services.

4.3 Expressing uncertainty

There was understandable ambiguity in the views about how uncertainty is represented in risk assessments. That there are uncertainties in scientific assessments was acknowledged; and yet there was also a need for decisiveness in conclusions so that they could be translated into effective management decisions. It was recognized that being either excessively confident about uncertain outcomes or excessively uncertain in circumstances where evidence was clear could undermine confidence in the scientific process. Also, vague statements about uncertainties in risk assessment, such as always emphasizing a need for more research in conclusions, were less than helpful for managers.

Participants in the survey were clear that whereas uncertainty was the business of risk assessment, what to do about it and if and whether or how to apply the precautionary principle was a matter for risk management.

Uncertainties, therefore, need to be expressed with clarity and consistency across opinions. Ideally, uncertainties should be represented in terms of (a) the effects on the range of outcomes and (b) the likelihood of these outcomes manifesting themselves with (c) some expression of how much confidence can be put into the conclusions about outcomes with respect to the scientific judgments involved.

Another possible consequence of uncertainty is disagreements within and across committees. There are mechanisms in place to handle disagreements in the *Rules of Procedure* (http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf). One message from the survey, though, was that if consensus was likely to lead to lack of clarity in conclusions then minority opinions would be a preferred route.

This Opinion is not concerned with uncertainty *per se*; other exercises are being carried out on the expression of uncertainty in risk assessment (ECHA 2008b, EFSA 2006, IPCS 2008, SCENIHR 2012).

Nevertheless, the expression of uncertainty is such an important part of both risk assessment and valuation in socio-economic analysis that it is treated in several sections of this document.

4.4 Taking account of all the options

It was well recognized that removing one set of risks can bring others through substitution. There was a view that risk assessments ought to be more comprehensive in this respect. Risk managers should have an understanding of what

the alternatives and substitutes might be and should be more proactive in ensuring these are considered in a more holistic manner. Risk assessors themselves may have understanding about the availability and feasibility of alternative substances and technologies. However, they should not take a unilateral view on which options should be considered in risk assessments since this again would breach the separation of responsibilities between assessors and managers. Thorough consideration of all options and which should be subject to risk assessment ought to be part of the structured dialogues described above with the aim of ensuring the development of a clearly defined and comprehensive cover of options in the mandates.

4.5 Taking account of all the outcomes

Another aspect of being more holistic is encouraging the use of approaches that integrate assessments of effects and their risks across sources and targets. Risk assessments can be too focused. There have been cases where a substance from different sources is assessed as presenting different risks to the same target; for example due to different exposure scenarios. For stakeholders who may not fully understand the differences between hazard and risk this can appear to be inconsistent and care is needed in identifying these situations and explaining them. These considerations and the even broader ones associated with use of risk assessments to further sustainable development policy need addressing with care in the context of management needs. Again they should be considered in the process of structured dialogues already described above.

4.6 Risk communication and cost-benefit frameworks

All recognized the profound challenges in communicating the results of evidence-based risk assessments to stakeholders who are often understandably unclear on the principles and practices of science. Risk assessment conclusions that are very technical and couched in uncertainties may fail to inform policy in a management arena that is complicated by political and public pressures from many sources including Parliament, Council, Member States and Pressure Groups. This is particularly the case in high profile and/or contentious policy areas. In this context both risk assessment and risk management might be failing to ensure the implementation of best advice in policies and regulations that are of key importance for the public.

A clear Cost Benefit Analysis is often a very useful and transparent platform, to communicate the consequences of policy alternatives associated with any Risk Assessment. The analysis should in particular give information about the objective of the policy, the options available to address the problem, the nature of the trade-offs between options and the risks and uncertainties inherent in each of the options. A good analysis should also identify the winners and losers from each of the options.
This emphasizes the need for clarity in framing the questions for assessment and in delivering opinions through all the processes already described above. Making assessments policy- and value-relevant so that the benefits of any management interventions can be clearly set against costs would be one way to focus minds in the political arena.

4.7 Conclusions

There is a pervasive view that effective risk management has to be based on sound science. But the guidance from risk assessment is often not as clear as it might be because it lacks policy relevance and uncertainties may be inappropriately expressed, if at all. There also seemed to be problems with public confidence in the scientific basis of policy.

Key to addressing problems with risk assessment will be effective dialogue between managers and assessors and *vice-versa*. In this context, no one is arguing for a blurring of functions; rather the aim will be to develop a system of more structured

and open dialogues whereby questions can be refined not only at the inception of a mandate but through the progress of the risk assessment. All relevant management options should be made explicit and subject to comprehensive assessment. There is also likely to be increasing demand for assessments that are integrated across sources and targets and that explore spatial, lifecycle and temporal variability in effects.

Key to addressing issues of public policy will be transparency in all aspects of the scientific committees' work.

In many respects, communicating risks is seen as the biggest challenge. Technically expressed assessments with an emphasis on uncertainties may well drown under "political" and other pressures. This is a powerful argument for expressing risk in terms of entities that matter to the public, and providing the possibility of drawing attention to the benefits and costs of management interventions.

5. Current Practices of Risk Assessment and Uncertainty

Public decisions must often be made in situations of uncertainty; situations whose development depends on unknown factors. One representation of this uncertainty is risk, i.e. a situation where it is possible to distinguish a set of potential outcomes, ascribe degrees of likelihood to them, and estimate the scale of the consequences. In the field of environment and health, this means that a hazard has been identified and that the effects of its occurrence on society can be assessed.

The measurement of risk therefore combines the probabilities of the occurrence of harm (hazard assessment) and its scale (exposure assessment).

Risk assessment (RA) is the process by which scientific evaluations are made on the potential for adverse effects in humans or ecosystems. It has been developed as a tool to organize knowledge about (eco)toxicity and exposure and to estimate risk levels for the people or environmental compartments exposed.

There are two situations in which RA is required. Assessing a theoretical risk to anticipate a situation of exposure before taking appropriate measures (such as authorization of the marketing of a chemical for a set of uses) and estimating the actual risk in a real exposure situation (such as the evaluation of the risk of workers, consumers or the environment under the current and/or real use conditions).

In the first case, a worst-case approach based on conservative hypotheses may be justified in terms of health protection and uncertainties are partly accounted for by applying conservatively chosen assessment factors, scenarios and input parameters. In such a deterministic assessment, the main concern usually is to avoid acceptance of substances/uses resulting in a potential risk, i.e. *avoid false negatives*.

In the second situation, the risk assessment should be as realistic as possible to identify the exposed groups/compartments and predict the health/ecosystem effects which may occur in the exposed populations and to take appropriate measures. The full distribution of the risk, i.e., the balance between false positives and false negatives should be known. This would require an analysis of all uncertainties and their impact on the outcome of the risk assessment.

When performing a RA, a tiered approach is usually advocated, which addresses both exposure and hazard. Tiers range from a worst case or conservative assessment, through one or more refined deterministic assessments to fully probabilistic assessments (EFSA, 2006; Verdonck et al., 2007; IPCS, 2008; ECHA, 2008). At all stages of a tiered approach, additional information received, e.g. monitoring data, dose-response data, information on uses, can improve the assessment and reduce, or sometimes increase, the uncertainty. The extent of assessment and nature of recommendations for generation of additional data are dependent upon the extent of the knowledge base, the magnitude of the public-health or environmental concern and the objective of the risk assessment.

Each source of uncertainty can be analysed separately for its influence on the outcome of the risk assessment. This can be done qualitatively, deterministically or probabilistically. In the risk characterisation, the combined effect of all identified uncertainties should be evaluated carefully. Any remaining uncertainty which cannot be quantified should also be taken in to account qualitatively.

5.1 Human health risk assessment

Human risk assessment is usually performed following the US-National Research Council (NRC) methodology conventionally divided into 4 steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation (NRC, 1983):

- Hazard Assessment: the determination of whether a particular agent or activity is or is not causally linked to particular health and or environmental effects; could be based on experimental or epidemiological data or both. If sufficient data are available, the mode(s) of action leading to toxic effects may be studied in this step. In particular the hypothesis of a threshold or non-threshold mode of action should be addressed.
- Dose-response assessment: the determination of the relationship between the magnitude of exposure and the probability of occurrence of the health and/or environmental effects in question.
- Exposure assessment: the determination of the extent of population exposure to the hazard, before and after application of regulatory controls.
- Risk Characterisation: the description of the nature and often the magnitude (probability) of risk, including any uncertainty.

These concepts are addressed in more details in Annex 1, and further recommendations on new developments in human risk assessment in response to changes in the science and pressures on the use of animals in toxicology are made in SCCS/SCHER/SCENIHR (2013). This methodology has recently been revised by the US-EPA and a new framework for Risk-Based Decision Making is proposed ("Science and Decisions", 2009).This framework was designed to improve risk assessment by enhancing the value of RA to policy-makers, and expanding stakeholder participation. In particular, it advocates that greater attention should be given to the design of the formative stages of RA, specifically on planning and scoping and problem formulation. At the first stages of the process, risk managers, risk assessors and various stakeholders should be brought together to discuss the major factors to be considered, the decision-making context and the timeline and depth needed to ensure that the right questions will be addressed and the outcomes will fit the needs.

The same document provides a working framework for dealing with uncertainties, see below section 5.3.

Threshold versus non-threshold approach

Two approaches are currently considered when assessing health risk for humans assuming a toxic compound mode of action: the threshold and non-threshold approaches. On the basis of experimental observations and theoretical considerations, it is assumed that there is a dose threshold for any kind of toxic agent, below which there is no effect, including for non-genotoxic carcinogens. On the same basis, it is assumed that there is no threshold for genotoxic carcinogens. But exceptions have been recorded: that is, toxicological and/or epidemiological observations have shown that some agents may behave without threshold; conversely, some genotoxic carcinogens may be shown to present a threshold.

The choice made as regards threshold or non-threshold mechanism for a stressor has far–reaching implications for risk managers. In the case of a threshold dose-response relationship, it is possible to estimate a potential zero-risk ('safe') exposure or dose level (due to statistical considerations, the threshold dose cannot be known exactly,

but only approached, with a limited uncertainty when studies are properly conducted). However when the level of exposure is above the threshold then an effect cannot be ruled out and depending on the data available it may be possible to estimate the probability of its occurrence.

When a non-threshold dose–response relationship is applicable, any dose is considered as conveying a risk. The risk may then be expressed as a probability of effects occurring in the exposed individuals. This probability increases with the level of exposure. The likelihood for effects on an individual can only be transformed into a population risk when the distribution of the exposure levels within the population is known. It is then up to the risk manager to define an 'acceptable' or 'tolerable' level of risk with its corresponding dose level. An example of acceptable risk chosen in developed countries is that of dying from cancer from an exposure to a chemical, set at one in a million annual risk or one in hundred thousand lifetime risk, *added* to the baseline cancer mortality rate (about 30% in such countries).

Exposure Assessment

Exposure assessment has become distinct discipline in the study of health risk. For any substance the potential different exposure contexts, the routes and the temporal course of exposures as well as the degradation or storage in the human body has to be taken into account. Aggregated exposure from all sources to a chemical may need to be considered. Aggregated exposure assessment will, for example, be required under EU pesticide regulation.

In occupational settings an exposure assessment may be relatively simple as direct measurements and various models to estimate the exposure exist (see e.g. REACH guidance documents). This is much more complex for the general public, in which exposure may occur via multiple pathways, routes, and media (aggregate exposure) and can be highly variable depending on life stages, individual behaviour and preferences.

Exposure assessment generally uses relevant available data, such as emissions data, measurement of the component in environmental media, and biomarker information. Fate and transport of the component in the environment, routes of exposure and pharmacokinetics of components once in the body may all be considered in the exposure assessment.

In case measured data (which are the preferred exposure data) are not available or if such data are too limited, it is necessary to rely on assumptions and to use modelling to provide relevant exposure estimates.

For a "worst case" estimate it may be necessary to assume maximum exposure based on the assessment of daily exposure from all sources. It is essential to define if the "worst case" conditions represent the real expected exposure for a limited number of people receiving the highest exposure; or represent a maximum theoretical level of exposure, e.g. based on unexpected combinations of worst case conditions, which is not expected in reality even for the highest exposed group.

Even more complicated is an estimate of "internal dose" for which it is strictly necessary to know the toxicokinetic processes to design appropriate biomonitoring studies or to build up PBPK models. This is because environmental concentrations typically are highly variable over time and the tissue concentrations they produce may therefore also vary over time.

The nature of the output from a risk assessment depends on its aim. In a regulatory context, the output is often to estimate a 'safe' dose or exposure, eventually endorsed by risk managers, either as proposed by risk assessors, or made more or less stringent. In a non-regulatory setting, the risk assessment output may be an estimate of mortality or morbidity for a given time frame (e.g. lifetime) undergone by a specified population (e.g., people living in the vicinity of an industrial plant, those exposed after an industrial accident, or the health consequences of an

exposure at the regional or national levels). Those estimates may appear either as an excess risk for an individual or may be expressed as an absolute risk, that is a number of incident cases (the product of risk for a unit dose times exposure times (sub)population size).

Attributable risk

In order to determine the social and economic impact of a potential risk, and once causality has been established with enough certainty, the risk attributable to an exposure to the substance under consideration has to be quantified. This requires a specific calculation of the size of the risk, and the probability and the distribution of exposure. Thus, a small risk can become very important, if a substantial proportion of the population is exposed. Knowing the attributable risk allows the calculation of the number of cases (or deaths) avoided when exposure decreases or stops.

5.2 Ecological risk assessment

The environmental assessment is intended to cover the likely impacts arising from chemicals and other agents on natural populations, communities and ecosystems. There are two major challenges. First, it is not altogether clear what is meant by impact on these ecological systems and second (and related), it is not always clear how to measure impact. As a matter of practicality the risk characterizations rely on standard ecotoxicological tests on a few species thought to relate to those in nature. Extrapolation from the endpoints measured in these tests to impacts on ecosystems is achieved by using standard, and probably conservative, application factors. Thus concentrations representing thresholds between adverse effects and no effects (usually worst case from the most sensitive tests) are identified from the tests and extrapolated to likely effect/no effect concentrations in nature by dividing them by the application factors to give the predicted no-effect concentration (PNEC). The risk characterization involves comparing likely environmental concentrations of chemicals (derived from models and sometimes measurements = PEC) with the PNECs. The risk characterization therefore involves considering the ratios of PECs to PNECs (RCRs) – such that if they are above one, risks are deemed to be unacceptable.

RCRs do not express risk in terms of the numbers of individuals in a species, or species in a community or amount of ecosystem services that are likely to be impacted by the concentration of the chemical. RCRs therefore cannot be valued for the purposes of a socioeconomic assessment. What often happens is that risk assessors make some judgement on how serious the ecological impacts might be from a particular RCR and make recommendations to risk managers accordingly. But these kinds of judgements are likely to be based on the values of the assessors rather than the citizens affected by the regulation. There is an urgent need, therefore, to review and revise these approaches to environmental risk assessment to make them more compatible with socioeconomic assessment. A number of initiatives are underway to address these challenges (e.g ECETOC Report No.113; SCCS/SCHER/SCENHIR, 2013). What is clearly needed are smart ways of extrapolating from the information obtained in environmental risk characterizations to value-relevant outputs.

5.3 Variability and uncertainty

The output of a risk assessment is seldom if ever a single figure for risk, e.g. to be overly simple, the product of a probability and a detriment. Usually, a risk assessment provides a range of values, which incorporates both variability and uncertainty. Variability represents the general situation in the real world; that is, for human beings, the distribution of a characteristic in a population, e.g. body weight (small variability, less than threefold for a given height) or exposure. In this latter case, variability can be large, with very significant impacts on health impact estimates: it is usually expressed as exposure quantiles such as centiles (median or

50th percentile, 95th percentile and so forth). For ecological systems, there can be variability in sensitivity both within- and between- species. There can also be variability in exposure concentrations through space and time. Variability can be characterized more or less accurately but not reduced.

Uncertainty is the expression of inadequate knowledge, *e.g*. in concluding that there is a causal relation between an exposure and a outcome for health or ecosystems (hazard assessment) – or in estimating exposure concentrations. The output of a risk assessment is therefore systematically associated with cumulated uncertainty resulting from the uncertainties from all risk assessment steps. It is often represented by making somewhat conservative estimates, but these, when conflated across all sources, can yield exaggerated risk estimates. In a few cases of comprehensive risk assessments, uncertainty propagation is assessed by using statistical modelling tools (e.g. Monte-Carlo simulations). A similar approach is described in section 6.4 for socio-economic purposes. Available tools offer the possibility of distinguishing the respective influence of variability and uncertainty on final risk estimates. Moreover, associated sensitivity analyses can sometimes pinpoint the most important uncertainty components, and suggest priorities for collecting useful information. Thus, uncertainty can be reduced to a certain extent.

6. Socio-Economic Analysis (SEA) and Uncertainty

6.1 Introduction

As noted in Section 4.6 the management of risk is often complicated by trade-offs and different views about how they should be handled. SEA provides a basis for resolving these issues in terms of the values, preferences and priorities of the public affected by management decisions and interventions.

There is sometimes concern that SEA puts too much emphasis on assigning monetary values to aspects of health and the environment, that are difficult—if not impossible—to quantify. There is also concern that decisions about health and environmental protection interventions might be made strictly on the basis of whether their quantifiable benefits outweigh their monetized, quantifiable costs. These concerns miss the point that monetary values are transparent and quantified expressions of public preferences and should, therefore, facilitate the decision-making process by making it more transparent, rational and less biased in favour of any particular interest group.

The following sections of this chapter consider the tools and principles of Socioeconomic Analysis in more detail with the aim of providing an overview

6.2 Principles of socio-economic analysis

The framework of SEA allows for the explicit estimation and comparison of the beneficial and adverse effects of an action, together with their probabilities.

The most commonly used forms of socioeconomic analysis used to evaluate risk reduction policies are Costs Benefit Analysis, Cost Effectiveness Analysis and Multi-Criteria Analysis (MCA) – see Annex 2 on socioeconomic analysis.

Socioeconomic evaluation as practised under many regulatory regimes such as REACH requires that the likelihood of adverse health and environmental effects are linked with data that evaluate the potential economic impacts of regulating a hazardous substance. The traditional approach to estimating these economic impacts is the *Damage Function* approach, which translates changes in emissions of a substance into associated changes in exposures. Exposure response functions are used to relate changes in exposure into changes in health and/or environmental endpoints, which are then valued in monetary terms. This is done by relating such changes in endpoints to the concept of human welfare. These endpoints must be what we shall call 'value relevant'. In other words, they must be features and qualities of the natural environment and human health that matter directly to people.

Economists have developed a variety of approaches and methods to estimate the monetary value of such endpoints. Annex 2 contains more details on the Damage Function approach and the principles underpinning the application of economic analysis to impacts evaluation, including monetary valuation of human health and environmental endpoints.

It is important to note here, though, that it is not economists who 'give' values to environmental and human health endpoints (in the sense that these values belong to economists). Rather they are values that the public hold, and which economists are only able to observe and estimate. It is useful to consider that in undertaking economic valuation, economists are concerned with values rather than prices. Such economic values are human constructs, which represent all of the diverse values that individuals have for the range of good they both use, but also which they do not use but wish to preserve. Furthermore, such economic values do not claim to represent the *total* value of goods, but rather the valuation of *changes* in provision, as given by marginal values. The spatial and temporal location of such goods may be of great importance to the economic value of many environmental and health changes. This may be most pronounced for example where there are interactions, tipping points and irreversibility between and within natural systems.

6.3 Linking risk assessment to socio-economic analysis

Socioeconomic analysis is generally thought of as being undertaken after the four stages of risk assessment have been undertaken. The final stage of the risk assessment process characterises risk so as to produce an estimate of the level of risk associated with the particular scenario being considered. It is this estimate of risk which is then available for the socioeconomic analysis to try to estimate the benefits associated with the change under consideration. The benefits analysis is typically based on quantification of changes in probabilities of different outcomes and valuation of those outcomes. This involves identifying economically meaningful health or environmental endpoints associated with the contaminant; estimating the change in probability of that effect expected from a change that reduces exposure to the contaminant, as well as the corresponding change in incidence in the exposed population (or relevant environmental medium); estimating the economic value of a statistical case of the effect avoided and multiplying this unit value by the reduced incidence in the population to derive the monetised benefits.

Typically this will require the estimation of a dose-response function that relates the probability of an effect in a relevant population to a particular dose. Furthermore, in assessing impacts, socioeconomic analysis requires the modelling of the relationship between exposure and incidence at various severity levels, rather than just exposure and severity level. As discussed in an earlier section, in order to calculate the number of cases avoided when exposure is reduced, it is necessary to have knowledge of the attributable risk associated with exposure to the substance under consideration.

Following on from the protective remit of risk assessment when undertaken for regulatory purposes, is the fact that uncertainty is built into the assumptions used to characterise risks by deliberately applying assessment factors that build in a margin of error so as to be protective of the population from risks. Socioeconomic analysis attempts instead to describe the distribution of risks in the population such that the decision maker can decide on what is an acceptable level of protection (i.e. there is a separation of the distribution of risks to the population from estimates of risk aversion). This description of the distribution is often summarised in terms of the expected level of risk (though decisions based on expected risk is, contrary to popular belief, not what is advocated by economists). This expected level of risk must nevertheless be central (i.e. be an average) with regard to the relevant segment of the population to which it is applied.

To illustrate this difference in approach taken by risk assessment and socioeconomic analysis, the box below describes the importance of correctly applying the same underlying dose response function for the different purposes within the remit of each approach. The approach is intended to be illustrative and not as a definitive assessment of the risks and socio-economics of the substance under consideration.

BOX – THE USE OF DOSE-RESPONSE FUNCTIONS IN RISK ASSESSMENT AND SOCIOECONOMIC ANALYSIS: THE CASE OF LEAD EXPOSURE AND IQ IMPACTS

Exposure to lead has long been recognised as causing significant biological and neurological damage linked to cognitive and behavioural impairment. Dose-response relationships have been established for example, which describe the relationship between children's performance on IQ tests and measures of blood lead concentrations during infancy. Such dose-response relationship are used in Risk Assessment and Socioeconomic Analysis to consider acceptable levels of protection in terms of individual and population disease burdens. The different remits of Risk Assessment and Socioeconomic Analysis in this respect give rise to differences in the way that such dose-response relationships are used in each case.

Consider the dose-response relationship for low-level lead exposures and IQ as derived from the findings of Lanphear et al (2005). In accordance with the protective remit of Risk Assessment, such a dose response relationship can be used in conjunction with the Benchmark Dose (BMD) approach to derive reference points for risk characterisation (and the setting of acceptable risk exposure limits). Based on the dose-response analysis of Lanphear et al (2005), EFSA (2010) derived a $BMDL_{01}$ reference point for the risk characterisation of lead for assessing the risk of intellectual deficits in children as measured by the Full Scale IQ. The $BMDL_{01}$ is associated with a BMR=1 %, i.e. a decrease of cognitive ability by 1 IQ point, and in this example is chosen to account for the fact that a shift of the distribution of the IQ by 1 IQ point to lower values would have an impact on the socioeconomic status of the population and its productivity. It is in this sense then possible to monetise the human health endpoint associated with lead exposure. This is because it is possible, using a causal model, to relate cognitive ability (in terms of IQ) to economic productivity and hence to monetised economic benefits (see later).

Using the lower confidence limit of the estimated inverse log-linear quantitative relationship between blood lead level and IQ loss (from Lanphear et al, 2005), and solving for the dose that gives rise to an expected IQ loss of 1 point, a $BMDL_{01}$ of 12 µg/L B-Pb is calculated. This can then be used as the basis for defining an exposure limit which would be protective under a 'worse case' exposure scenario, and hence of most individuals in a population (for example by adding in assessment factors that build in a margin of error, etc.). At this benchmark dose exposure, the IQ loss per 1 µg/L increase in blood lead level is 0.083 IQ point.

Whilst this is the loss in IQ points per 1 µg/L for any individual exposed to the benchmark dose level of exposure, the estimation of population disease burden used for socioeconomic analysis looks at what the expected IQ loss would be in the population based on realistic scenarios of exposure in that population. In this respect the approach taken to derive a Benchmark Dose estimates a value of IQ loss per 1 µg/L that is based only on that part of the dose-response curve that is relevant to deriving a 'worse case' exposure, which whilst protective of most individuals, does not represent the typical or average risk faced by the population. For the purposes then of estimating a 'realistic' population disease burden, it is necessary to estimate a 'best-estimate' of expected IQ loss per 1 µg/L (for an 'averagely' exposed individual in the population).

As such, the average (or expected) IQ loss per 1_µg/L is estimated at 0.0513 IQ points for blood lead exposures below 100 µg/L (assuming an even distribution of IQ

loss in the range below 100 µg/L). This converts to an expected loss of 1 IQ point per 19.48 µg/L blood lead level. It is this 'average' IQ loss rather than the loss associated with the 'worse case' (BMD) exposure scenario that is then used for estimating the socioeconomic impact of lead exposures in the population.

As mentioned earlier, IQ losses can be related to economic productivity and hence to socioeconomic benefits. The relationship between earnings and cognitive ability is in simple terms governed by the fact that earnings are the product of the likelihood of employment and the wages earned if employed, which are both directly affected by cognitive ability. In addition, cognitive ability also affects education, which in turn affects wages and employment. It should nevertheless be emphasised that the impact on lifetime earnings serves as a conservative (lower bound) estimate of the total value individuals place on changes in IQ, since they will value such changes independently of the impact on earnings. Many studies have estimated the impact of IQ changes on lifetime earnings. As an example, based on the present value of labour market earnings and household production over a lifetime for an infant, estimated by Grosse (2003) to be around €1,051,758 in 2010 (adjusting for US/EU purchasing power parity and price levels), as well as an estimate of the wage premium for each 1 point increase in IQ estimated by Zak and Rees (2002) of between 0.8 and 1.4%, suggests that the reduction in labour market earnings and household production per IQ point is around €8400 to €14,700

It should be clear that estimation of population disease burden (in terms of IQ losses) based on the worst case assumptions embodied in the BMD approach will give a quite different picture compared to the realistic or typical assumptions used under the socioeconomic approach.

Other case studies illustrating the application of socio-economic analysis to appropriately expressed risk assessments are given in Annex 3 (covering swimming in polluted recreational waters) and in Annex 4 (covering air pollution).

There is also the issue of how to account for the public perception of risk in SEA and risk management. Clearly the public risk perception is contextual in terms social, political, ethical, institutional and economic conditions, but also in terms of how people acquire information and learn about environmental risks. Individuals in society may be more tolerant of risks that they voluntarily choose, or may be more willing to tolerate familiar risks. Some deaths may even be treated as worse than others due to the dread associated with them. Whilst many commentators argue that the public hold incorrect perceptions and hence should not be the basis of assessment, what economists advocate is that the monetization of benefits should be restricted to placing cash values on the estimates of the expected number of lives saved based on scientific evidence rather than on public perceptions. Nevertheless it is important to understand the appropriate degree of information necessary for the public to make informed choices. This requires consideration of the value of additional information and the consequences for their choices of the additional information. The values being assessed must be distinguished according to the levels of information associated with them.

Finally, in assessing the impacts of a policy to reduce risk, it is necessary to compare the situation before and after the risk reduction measure – that is to compare the baseline or status quo with the situation following the intervention. Hence, both risk assessment and socioeconomic analysis have to consider the establishment of a baseline level of risk, taking into account that risks may indeed change in the absence of any intervention; for example as a result of mitigating and averting behavioural responses to risks.

6.4 Variability and uncertainty in socio-economic analysis

Over and above the variability and uncertainties in the risk assessment itself described in Section 5.6 there is also the possibility of variability and uncertainty associated with the valuation estimates. For example, values for the same kinds of entities can vary from place to place and time to time due to socioeconomic circumstances. Also uncertainties arise from imperfections in studies seeking to monetise the benefits of environmental and human health impacts. Although a considerable literature outlines requirements that such studies should meet to be reliable, from a statistical standpoint, all such estimates have an associated estimated error, and it is feasible to construct pertinent confidence intervals around these values.

Uncertainty is incorporated into economic evaluations through the use of sensitivity analysis or scenario analysis. Similar approaches are used in probabilistic exposure assessment as discussed in section 5.3.

There is also uncertainty about future physical and economic conditions. For example, change in general economic conditions could cause a change in use of a substance, which could impact on pollution concentrations thereby affect the value of impacts. Likewise, individuals can alter their behaviour in response to changes in environmental and/or health outcomes. For example, an increase in pollution might be responded to by individuals through a change in use patterns

Many important environmental and health problems suffer from true uncertainty, not merely risk. In an economic sense, such pure uncertainty can be considered as 'social uncertainty' or 'natural uncertainty'. Whereas social uncertainty derives from factors such as future incomes and technology, natural uncertainty is associated with our imperfect knowledge of the environment and/or health. A practical means of dealing with such complete uncertainty is to complement the use of cost–benefit analysis with a safe minimum standards (SMS) decision rule. The safe minimum standards decision rule recommends that an activity (such as use of some chemical substance) is not permitted if it has an impact on the environment that threatens to breach an irreversible threshold (unless the costs of foregoing the activity are regarded as 'unacceptably large'). It is based on a modified principle of minimising the maximum possible loss. In this sense it differs from routine trade-offs, which are based on maximising expected gains. A critical aspect in the application of the SMS decision rule is specification of the threshold for unacceptable costs of foregoing the activity. The degree of sacrifice is determined through full cost benefit analysis of the proposed activity, including estimable costs of damage from it to the environment. The decision as to whether the activity should not be permitted is political, constrained by society's goals. In this sense, the SMS approach provides a mechanism for incorporating the precautionary principle into decision-making.

Moreover, uncertainty can be reduced by gathering information. Where there is such an opportunity for learning (gathering more information), it may pay to delay making a decision that would be irreversible. The value of the information gained from that delay is the quasi option value. This is similar to the concept of real option value found in the financial and investment literature.

7. Further alignment of risk assessment and socio-economic analysis

7.1 The core of the problem

It will now be clear from Section 6 that the decision to use SEA as a basis for risk management has important implications for the way that the risk assessment is carried out (Section 5) and this Section aims to clarify this further.

Consider the situation where the risk characterization is carried out on the presumption that there is a threshold response to the risk agent – something that in the EU dominates in risk characterizations for the environment and which is used for

non-carcinogens in human health assessments. Below the threshold, where the presumption on the basis of worst case assumptions is that impacts are unlikely, there is no need for a SEA. But what happens when the characterization is above the threshold of effect? How should management be applied and to what extent? Because there are no straightforward relationships between risk characterization ratios as used in ecology or the margins of exposure or safety used in human health assessments (ANNEX 1) and impacts on ecosystems and human health, judgements have to be made by either the risk assessors or managers on how seriously they should be taken and hence what management should be applied. But that is not a very transparent process and the judgements made by the scientist or the risk managers may not square with those of the public affected in terms of the willingness to accept restrictions or banning of products for the sake of avoided impacts on things that matter in terms of human health and environment.

To be more transparent it is important to be able to calibrate any proposed managed changes in exposure with changes in impacts that matter and can be valued. The changes in exposure will come at a cost to producers and consumers; but they will also bring benefits from the reduced impacts. SEA seeks to express both the costs and benefits in the same units, money, that embody public preferences.

There are two implications for risk assessment:

1. It is best to express changes in impacts in terms of changes in exposure (dose/concentration response relationships) because then the benefits of marginal reductions in exposure can be calibrated against costs and this means that decisions can be fine-tuned to get most benefit for least cost.
2. The endpoints should be expressed in terms of things that matter – human lives, lifespan, healthy lives and ecosystem services – so that they can be valued. If other intermediate endpoints are used – such as the responses of molecular and cellular systems within humans – they still need to be translated into the effects that matter. Again this is usually done by the risk managers and may not lead to outcome that is understood or acceptable.

There are circumstances where cost-benefit analysis is not deemed appropriate. For example, in the EU Cosmetics Directive the requirement (under Article 2) is that a product on the market must not cause damage to human health under normal conditions. Here the primary legislation makes a decision, on behalf of the consumer, that the costs of restricting any harmful substance are always worthwhile.

7.2 Implications for integrated risk assessment and sustainable development

Integrated (holistic) risk assessment has been widely promoted as a concept (see for example WHO/IPCS 2001) albeit the term has been used differently by different risk assessors. Nonetheless the concept, in each case, is interpreted as bringing together risk assessments that are conventionally kept separate. These integrations inevitably involve comparison of impacts on different entities that cannot be compared on scientific grounds; they involve value judgements. For example this is the case in comparing the reduced impacts on climate change from energy-saving light bulbs with increased impacts of the mercury they contain on human health and ecosystems in the event of breakage or after disposal. Yet risk managers need to balance impacts in coming to decisions. One way of doing this is to use the values that people put on climate effects, human health and ecosystem services as weighting factors. This requires that the impacts obtained through scientific risk assessment are expressed in terms that can be associated with these values. This means that the challenges for risk assessment in integration are the same as the challenges in cost-benefit analysis.

The challenges of sustainable development policy are also very similar to those of integrated risk assessment. Sustainable development requires the balancing of potential trade-offs across human capital, natural capital and social capital – taking

into account the complications of cross-generational trade-offs. This means that the impacts on natural capital (identified from risk assessments) need to be monetised and hence expressed in value-relevant terms. What kind of balances should be considered and how within- and cross-generational aspects are taken into account goes beyond the remit of the group.

7.3 More collaboration between risk assessors, risk managers and economists

Closer collaboration between economists and risk assessment scientists can help to ensure more correspondence between outputs of risk assessment and inputs for economists. For example, interaction between economists and risk assessors is necessary in determining which effects are most likely, taking into account scientific studies of mode of action and the susceptibility of field versus laboratory populations to various effects. As a minimum, a clear qualitative description of the possibility and nature of the relevant effect(s) (not just risk characterisation ratios) are needed for a meaningful assessment of the benefits of reducing the risk.

There is also the need for greater cross-disciplinary understanding of risk assessment and socioeconomic analysis. The division of labour between risk assessment and the socioeconomic analysis framework underpinning risk management raises problems for policy analysis of regulatory control of hazardous agents. The division suggests that risk assessors provide risk managers with scientifically defensible estimates of actual population risks, along with the variability and uncertainty associated with the risk. Risk managers would then choose the optimal means of regulation, so as to balance protection of health and the environment with other social and economic objectives. However, risk assessment evidence often provides uncertain predictions of human health and/or environmental hazards, and this uncertainty raises problems regarding appropriate methods to assess and manage risks.

8. The Way Forward

In considering the way forward a distinction should be made between regulatory risk assessments (e.g. associated with REACH and the Cosmetic Directive) and more *ad hoc* assessments, for example the opinions given by the Commission non-food advisory committees in response to questions provided by the Commission Services.

The procedures for regulatory risk assessments are more fixed since they are specified in the primary legislation. For example, for REACH, there is a requirement for both risk assessments and socio-economic analyses that are specified further by detailed technical guidance documents that are the responsibility of ECHA. The Cosmetics directive requires that products on the market must not cause damage to human health without provision of any cost-benefit analysis, and the assessments of risk is the responsibility of SCCS.

For these reason the recommendations here apply largely to the *ad hoc* assessments where more flexibility is possible. However, if clear advantages can be demonstrated to risk managers and other stakeholders from the approaches being proposed here, it is hoped that they will have some effect on the regulatory assessments through changes in policy and legislation.

There are two recurrent themes that run through this report:

i) the recognition of a need for more alignment between what is done in risk assessment and the requirements of risk managers, regulators and ultimately all stakeholders

ii) a need for more effective dialogue between the assessors, managers and other stakeholders.

8.1 Alignment between risk assessment and risk management

The issue

A risk assessment focused on the derivation of an acceptable threshold or "acceptable/tolerable" value may be sufficient when the exposure is below the "acceptable/tolerable" value. However, as discussed in Section 7 when the outcome of the risk assessment is that the risks are not, or cannot be, adequately controlled this kind of risk assessment does not provide the information required for the socio-economic analysis. In these cases, e.g. restriction proposals or authorisation applications following the "SEA route" under the REACH Regulation, the problem formulation and risk assessment methodology should be designed taking into account the SEA needs for receiving a realistic estimation of the risks in the current and/or predicted situations.

Epidemiological studies offer a primary source of information with regard to human health issues, but if not available or insufficient, current health risk-assessment methodologies need to be expressed in terms of dose-responses and the likelihood for effects at the population level, including vulnerable subpopulations, for both threshold and non-threshold substances.

The situation is very different regarding the ecological risk assessments. Some screening methods for "categorizing" the expected level of impact based on the comparison of exposure and laboratory ecotoxicity data have been proposed (ECETOC 2011, Moreno-Jiménez et al. 2011). But the current level of knowledge only allows an estimation of the expected ecological impacts in the case of higher tier site-specific risk assessments.

Future approach

The challenge is to try to better integrate risk assessment and socioeconomic analysis, and in particular to improve the alignment between them in support of better hazardous substance risk management decision-making. This requires that risk assessors adapt their analyses to incorporate the respective needs and requirements of risk managers. This will depend on the development of a common language and understanding of the respective methods used by each discipline.

A catalyst for such improvement is the current increased interest in integrating risk assessment and socioeconomic analysis at both the scientific disciplinary level, but also driven by the increased interaction by respective regulatory committees in practice, e.g. the Risk Assessment Committee (RAC) and the Socioeconomic Analysis Committee (SEAC) of the European Chemicals Agency (ECHA). There is an opportunity to learn the lessons of the interactions that will undoubtedly take place as a result of the interactions of the ECHA SEAC and RAC, especially with respect to any case-studies developed for proposed regulatory actions considered by the committees, and other workshops and meetings held between their members.

One area where some degree of progress in aligning risk assessments and socioeconomic analysis might be particularly fruitful is with respect to substitution risks. Analysing substitution possibilities is one area that economists are well versed in, thereby providing input into the risk assessors examination of the risks associated with substitution arising from regulatory actions. Socioeconomic analysis can help describe how and by how much a policy might alter behaviours in terms of substitution of one risk for another.

To make assessments more informative for risk management purposes involving socio-economic analyses they should:

(a) express effects (endpoints) in terms that are of relevance for protection of human health (mortality and morbidity) and ecosystem services;

(b) relate changes in these effects explicitly to changes in exposure (dose (concentration)-response relationships), to the extent possible through calculating attributable risk for populations;

(c) be explicit about how precautionary any threshold values might be in terms of the dose- response;

(d) be explicit about variability and uncertainty in effects and exposures.

These recommendations can be summarized as the need for a more concerted effort to translate risk characterizations into assessments of impacts on human health and ecosystem services. This amounts to translating endpoints into more obviously relevant effects, and to consider non threshold and probabilistic expressions of risk. This view is comparable to that expressed in the NSF "silver book" (US NRC, 2009):

The above recommendations/considerations should be clearly reflected in the risk assessment reports so that the impact of uncertainties and variability on the outcome of risk assessment can be clearly communicated to decision makers, public and other stakeholders. A sensitivity analysis can help to identify parameters whose uncertainty might most impact a decision (see glossary). RA reports ought to follow a harmonized/structure framework and include:

- Evaluation of different scenarios/options including potential risks of inaction
- Full characterization of the whole population at risk, explicitly addressing subpopulations that may be particularly vulnerable or more highly exposed
- Systematic description of the weight of the evidence and identified data gaps.
- Identification and assessment of uncertainties and variability. This characterization should correspond to the needs of RM including an indication of potential impact of the variability and uncertainty on the conclusions of the risk assessment.
- Explicit description and justification of the hypotheses used in the absence of adequate data.

8.2 Improving the dialogue

Making risk assessments more relevant for risk managers requires that there is more dialogue between the parties, while at the same time guarding against bias. This section suggests a way of addressing this.

The issue

The distinction between the responsibilities of risk assessors and risk managers is clear at least in principle. Assessors apply best available science to working out connections between likely exposures and effects. Managers have to take values into account in making decisions about interventions to alleviate effects by managing likely causes. The science tries to exclude as far as possible value judgments; the management should not be biased by the values of the scientists. This has led to a proper separation of the scientific activity from the management process. Currently, dialogue between risk assessors, risk managers and other stakeholders is quite limited for most requests from the Commission Services to the non-food advisory committees. Feedback is also very varied once an opinion has been acted upon. Consideration needs to be given to improved interactions at various stages in the risk assessment process namely;

- in framing the questions (problems);

- at an early stage in the drafting of an opinion;

- once a draft opinion has been developed;

- responses to the draft opinion;

- feedback on the utility of the opinion for risk management purposes.

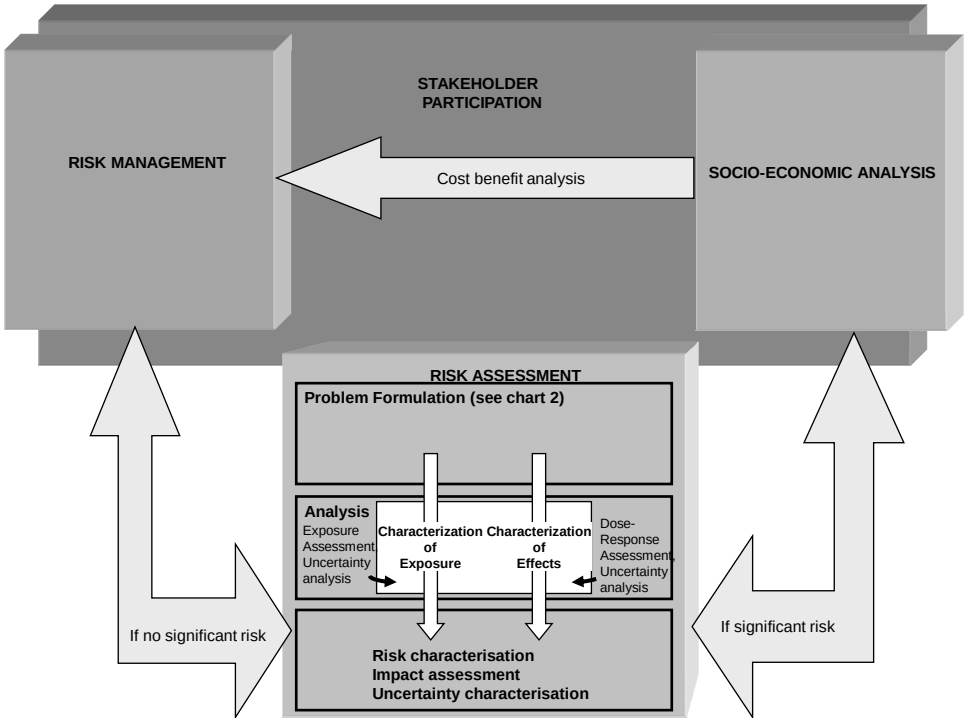
This approach is likely to be of particular importance for the following types of risk assessment:

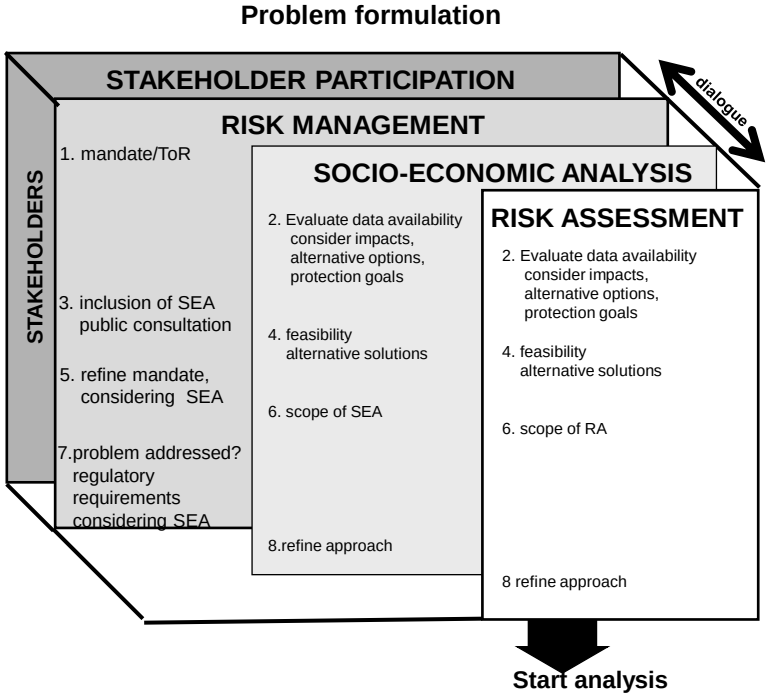
- Emerging issues
- Complex /multifactor risks
- Comparisons between a stressor and its possible alternatives

Future approach

A schematic for the future interactions between risk assessors, socioeconomic experts, risk managers and other stakeholders is set out in the flow chart below. In principle, and ideally, the risk assessment and socioeconomic analysis should be planned jointly as part of the problem formulation. The risk assessment needs to be planned and executed in terms of protecting the entities that matter to people – and so should be informed by the analysis of what is valued in the socioeconomic analysis. However, there remain misunderstandings about the process of valuation in the socio-economic analysis and the possible biases that might be introduced into the science. The socio-economic analysts do not use their own values in their analyses but capture the values of those affected for the entities under consideration. The risk assessors do not use values to make decisions about risk but rather assess risk for those entities that are valued. To facilitate this we advocate that the risk assessment and socio-economic analysis be carried out along separate tracks with sufficient opportunities for dialogue between risk managers, socio-economists, and risk assessors, especially at problem formulation and at risk and impact characterisation (see Figure 8.1). Stakeholder involvement can also be sought at various stages in this process. The process should be tiered: based on the results of the data analysis and the risk characterisation it should be decided whether a socio-economic analysis is needed. If data are insufficient or risks are low, a SEA is not possible or not required.

Figure 8.1: Interactions between risk assessors, socioeconomic experts, risk managers and other stakeholders (adapted from WHO/IPCS 2001)





Framing the question(s)

The role of framing should be to identify:

a) all the potentially relevant ways in which an impact on human health and/or ecosystems (individual, local, regional and global impacts) may occur from a chemical/product or other stressor or stressors even if, at the request of the Commission services, they are then not further considered in any detail in the Opinion.

b) the extent to which all the relevant issues can be addressed in terms that are relevant to the risk managers and understood by other stakeholders.

This report emphasises the need for dialogue at all stages in the framing process and especially in stage 2 in Figure 8.1, where the value relevance of endpoints intended for use in the risk assessment ought to be tested in terms of the needs of the socioeconomic analysis. This should be taken into account in the refining of the mandate by the risk managers (stage 5 in Fig 8.1).

The nature and scope of the RA and/or SEA conducted on a particular issue are determined largely by the nature of the problem (question) as defined by the risk managers. Currently questions are normally produced within the Commission Services without reference to other stakeholders or the scientific committees (SCs) The scientific committees are able to clarify the meaning of the question or questions and may be able to modify them to some degree to a form which is more amenable to answer by the SCs. This procedure may be appropriate for simple non-controversial and statutory tasks but is not sufficient for complex and controversial issues. In *such cases* ownership of the problem (question) by those who may be affected by the outcome (stakeholders) is important.

There are several ways that a satisfactory stakeholder input to framing the question(s) can be achieved but this opinion focusses on some kind of workshop.

Here the framework might comprise headings such as:

- The risk management options and the form in which the risks are most helpfully expressed
- What are the protection goals and hence the relevant endpoints?
- Should both human and ecosystem impacts be addressed?
- Are there specific population groups or ecosystems that need to be specifically addressed?
- The likely availability of relevant information
- Life-cycle aspects that need to be specifically addressed based on consideration of exposure scenarios etc.
- Sources of potential exposure to the chemical/product /stressor
- Sources of exposure to closely related chemicals /stressors
- How uncertainty should be expressed and its potential implications

Another important conclusion is the need for managers, policy makers and public to have a better appreciation of what risk assessments can deliver and in particular that threshold effects will often be very cautionary and deterministic outcomes will usually be artificial. All need to have a better appreciation of dose/concentration relationships where variability and uncertainties are explicit and their implications for management and policy. Therefore, there is a need for forums for exchanging information on these issues. One specific recommendation is the development of a manual on risk assessment for managers that clearly indicates how the process is carried out and what assumptions are incorporated. A crucial first step is to

reconsider the procedure for setting the questions (problem formulation) for complex issues.

Once the work of the scientific committees has started there are likely to be different needs for different kinds of dialogue, as follows:

At an early stage in the drafting of the opinion

It is vital that once the development of an opinion is underway the independence of the Committee/working group is not compromised nor perceived to be compromised and affected by special interests

Any dialogue with the risk managers at this stage should only address specific issues raised by the committee/working group for which clarification by the risk managers is necessary. This dialogue should be at a full meeting of the committee /working group and the issues discussed need to be well described in the minutes.

Once a draft opinion has been developed

Once an opinion is in draft form a specific discussion is needed between the full committee/ working group and the risk managers to ensure that the opinion is:

- unambiguous,

- well founded scientifically, and

- answers the needs of the risk manager.

It is essential that any issues identified are fully recorded in the minutes.

For non-routine, non-urgent opinions particularly those addressing controversial and/or politically sensitive topics, some form of consultation with stakeholders and the general public should be embarked on. Various approaches have been tried to ensure effective dialogue at this stage. Most commonly workshops and/or internet consultation have been favoured. Further work is needed to identify ways to optimise the value of these consultations for risk assessors, risk managers and other stakeholders.

Feedback on the usefulness of the opinion for risk management purposes

A primary objective for the risk assessors is to optimise the value of the opinions they produce for risk management purposes. A crucial element of this is to obtain both early and longer term feedback on how an opinion has been used; i.e. whether there were important gaps that the opinion ought to have addressed or ambiguities picked up by stakeholders. Currently, this feedback is very limited.

Additional dialogue with risk managers

There are two important general areas where further dialogue is essential:

- To ensure that risk managers understand the procedures and methodology being used for risk assessment.

- Regular updating of the above procedures through dialogue with risk managers.

Finally, it is worth noting, as a caveat, that this opinion mainly covers the dialogue between risk assessors, socio-economic experts and risk managers. Risk communication, is a much bigger issue and requires a holistic approach. Risk communication linked to assessments intended to demonstrate a "regulatory safe" or "low risk" situation is unlikely to be significantly improved by the measures recommended here. However, when the policy decision is linked to the comparison of risks versus benefits/costs and/or in the comparison of the risk of different alternatives, expressing the risks as expected impacts in terms that matter and are relevant for society, and offering a transparent outcome of the socio-economic assessment, are key elements for a allowing a proper risk communication.

9. Need for further research

This report has identified the need to review the types of information required by both risk assessment and socioeconomic analysis, what overlaps exist in this respect, as well as the opportunities and barriers to obtaining and developing information for both types of analyses. It has shown that there are important gaps in information between the two types of analysis, such that it will often be difficult to develop the required information for socioeconomic analysis from risk assessments.

The primary question that must be addressed therefore is how to bridge the gaps between economists and risk assessors in order to improve substantially the usefulness and transparency of the assessment process. The following are considered to be the first priorities:

a) Develop an integrated methodology that takes current endpoints used in toxicology/ecotoxicological risk assessment in order to estimate the likelihood and the magnitude of health and ecosystems impacts and translate them into form(s) that stakeholders, including the general public, understand and regards as important.

b) Express risks in probabilistic terms rather than deterministic terms. This must include a framework for the evaluation of uncertainties with data and use statistical approaches to characterize the distribution of uncertainties. The methodology should enable the weighting of different assumptions to examine contribution to uncertainty from various components (including dose-response, emissions, concentrations, exposure, valuation).

10. Next Steps

1. Ask the SANCO Committees to consider the challenges in changing the form of risk characterizations that they carry out currently to that of expressing risks as impacts on human health and ecosystems as set out in this report. This question could then be posed to other committees such as EFSA and REACH Committees

2. On the basis of this work to have a small workshop with risk managers to identify a follow up that optimises the benefit of the changes to risk managers while remaining a fundamentally science based assessment.

3. Following further deliberations of the committees hold a workshop with a variety of stakeholders to discuss the implications of the changes proposed in risk assessment procedures.

11. Conclusions and Recommendations

- A major motivation for this work has been a view that risk assessments do not inform management decisions as effectively as they should.

- This was not based on a comprehensive review of all the instruments involving risk assessment in EU law (Term of Reference 1) but rather on the collective views of risk assessment practitioners across the Commission Scientific Committees and risk managers across a number of customer Directorate Generals. It was also informed by an extensive public consultation.

- Members of the Scientific Committees were particularly concerned to obtain the views of the risk managers and policymakers as required by the Term of Reference 2. The rationale for this being that the risk assessments make no sense unless they can be used to advantage in making decisions in policy and regulations.

- Key messages from the risk managers and policymakers (summarized in Section 4) were that the outputs of risk assessment needed to be more policy and management relevant and this ought to be facilitated by more dialogue.

- Given that management decisions are often taken against a backdrop of tradeoffs between the benefits of interventions for human health and environment and the costs of restrictions on other parts of societal welfare, it follows that to be "management relevant" risk assessments need to inform these cost/benefit analyses.

- A similar problem is encountered in integrated risk assessments where it is often necessary to compare impacts across very different entities, such as humans and ecosystems. Such comparisons can only be achieved by weighting on the basis of people's preference if social-decision rules are to be based on democratic decision-making – and one expression of public preference is economic value – so the risk assessment outputs need to be compatible with such valuation.

- In pursuing Term of Reference 3, "identifying risk assessments that …are informative", the Scientific Committees therefore focused on the extent to which risk assessments are compatible with socio-economic analyses, and put some emphasis on the process for introducing market-restrictions in REACH where these issues are made explicit in the regulatory requirements (Sections 5 and 6). The Scientific Committees concluded that there is considerable confusion on the needs that socio-economic analysis put on risk assessment and that to be more useful (Term of Reference 3) risk assessments should be expressed in terms of value-relevant impacts on humans and ecosystems rather than on the somewhat technical surrogates often included in the routine risk characterizations (Section 7).

- A key recommendation was that the European Commission Scientific Committees be invited to express Opinions on risk in terms of likely impacts on human health and ecosystems services expressed to the extent possible in probabilistic and value-relevant terms.

- To make this change, the Scientific Committees recommend more dialogue between risk assessors and socio-economists.

- Expressing risk in terms that matter for regulators will also facilitate communication – but to enhance that the Scientific Committees make recommendations on a system of dialogue that facilitates the exchange of information between risk assessors and risk managers while ensuring the scientific integrity of the of the risk assessment (Section 8).

- The Scientific Committees also recommend extending this dialogue to all stakeholders in both initial forums and final consultations as a way of clarifying issues and ensuring more buy in. This will be especially important where the issues are complex and the outcomes are likely to be of major socio-economic importance.

- Recommendations were also made for improving risk assessment reports, in particular in terms of: the evaluation of different possible scenarios; full characterization of the whole populations/ ecosystems at risk with attention to particularly sensitive subpopulations/species; clear expression of uncertainty; explicit disclosure of hypotheses used without supporting evidence.

- One step in facilitating the development of better practice could be to arrange training for both assessors and managers based on a common manual – and

the text in this Opinion (particularly Annex 1 and 2) could provide a starting point for that.

- Throughout there are important concerns about uncertainty. It impinges on all aspects of risk assessment and socio-economic analyses. It needs to be made transparent. However, the Scientific Committees have not made detailed recommendation since that was not part of the TOR and is being addressed by other groups.

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ANNEX 1. Risk Assessment steps

Hazard identification

Toxicological evaluation of substances requires knowledge on the toxic effects (hazard identification) seen at different exposure times via routes relevant to the common use of the substance. Organ specificity and other relevant endpoints like fertility, pre- and postnatal toxicity or carcinogenicity, their dose-response and the NOEL (or BMD) are identified by appropriate repeated dose studies in animals. *In vitro* testing and information on the mode of action of the adverse effect can contribute important pieces of information on the toxic potential of a chemical substance.

Epidemiological evaluation starts either with observed exposures (new, increased or accidental) and relates these to observed health effects or starts with observed changes in health of populations and relating these to suspected exposures. Once a toxic potential of a substance is recognized and it is expected to be related to certain health effects, these need to be observed and/or measured in exposed or potentially exposed populations. Often industrial workers are the first to be in contact with a toxic substance. Populations may also observe an increase in certain diseases, or registries might suggest these. The approach is different, when populations are accidentally exposed to known toxic agents. In these cases new insights on the potential damage might be gained.

Dose-response assessment

For most toxicants except genotoxic cancerogens, it is generally assumed that there is a threshold dose below which no toxic effects will occur. In animal experiments, the threshold may be approximated by the NOAEL[1], LOAEL[2] or BMD/BMDL[3]. In the dose-response assessment, an attempt is made to identify this threshold and then extrapolate this dose to a human equivalent dose that is considered to be of no concern for human health. To do so, some "uncertainty" or "safety" factors are applied to take into account inter and intraspecies variability and so on.

For mutagenic substances or for those carcinogenic substances with a genotoxic mode of action, it is generally assumed that there will be a risk of tumour even at very low doses, and that the risk is proportional to the dose. This means that no threshold can be identified below which there is a zero risk. Mathematical models have been developed to quantify the risk for such compounds.

Exposure assessment

Since toxic effects are dose-dependent, knowledge of the distribution, extent and duration of exposure is an integral part of the risk assessment process. Exposure defines the amount of a chemical to which a population or individuals are exposed via inhalation, oral and dermal routes. Animal or human exposure is usually defined as the daily dose, e.g., in mg of the chemical/kg body weight/day. This daily dose may result from oral, inhalation or dermal exposure or as a sum thereof. Ultimately, it is the dose, which reaches the cellular target over a given time period that results

[1] **NO(A)EL** No Observed (Adverse) Effect Level: the highest dose or exposure level within a specific test system, where no (adverse) treatment-related findings are observed
[based on EC B.26]

[2] **LO(A)EL** Lowest Observed (Adverse) Effect Level: the lowest dose or exposure level within a specific test system, where (adverse) treatment-related findings are observed
[ECB 2003]

[3] **BMD** BenchMark Dose/ **BMDL** BMD Lower limit

in the toxicological response. Thus, the toxic potency of a chemical is the product of the interrelated external, internal, and target doses.

For evaluation of time dependency of exposure, it is essential to know whether the substance is rapidly excreted or metabolized or accumulating in the body. [ehesp: *This arguable, see e.g. epigenetic processes*.] The relevant time frame depends on this knowledge. In ubiquitous exposures occurring through e.g. air or water pollution, the exact exposure need to be measured or estimated, as in these cases there are no unexposed individuals or populations.

Risk Characterisation

Relating exposure to effect and dose-response relationship

In case no information from studies in humans is available in general, the NOEL (or BMD) is one of the major starting points for risk assessment, standard setting, regulations, classification and labelling, which may lead to restrictions or authorisations. In case of non-threshold effects such as genotoxic carcinogens the cancer incidence at a given human exposure is calculated by extrapolating the dose response seen in the animal studies to the extent of human exposure. Alternatively the Margin of Exposure (MoE) is determined, which describes the difference between a defined cancer incidence in animal studies and the human exposure.

In case epidemiological information permits identification of the NOEL (or BMD) or in case of non-threshold compounds a description of the risk at a given exposure such information is always seen more relevant than information gained from experimental studies.

When a threshold is considered to occur, based on experimental or epidemiological study, it is possible to identify a dose usually called "point of departure" (POD) under which no toxicity does occur in the tested population. This could be a NOAEL/LOAEL (a deterministic approach) or a BMD[4]. To characterize the risk, a Margin of safety (MoS) is calculated according to the formula:

MoS = NOAEL (or BMD)/ SED

where SED represents the Systemic Exposure Dosage. It is generally accepted that the MoS should at least be 100 to declare a substance safe for use. In a similar approach, the SED could be compared to a Human Toxicity Value (HTV) which is obtained by dividing the POD by uncertainty or safety factors accounting for inter-species differences (kinetics and dynamics) and inter-individual variations within the human population. Other factors may also be applied to take into account other sources of uncertainties (poor toxicological data base, time extrapolation…). When estimating the risk for exposed people, an Hazard Index (HI) is calculated by dividing the HTV by SED. In this case, if the exposure is under the HTV, it is usually considered that no effect will occur to the general population and if HI > 1, the concentration (or dose) of compound exceeds the level considered to be acceptable.

In the threshold approach, one should recognize that, if the exposure is below the HTV or below the POD with sufficient MoS, then the risk can be excluded. However if not, then there is no way to express the outcome in terms of incidence. It is just assumed that the higher the exposure will be, the more serious the outcome could be for the exposed individual. But for the whole population, it is not an indication of the extent of people affected.

[4] The Benchmark Dose (BMD) is proposed as an alternative for the classical NOAEL and LOAEL values. The BMD is based on a mathematical model being fitted to the experimental data within the observable range and estimates the dose that causes a low but measurable response (the benchmark response BMR) typically chosen at 5 or 10% incidence above the control.

On the other hand, a non-threshold approach has to be chosen when available observations (within the observable range, be they epidemiological or experimental) are such that no dose threshold can be evidenced. It is then postulated that the dose-response relationship is without threshold, and that any dose conveys a risk. The non observable dose-range is modeled towards the null dose upon the observable range dosing, providing an estimated dose-response slope. This approach is considered appropriate for radiation and for some genotoxic carcinogens and also in rare case so far for some deterministic effects, e.g. the adverse effect of blood lead concentrations on children neurodevelopment..In such cases, the HTV is expressed as a probability of an excess lifetime risk of disease per unit dose of exposure at a population scale. In the risk characterization step, the concentration corresponding to a risk level of 10^{-6} or 10^{-5} or any other level judged through the decision-making process as 'tolerable'

Threshold of Toxicological Concern

The Threshold of Toxicological Concern (TTC) is a concept to establish a level of exposure for chemicals, regardless their chemical-specific toxicity data, below which no appreciable risk to human health is expected. The concept is based on structural alerts of the chemical, its concentration in a product and the daily human exposure. The TTC is defined as a nominal oral dose which poses no or negligible risk to human health after a daily lifetime exposure. In case of food contaminants a mean dietary intake below the level of the TTC further toxicology safety evaluation or testing is seen not necessary or warranted. There is ongoing discussion on its general applicability for safety assessment of substances that are present at low levels in consumer products such as cosmetics, for impurities or degradation products.

ANNEX 2. The Framework of Socioeconomic Analysis

The framework of SEA allows for the explicit estimation and comparison of the beneficial and adverse effects of an action, together with their probabilities. This comparison requires a method for valuing the impact on risk (or risk reduction benefits) in such a way that it can be compared to the value of the resources given up to mitigate the risk. This latter value is the *opportunity cost* of the control measures needed to mitigate the risk. In comparing these benefits and costs, all significant impacts of the control measure should be included in the analysis, including any effects in other risks that may arise as a result of the control measure.

The most commonly used forms of socioeconomic analysis used to evaluate risk reduction policies are Costs Benefit Analysis and Cost Effectiveness Analysis.

Cost Benefit Analysis (CBA) provides a systematic assessment of the costs and benefits associated with an intervention. The benefits of an action are contrasted with the associated (opportunity) costs within a common analytical framework. Economic theory defines a benefit as a change that increases human well-being, whilst a cost is defined as a change that decreases human well-being. As described later, and for the purpose of comparison, these increases and decreases in well-being are measured using the common denominator of money. The net benefit of a change is given by the difference between the costs and benefits. Delayed benefits and costs are converted to their present day equivalents through a process called discounting. The change is said to be economically efficient if the present value of net benefits (NPV) is positive, or the ratio of total benefits to total costs (B-C ratio) is greater than one.

Cost-effectiveness analysis – CEA (also known as least cost analysis under certain guises) is used to identify the most cost-effective option for achieving a pre-set objective or criterion that is not measurable in monetary terms (for example cases of some health outcome). The relevant objective is set, options for achieving it are identified, and the most cost-effective option is identified as that with the lowest present value of costs. Where the costs are related to an effect that differs in magnitude between alternative interventions, then the results can be stated in terms of net cost per unit of effect.

Cost-effectiveness analysis is suitable for use in situations where valid and reliable estimation of the benefits of alternative options is not feasible. Instead of attempting to identify and value the benefits, the most cost-effective means of achieving a desired objective is identified. Cost effectiveness analysis is suited, for example, to situations where clear and defensible health goals exist which can be measured in terms of appropriate units. For example, health goals relating to mortality and morbidity effects of interventions are sometimes combined into single units such as QALYs (Quality Adjusted Live Years), DALYs (Disability Adjusted Live Years), HYEs (Health Years Equivalent), and other health indices. CEA can also be used to identify the most effective option for a fixed amount of funding that has been allocated to achieve a policy objective. The drawback of cost-effectiveness analysis is that it does not identify the benefits of actions or the willingness of society to pay for improvements. For these reasons, CBA is, if practicable, the preferred approach for evaluation.

In promoting socioeconomic evaluation, there is concern that there is too much emphasis on assigning monetary values to aspects of health and the environment, that are difficult—if not impossible—to quantify. There is also concern that decisions about health and environmental protection interventions might be made strictly on the basis of whether their quantifiable benefits outweigh their monetized, quantifiable costs.

It should be noted though, that decision-makers will often find it hard to interpret and decide upon health or environmental endpoints that are the subject of interventions. They will generally find it easier to interpret monetary values for the

purposes of making decisions about an intervention. Considering the incremental costs and benefits associated with alternative interventions (including doing nothing) can help to clarify the tradeoffs and implications associated with those interventions and help to set priorities.

Impact Valuation: The Damage Function Approach

Risk assessment is not designed to provide estimates of actual health and environmental risks, but rather to determine whether a chemical poses any appreciable risk. This focus differs from that taken by the economic perspective, which is characterised by a preoccupation with efficiency. Nevertheless, socioeconomic evaluation as practised under many regulatory regimes such as REACH requires that the likelihood of adverse health and environmental effects are linked with data that evaluates the potential economic impacts of regulating a hazardous substance. As discussed earlier, such exercises are undertaken in order to determine whether the potential benefits of reducing risks to human health and/or the environment are sufficiently balanced by the costs of regulation.

The traditional approach to estimating these potential economic benefit impacts is the *Damage Function* approach, which translates changes in emissions of a substance into associated changes in exposures. Exposure response functions are used to relates changes in exposure into changes in health and/or environmental endpoints, which are then valued in monetary terms.

In particular, the following steps are necessary under the damage function approach to evaluate the socioeconomic benefits associated with a chemical regulation:

Identify each relevant category of harm – eliminate those that are "trivially" small, though noting that the aggregate affect of some hazardous chemicals may well be significant, particularly in relation to some environmental stressors where they cumulate with other chemicals and or interact synergistically with them.

Quantify the relationship between emissions, (and ambient environmental concentration where appropriate), exposures and each environmental and/or human health effect endpoint.

For each year, assess the changes in emissions as a result of the regulation and estimate the physical benefits in terms of the categories identified in 1 and quantified in 2, i.e. environmental and/or human health effect endpoints (e.g. for the latter endpoints such as premature deaths, cases of each disease, quality adjusted life-years, etc). Value these estimated physical benefits in money terms. [

Given these general steps, there are two key areas of focus under the damage function approach: the first concerns environmental and human health risk assessment necessary to relate changes in emissions to environmental and human health endpoints (biophysical consequences of the emissions of the substance). The second concerns the assessment of economic valuation estimates that would be needed to estimate the monetary value of human health and/or environmental impacts (economic loss associated with biophysical consequences. The damage function approach thus separates the risk assessment from the valuation of health and environmental endpoints, such that unit health and environmental values are applied to objectively measured changes in endpoints. Whilst many non-economists think that step 4 above is the hardest and cannot be done, as we shall discuss below, economists are accustomed to estimating such values. Whilst there are important uncertainties associated with each method of doing so, valuation is not the main source of uncertainty in estimating impacts. In general step 2 and 3 adds more uncertainty than step 4. Prior to considering the nature of some of these issues in more detail, we consider the nature of what economists do in undertaking economic valuation of impacts, outline the principles that underpin economic evaluation, and examine the links between the human health and environmental endpoints considered by risk assessment and their economic valuation.

What is Economic Value?

In order to understand what economic analysis is about, let us assume that risk assessment provides us with the human health and/or environmental endpoint information that fully describes the biophysical consequences associated with emissions of a substance. Economic evaluation of these biophysical impacts requires that we relate it to the concept of human welfare, such that the impacts are weighted in such a way that allows the comparison of the costs of control with the benefits. The concept of human welfare, which is also known as wellbeing, utility or happiness is central to the economic approach. Because human welfare is rather an intangible concept that cannot be directly measured, economists use a transformation of welfare into a more general single scale numeraire. It is then possible to define economic value very narrowly in terms of economic behaviour in the context of supply and demand. Put simply it is the maximum amount of goods or service – or equivalent money income that an individual is willing to forego (willingness to pay - WTP) in order to obtain some outcome that increases their welfare[5]. These sums of money are demonstrated or implied by the choices people make, and thus reflect individuals' preferences for the change in question. Economists use money as the measure of human welfare because they need a uniform measure to compare different impacts. Many things are denominated in terms of money values, in particular costs hence money is a convenient measure. Nevertheless, other scales could be used instead.

It should be noted that economics seeks to maximise overall human (social) wellbeing. As such its focus is not just on company profits, but rather on what might be termed "social profits", including aspects of wellbeing that derive not just from the consumption of everyday goods that are bought and sold in the market, but also from the natural environment and other 'non-market' goods. There are of course alternative societal goals, such as what is fairest, or cheapest, or healthiest, or morally acceptable, etc. The choice of social objective will vary between groups in society, experts and governments. What will always be constructive however is to take those social objectives and subject them, and the ways of achieving them, to economic analysis in an effort to inform the decision-making process and make it as efficient as possible.

A key challenge for the economic approach is how to assess willingness to pay for goods and services that are often not traded in markets (such as improvements in human health and/or environment). Unlike marketed good and services, the price and quantities of such goods and services will often not be directly observed in markets. As we shall see however, economists have at their disposal a variety of approaches and methods to estimate the values of such goods. A common misconception of non-economists is that economists give values to such goods and services. In fact, economics does not impose values – it detects, reveals or uncovers the values that people hold. We now consider some of the key principles underpinning the evaluation of economic values.

Economic Evaluation Principles

In applying economic analysis to human health and/or environmental impacts evaluation, the following set of principles is applied.

First, economic analysis is concerned with values rather than prices. There is much confusion between these two terms, which are not in fact equivalent. To explain, consider the difference between water and diamonds – clearly whilst diamonds have little practical purpose they command a much higher price than water, which in the

[5] If the outcome reduces welfare then this utility loss is measured by the minimum amount of money that the individual would require in compensation (willingness to accept WTA) in order to offset the outcome.

extreme is of infinite value. The reason for this difference is of course due to the difference in supply and demand of the two goods. Although demand for water is very high, so is its supply, leading to the relatively low price, whereas diamonds have very small supply relative to their demand, resulting in a high price. As such the price of goods can be below the value that people have for those goods – the excess between price and value being known as the consumer surplus. Economists are interested in value rather than price, since this reflects the entire benefit (utility or wellbeing) that consumers derive from the consumption of a good). The fundamental problem facing any economic analysis is one of how to measure the value provided by any given good. As noted above, economic values are approximated by measures such as individuals' willingness to pay (WTP) for the good in question, i.e value is related to willingness to pay rather than what actually has to be paid (ie the price). Under certain conditions (notably private goods traded in competitive markets) prices may be an acceptable approximation of such values. However, In other cases (notably public goods which are not traded in markets) price may be absent or a poor guide to value. In the latter cases a variety of methodologies exist for estimating values. These include the following:

- Adjusted market prices: For goods which are traded in markets and have prices we can estimate WTP by examining the reaction of demand to observed variations in prices. This allows the analyst to estimate consumer surplus and hence values. For example, one can estimate part of the value of improved water quality by examining the increased value of commercial fishing catches. Adjustments are necessary to account for any imperfect market or policy distortions(e.g. taxes and subsidies), etc.
- Productivity methods: the natural environment often provides the factors of production required to produce marketed goods. Production functions relating inputs to the output of goods can be estimated and the contribution of individual factors assessed. Continuing the water quality improvement example, one could also estimate the value generated by the decreased costs of providing clean drinking water.
- Revealed preference methods: Many goods which incorporate environment or health characteristics can only be enjoyed through money purchases. For example, individuals may pay extra for environmentally friendly or safer products. By relating behaviour to the characteristics of those goods one can observe the money-environment and/or health trade-off and so reveal the values held by individuals for the environment and/or health. The "compensating-wage-differential" method is a revealed-preference method that is commonly used to estimate the value of changes in mortality risk, using data on workplace fatality risk and wages.
- Stated preference methods: The most direct of all approaches is to ask individuals to state their willingness to pay for some change in health and/or the environment. This relies on asking survey respondents what choices they would make in a hypothetical setting and interpreting their answers under the assumption that the choices they report are the ones they most prefer. Stated-preference methods are not limited to situations where people's actual choices can be observed.

In practice the costs of conducting novel valuation research across the multitude of potential decision situations often means that analysts are forced to rely upon value transfer methods which transfer existing benefit estimates from studies already completed for another issue.

In addition to the various valuation methods described above, many studies adopt simpler 'pricing methods' such as avoided damage approaches which examine the costs of avoiding damages (e.g. the cost of protective equipment to protect against emissions). These are not true valuation methods as they are not based upon WTP.

The common error arising from using such methods is to assume that the costs of avoiding damage somehow relate to the true value of the issue under assessment (e.g. the costs of protective equipment are a proxy for the value of good health).

Alternatively, the value of health risk reductions are often estimated using cost-of-illness methods rather than willingness to pay. This estimates the monetary value of the loss from sickness or death in terms of the costs of treating the illness and any lost productivity (arising from having been sick or dead). These methods underestimate the economic value of health risk because they do not include all non-market consequences of ill health. However, to the extent that the use of conservative assumptions in risk assessment yield overestimates of the initial risk and of the reduction due to reducing human exposures, benefits might be overestimated.

It should be noted that not all environmental and health impacts (notably those for which individuals have low experience or knowledge) may be amenable to valuation due to the absence of robust preferences (as required by economic theory). Cost-effective solutions for delivering safe minimum standards (SMS) may be appropriate here (see later).

A second principle is that economic values are human constructs. Economic valuation seeks to assess all of the diverse values which individuals have for the range of good they enjoy. These include the values individuals' obtain from using goods (use value), but they also include values for goods which individuals do not use but wish to preserve (non-use values). The economic definition of value is entirely anthropocentric with values being seen as a uniquely human construct. As such, 'intrinsic' values arguably possessed by non-human entities cannot be included within economic analysis. Some critics thus reject the economic approach and argue for a rights based approach under which non-humans are accorded equal rights with humans. While the need to protect human health and/or the environment is clear, the logical consequence of such a rights based approach is to stifle all economic change, irrespective of the benefits it may bring.

A third principle is that economic assessment requires that environmental and human health endpoints or outcomes are chosen such that their value can be credibly revealed through choices or human preferences, i.e. endpoints that have direct, concrete meaning to people. In this respect, the endpoints should be clearly and consistently distinguished from the value placed on those endpoints, i.e. physical quantity measures are clearly distinguished from price or value measures. All such endpoints that contribute to welfare should be counted, but only be counted once. In practice this requires a distinction between the final outcomes valued by individuals and the various underlying processes or functions which are required for the production of those outcomes. Attempts to value those underlying processes or functions rather than final outcomes are liable to result in double counting. We discuss environmental and human health endpoints further below.

A fourth principle is that economic analysis focuses upon marginal values. Economics does not claim to be able to assess the *total* value of certain goods, such as those associated with the life support functions of the environment. Instead economics confines itself to the valuation of *changes* in provision. A key concept here is the value of an additional unit of provision, referred to as the marginal unit, whose value is known as the marginal willingness to pay. It is a general fact in economics that the marginal willingness to pay (MWTP) for a marginal unit of a good diminishes as the quantity consumed increases. Therefore MWTP rises as we consider progressive losses of a good. MWTP will eventually become infinite for vital goods. Therefore attempts to assess the total value of such goods (driving their availability to zero) are to be avoided. As mentioned economic analysis focuses upon assessing the value of feasible (non-total) changes in the provision of goods. This requires a clear understanding of the change in provision of the good under consideration (i.e. the number of extra units being provided); a robust and reliable estimate of the marginal

(i.e. per unit) willingness to pay (MWTP); and knowledge of how (ii) might alter as (i) changes.

A fifth principle is that spatial issues are fundamental to the economic assessment of many environmental and health changes. Variations in the natural environment characteristics of areas play a part in determining the change in quantity of environmental services and hence goods which can be provided by that area. The natural environment characteristics will vary substantially by location. Spatial relationships also affect the value of any given change in provision. The use values generated by spatially confined goods (such as a river used for fishing) tend to decay with distance. Therefore the location of those goods relative to populations will alter their value. The value of a good is also influenced by the presence of substitutes, Since the substitutability of one good for another may partially depend on their spatial proximity, then the location of substitutes relative to spatially confined goods will alter their value. Spatial effects therefore have to be allowed for in assessing the value of spatially confined goods.

It is also important to note that spatial definition is also crucial in the analysis of ecosystem function and the welfare end points which follow from changes to them. Thus an analysis of water pollution should be done at the level of the hydrologically separate water unit – the catchment and not a sub division of a catchment. The issue of double counting already referred to before is crucial here though, as services which are termed Supporting under the Millennium Ecosystem Assessment (MA) also affect services which are Provisioning, Cultural and Regulating[6]

A sixth principle is that values also vary temporally, in addition to their spatial variation. In part this is due to the fact that preferences may change over time. Furthermore, the socioeconomic and other characteristics of populations may alter resulting in changes in WTP over time. It is facet of preferences that individuals prefer benefits to be provided sooner rather than later, whilst the opposite is true for costs. As such the present day value of benefits and costs are progressively discounted the further into the future they occur. An additional, and not well understood temporal issues is that as time passes so the probability increases of interactions, tipping points and irreversibility between and within natural systems. The uncertainties induced by such effects increase the desirability of SMS and precautionary approaches (see below for further discussion of this issue).

Another approach to the issue of uncertainty and irreversibility is provided by reformulating the cost-benefit analysis decision rule. We have seen that in the context of issues such as environmental degradation, there is often only limited information about impacts. In this case, the rules of CBA are difficult to apply – benefits are uncertain, losses may be irreversible and the scale of loss can be substantial. Nevertheless, there is scope within Socio Economic Analysis to attribute "an insurance" premium which captures the public's willingness to pay to avoid unknown, but adverse outcomes resulting from the release of hazardous chemicals into the environment; thus in a sense capturing the public at larges' sense of precaution. Such 'Option values' as they are termed in the environmental economics literature thus act to ensure the supply of something the availability of which would otherwise be uncertain.

Ecosystem Service Approach to defining meaningful endpoints

One approach to defining economically meaningful endpoints in the context of environmental risks is provided by the 'ecosystem services approach'. All life is embedded in various categories of ecosystems, and all ecosystems generate services which essentially help to maintain life on earth for humans. In this respect then they

[6] "Ecosystems and Human Well-Being : synthesis" Report of the Millennium Ecosystem Assessment, 2005

have an economic value based on the benefits that humans receive from those ecosystems. Whilst natural scientists define ecological services to be important from their own disciplinary perspective, economists focus on their importance in terms of how humans benefit. Thus it useful to distinguish two types of ecosystem services, those which might be termed final, that is directly benefit human kind and those which could be termed intermediate, that is are necessary to the functioning of the ecosystem, but do not relate directly to a human welfare end point. Some of the types of services provided by ecosystems that have obvious human benefit, directly or as intermediate processes include:

- Purification services – e.g. wetland ecosystems filter water
- Ecological cycling – growing vegetation sequesters or 'fixes' some environmental pollutants
- Regulation – ecosystems provide natural regulatory services such as pest control, watershed management, etc
- Habitat provision – aside from their providing a source of food, recreation, etc, habitats are stores of biodiversity, which may be linked to natural processes that provide resilience to the risk of ecosystem degradation and collapse.
- Regeneration and production – ecosystems covert light, energy and nutrients into biomass, which provides, food, raw materials and energy and also provides an organic waste disposal function.
- Information and life support – ecosystems incorporate value related to the scientific information embodied in them, as well as being a source of life support.
- Provisioning of water and food for the Human population is shown separately within the MA. As a rule the Provisioning category of services in the MA refers to a direct welfare end point in common with Cultural Services heading, also found within the MA.(The other two categories within the MA are Regulatory and Supporting services.).As a general rule the Supporting Heading provides services which are intermediate and have no direct welfare end point. While the Regulatory heading provides services that bridge both Final and intermediate headings.

The distinction between final and intermediate services is important; as it helps with the risk of double counting. As an example, an environmentally beneficial intervention may both improve soil quality (a supporting service) and thus, increase food production (a Provisioning service). The benefit of the intervention is captured by food production and thus to count in the supporting, soil quality within the calculation of benefit as well as the increase in food production would amount to double counting.

Clearly ecosystems are capable of producing a multi-functional array of ecological-economic services. The goods that derive from that array of services is not usually known with complete certainty, and the goods can also range from being purely private goods (e.g. food, fuel) to being local public goods (e.g. watershed protection, water pollution reduction) and global public goods (e.g. carbon sequestration), as well as the non-use value of the ecosystems as well as the intermediate services to which we referred earlier.

Although the valuation of all the services provided by ecosystems can in principle be achieved by application of the valuation techniques described earlier, there is a difficulty in that the services depend on each other. In other words, the economic value of any one service may depend on its relationship to the other services, both final and intermediate, and since valuation is about valuing changes in an ecosystem, then the values will be dependent on how everything in the ecosystem changes, not

just on the specific services being considered. Thus valuation requires an understanding of the functioning of an ecosystem as a whole. Often this is not possible given the current levels of ecological understanding. Valuation of ecosystem services is clearly a complicated task, especially given this interaction of services, but also because of the considerable uncertainty about how ecosystems function and what life support functions they provide. How to deal with such uncertainties, as well as the irreversibilites and non-linearities that can characterise such systems, may generate unexpectedly large losses from environmental degradation, amongst other things, is the subject of the next subsection.

The critical question is if we identify all the relevant welfare end points associated with an intervention accurately and cumulate them together, have we captured everything we need to know? There are 2 distinct issues here:

One could be termed the tyranny of small choices. Economists like to look at decisions involving small movements along a choice frontier. Looking at compounds separately means that we cannot take account of the possibility that some hazardous chemicals cumulate and interact synergistically together. It means that there may well be irreversibilities and thresholds occasioned by a series of small decisions made independently, but interacting together. Ideally Cost Benefit Analysis should be drawn at a group level. Options for the control of Compounds which have cumulative and or synergistic effects should be drawn up for the management of all these compounds at the same time. To try and regulate such compounds at the individual compound level means that this cumulative and synergistic properties are difficult, if impossible to analyse. Thus we might wish to consider control options for PBT chemicals as a whole or break them up into groups such as Aeolian, volatile and sediment born or some other meaningful classification, for instance. This approach may make it easier to cope with the concept of "glue value", the degeneration in intermediate services occasioned by the build-up of a toxic load in the environment. This is because the aggregate process of environmental degradation should be more obvious (scientific understanding allowing) when a non-marginal, step change in the regulation of hazardous chemicals is considered; than in the current world of incremental, substance by substance decision making.

The second issue to which we have referred is uncertainty. This uncertainty refers to both the final ecosystem service end points and intermediate services effects, which in the long term may affect the community's welfare. This is an issue of understanding, but in the absence of such knowledge, it is possible to surmise that the community might be willing to pay for the avoidance of unknown but adverse and possibly calamitous outcomes in the future. In essence there may be a case for the inclusion of an "insurance premium" within the Cost Benefit Analysis, to give some representation of the society's aversion to risky unknown outcomes.

Uncertainty in Socio-economic Analysis

There is variability and uncertainty in socio-economic valuation that are not always appreciated. Risk can be incorporated into an economic evaluation by attributing probabilities to possible outcomes, thereby estimating directly the expected value of costs and benefits or their 'certainty equivalents'. 'Risk neutrality' is typically assumed on the part of decision-makers in estimating such expected values, meaning that they do not care about probabilities that very small returns or even negative returns might result from a decision. Such an assumption might not be an unreasonable assumption in the case of government decisions, especially since governments can "pool" the risks of decisions by spreading them across many policies with different risk profiles, and by spreading the costs out across many taxpayers. However, there is much evidence that individuals are in fact risk averse, such that there exists a certainty premium to eliminate risks altogether. Such factors need to be kept in mind when undertaking socioeconomic analysis.

In an economic evaluation, uncertainty is associated with physical outcomes and their economic consequences. For environment and/or health impacts, the necessary assessment of possible outcomes and the likelihood of perturbations to what are often highly complex systems is inevitably fraught with difficulty. However, this is a necessary component of an economic evaluation. For each management or policy option under consideration, the range of possible impacts needs to be identified and quantified as far as possible. A particularly important issue relating to uncertainty in physical effects is the possible existence of thresholds beyond which disproportional and irreversible effects can occur.

There is also uncertainty that relates to the physical and economic conditions that will prevail in the future. For example, change in the general economic conditions could cause a change in use of a substance, which could impact on pollution concentrations thereby affect the value of impacts. Likewise, individuals can alter their behaviour in response to changes in environmental and/or health outcomes. For example, an increase in pollution might be responded to by individuals through a change in use patterns.

Uncertainty is incorporated into economic evaluations through the use of sensitivity analysis or scenario analysis. Similar approaches are used in probabilistic exposure assessment. In sensitivity analysis, various possible values are used for key variables in the evaluation, such as the discount rate, the extent of economically meaningful endpoints, and economic values. This provides a range of estimates within which the true result can be expected to fall. It can create ambiguity but is a necessary component of any economic evaluation. Scenario analysis can also be used to incorporate uncertainty through comparison of results using parameter values that represent different possible future scenarios.

It should be pointed out that 'many important environmental and health problems suffer from true uncertainty, not merely risk.' In an economic sense, such pure uncertainty can be considered as 'social uncertainty' or 'natural uncertainty'. Whereas social uncertainty derives from factors such as future incomes and technology, natural uncertainty is associated with our imperfect knowledge of the environment and/or health. A practical means of dealing with such complete uncertainty is to complement the use of cost–benefit analysis with a safe minimum standards (SMS) decision rule. This recommends that when some activity that impacts on the environment threatens to breach an irreversible threshold, that conservation is adopted unless the costs of forgoing the development are regarded as 'unacceptably large'. It is based on a modified principle of minimizing the maximum possible loss and therefore differs from routine trade-offs which are based on maximizing expected gains for example cost–benefit and risk analysis. However, activities that result in potential irreversible change are not rejected if the associated costs are regarded as intolerably high. It is worth considering however whether such effects are really a threshold effect or just the accumulation of several unintended and unconsidered effects and if they might be captured through grouping compounds in the analysis as described above.

A critical aspect in the application of the SMS decision rule is specification of the threshold for unacceptable costs of forgoing development. The degree of sacrifice is determined through full cost–benefit assessment of the development option, including estimable costs of damage to the environment. The decision as to whether conservation (and hence rejection of the development activity) can be justified is political, constrained by society's various goals. (Though there is a willingness to pay component in this process, which is peoples' preference for the avoidance of unknown but environmentally and human health destructive outcomes.) In this sense, SMS provide a mechanism for incorporating the precautionary principle into decision making: society may choose to conserve even in the absence of proof that damage will occur in order to limit potential costs in the future. It can promote a

more sustainable approach to current development and can provide an appropriate supplement to standard analysis of economic efficiency.

Moreover, uncertainty can be reduced by gathering information. Where there is such an opportunity for learning (gathering more information), it may pay to delay making a decision that would be irreversible. The value of the information gained from that delay is the quasi option value. This is similar to the concept of real option value found in the financial and investment literature. It should be noted that if the potential for learning is not there, then quasi option value does not arise. With regards to what difference this concept can make for decision making in the context of uncertainty such as that faced for hazardous substances, the concept should remind us that decisions should be made on the basis of maximum feasible information about the costs and benefits, including the fact that we know that we do not know. In the case where that ignorance can be resolved by delaying a decision, then the quality of the decision can be improved. The gain from doing so (and hence the value of quasi option value) is the difference between the decision made on the basis of ignorance and on it made with the ignorance resolved by waiting. This difference can be explored through peoples' attitudes to uncertainty about undesirable and damaging consequences in a Willingness to Pay sense. Though as has also been noted, to do so meaningfully requires that people's preferences are well formed and informed. But such an approach may at least help to identify a lower bound to this quasi option value.

ANNEX 3. Case Study on Swimming in Polluted Recreational Waters

This case study considers the economic benefit impacts of reducing the health risks from swimming in polluted coastal recreational waters using the *Damage Function* approach. It assesses how changes in the microbiological quality of UK coastal bathing waters result in changes in the excess risk of gastrointestinal illness associated with recreational bathing in these waters. Using this information alongside population data on the swimming behaviour of the English and Welsh population, the change in absolute disease burden for gastrointestinal illness arising from bathing in faecally contaminated UK coastal waters is estimated. Finally, using an estimate of the monetary value associated with reducing an episode of the gastrointestinal illness health endpoint, the monetary value of the change in disease burden is estimated

A. Assessment of change in excess risk of gastrointestinal illness

Whilst the main focus of the following analysis concerns the excess risks of gastrointestinal illness associated with swimmers' exposure to the faecally contaminated bathing waters, this is not the only illness associated with faecal contamination of bathing waters. Nevertheless it has been the main focus of most of the epidemiological work, and the illness for which there is the most credible scientific evidence of a clear dose-response relationship with water quality.

In order the assess the risk of illness for a distribution of pollutant exposure, the relevant dose response function, as derived for example from epidemiological studies, has to be used along with the statistical distribution of the related exposure parameter densities of the relevant pollutant. Such a distribution describes the exposure of the population to the different pollutant levels. In this way the proportion of the population likely to suffer from illness can be derived for the statistical distribution of the pollutant for any relevant period.

This estimation procedure in now described in more detail for the case of gastrointestinal illness associates with swimming in faecally contaminated recreational bathing waters.

The Epidemiological Model

The epidemiological relationship that the excess risk of gastrointestinal illness from exposure is based on derives from the study by Kay et al (1994). This found that the dose-response relationship linking water quality exposure (x), indexed by the faecal streptococci density at chest depth, and the excess probability of gastroenteritis (y) is given by the following:

For exposures between 32 and 158 faecal streptococci per 100ml:

$$y_{(x=32:158)} = \frac{1}{1+e^{-m}} - p_{32}$$

where, m is the natural logarithm of the odds of getting gastroenteritis from swimming, derived from the logistic regression equation:

$$m = 0.20102\sqrt{x-32} - 2.3561$$

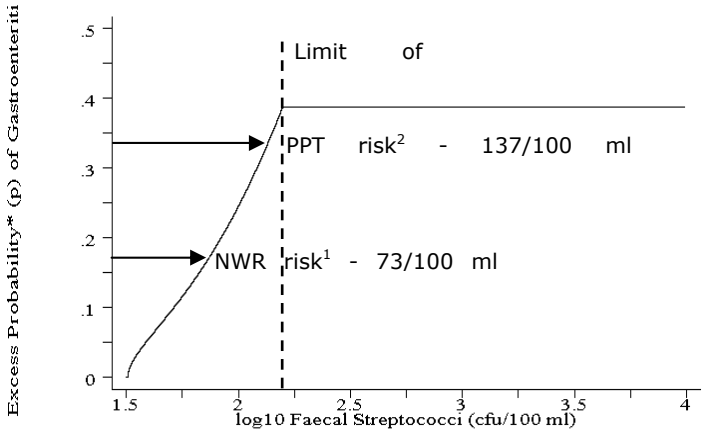
and the term p_{32} is the probability of gastroenteritis where x = 32 cfu per 100ml (p=0.0866) and adjusts the relationship to reflect excess rather than absolute probability of illness relative to those who do not swim.

For exposure above 158 faecal streptococci per 100ml:

$$y_{(x>158)} = y_{(x=158)}$$

The model, as illustrated in Figure 1, predicts the excess probability of gastroenteritis commencing at 32 faecal streptococci per 100ml, this being the concentration point below which there is no excess illness attributable to exposure. The 158 faecal streptococci per 100ml upper limit beyond which the excess probability remains constant is an assumption due to the fact that no bathers were exposed to higher concentration than this in the epidemiological study[7]. The probabilities of gastroenterities associated with non-water related risks and person to person transmission factors are also shown in the figure.

The dose-response functions are used to calculate the proportion of swimmers exposed to faecal streptococci concentrations, as defined by the faecal streptococci distribution, likely to suffer from gastroenteritis. Statistical distributions of faecal streptococci densities in samples taken from beaches around the UK coast show a $\log_{10}$-normal pattern (Wyer et al, 1995). The mean and standard deviation of the log-arithmetically transformed organism concentration can be used to produce probability density functions, assuming normality. Such a normal probability density function is shown in Figure 2 based on the $\log_{10}$ mean and $\log_{10}$ standard deviation concentrations of faecal streptococci found at identified beaches around the UK coast for the period 1999-2001.

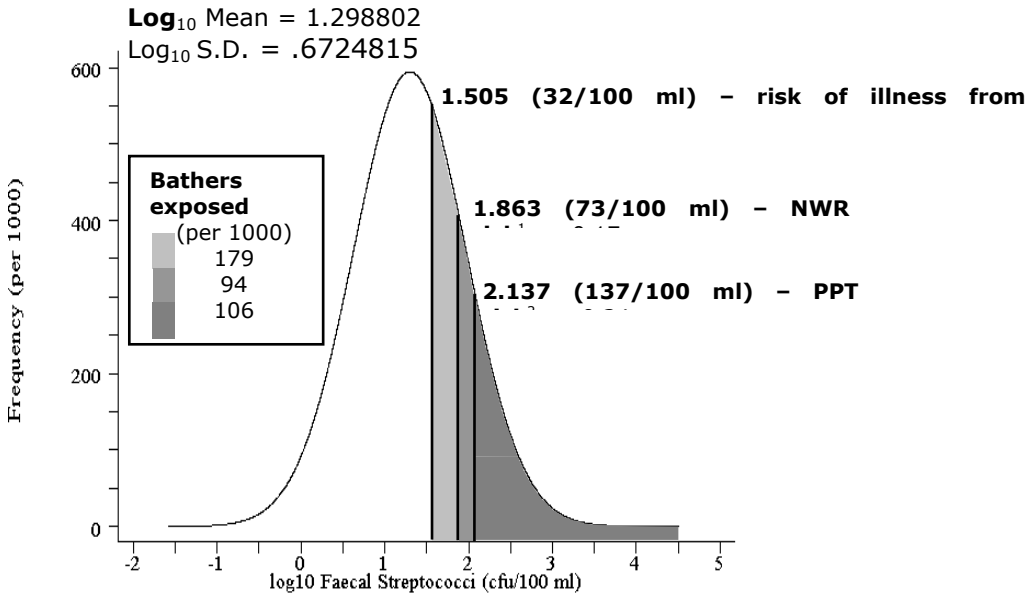


[1] Non water related risk factor – equivalent to every day activities
[2] Person to person transmission factor – equivalent to contact with ill family members

Source: Wyer et al (1999); adapted from Kay et al (1994)

Figure 1 Relationship between exposure to faecal streptococci (cfu/100 ml) at chest depth in marine water and the probability (*p*) of developing gastroenteritis

[7] This assumption is likely to lead to some underestimate in the excess risk of illness.



[1] Non water related risk factor – equivalent to every day activities
[2] Person to person transmission factor – equivalent to contact with ill family members

Figure 2 Probability density function for faecal streptococci exposure and proportions of the area under the curve exceeding threshold risk factors (defined in Fig 2) based on data for average UK bathing water quality 1999–2001 (total curve area adjusted to 1000).

Adapted from Wyer et al (1999)

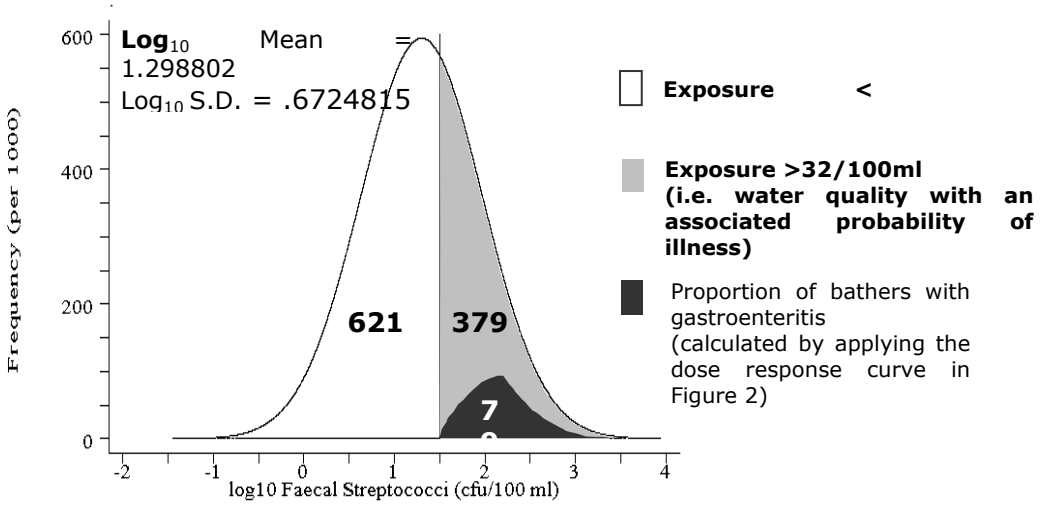
The statistical distribution of the faecal streptococci densities can be used to define the probability of exposure to water at different qualities. The greatest probability of exposure is around the $\log_{10}$ mean value of the distribution. The area under the curve between any two points represents that proportion of the population exposed to water quality represented by the two points. For example, in Figure 2 the area under the curve below 32 FS per 100ml ($\log_{10}$ 1.505) gives the proportion of the population exposed to water quality with an associated probability of gastroenteritis equivalent to not swimming. The integration of areas is based on a total exposed population of 1000, being the total area under the curve.

The dose response function is then applied to such a faecal streptococci probability density function, with the corresponding integrated area showing the proportion of swimmers exposed to concentrations above 32 per 100ml, who are likely to suffer from gastroenteritis. An example of such integration is shown in Figure 3, with the integrated area defining the population reporting gastoenteritis for a faecal streptococci exposure distribution based on the average UK bathing water quality data 1999-2001. The proportion of this area to the total area under the curve, gives the expected excess rate of gastroenteritis (per 1000) for a beach with water quality described by the $\log_{10}$ mean and $\log_{10}$ standard deviation of the distribution. As shown in Figure 3, of the 1000 persons assumed to be exposed, 621 experience water quality unlikely to produce any health effect. Of the 379 who experience water quality that might make them ill, 79 become ill with symptoms of gastroenteritis.

Using the procedure described above, the risks of gastrointestinal illness associated with bathers' exposure to the quality of UK coastal bathing waters present over the period 1999-2001 were derived[8]. Table 1 shows the risks of gastrointestinal illness for

[8] This was done using the statistics software package - Stata© - Stata Corporation.

the combined years data (1999-2001) as well as the risks for each individual year. As can be seen the excess risks of illness have been falling as the quality of bathing water



has improved over the period.

Figure 3 Integration to calculate total excess gastroenteritis for a faecal streptococci exposure distribution based on the average UK bathing water quality data 1999–2001 (total curve area adjusted to 1000).

Adapted from Wyer et al (1999)

Table 1. Excess Risk of Gastrointestinal Illness Associated with UK Bathing Waters (1999-2001)

Year	Log_{10} Faecal Streptococci Concentration (cfu/100 ml)[1]		Estimated Excess Risk - Number ill/1000 exposures
	Mean	Std Deviation	
1999-2001	1.298802	0.6724815	79.01
1999	1.338799	0.7100151	90.02
2000	1.322392	0.6650758	82.31
2001	1.235384	0.6363582	65.01

[1] Includes inland bathing waters. Takes no account of abnormal weather waivers. Also includes waters for which, more than or less than the usual 20 samples were obtained.

B. Assessment of population swimming behaviour and the change in absolute disease burden for gastrointestinal illness associated with UK bathing waters

The question of applying the gastrointestinal illness risk estimates to data on swimming behaviour amongst the English and Welsh population in order to estimate the absolute disease burden for gastrointestinal illness arising from bathing in faecally contaminated UK coastal waters is now considered.

The data on swimming behaviour was taken from a questionnaire survey on coastal recreation bathing behaviour for a representative sample of 809 people from the English and Welsh population, such as could then be combined with the epidemiological risks of gastrointestinal illness established earlier.

The calculations presented in Table 2 show various statistics from the survey sample related to swimming activity in which the head was submerged. As can be seen a total of 460 swimming episodes involving head submersion were recorded, which gives a mean number of swimming episodes of 8.85. In order to establish the mean for the sample of respondents one must divide the total by the 809 respondents in the sample rather than by the number who undertook the activity (52 in the case of those who went for a swim/dip).

Table 2. Exposure to Coastal Water from Swimming Episodes Involving Head Submersion in 2001

No. of people who went swimming in UK coastal waters	No. of episodes of swimming in 2001 (95% confidence interval)	Mean episodes per person (95% confidence interval)	Median episodes per person
52	460 (313-607)	8.85 (6.02-11.67)	5

Using the data from Table 2 it is possible to apply these figures to the excess risk of gastrointestinal illness estimates derived earlier and, multiplying by the number of people in the English and Welsh population, establish the gastrointestinal illness disease burden for England and Wales arising from faecal contamination of UK coastal waters. Table 3 below shows the relevant calculations in order to estimate the gastrointestinal illness disease burden under a number of different assumptions regarding the excess risk of suffering gastrointestinal illness. The total number of swimming episodes for the survey sample can be estimated using either the mean or median number of exposures per person figures from Table 2. This total number of episodes figure is then divided by the total number of people in the survey sample (809) to give the exposure (to risk) rate for the total sample (rather than for just those that went swimming). This is then multiplied by the excess risk of gastrointestinal illness and the population of England and Wales (52.9 million) to give the disease burden for England and Wales arising from swimming in faecally contaminated UK bathing waters.

As can be seen from the shaded cells in Table 3 the predicted 'baseline' gastrointestinal illness disease burden resulting from swimming in faecally contaminated UK coastal waters for the year 1999 ranges between 1.52 and 2.71 million cases depending on whether the mean or median number of swim episodes per person is used as the basis of the total number of exposures calculation.

The table also shows the predicted gastrointestinal illness disease burden for the year 2001 following the improvement in UK coastal bathing waters that occurred since 1999. These range between 1.1 million cases and 1.96 million cases, depending again on the basis of the total number of swimming episodes calculation.

Table 3 Gastrointestinal Illness Disease Burden for the English and Welsh Population

Total swimming episodes calculation basis[1]	**(1) Total no. of exposures in 2001 (95% confidence interval)**	**(2) Total Sample Exposure Rate [=(1)/809] (95% confidence interval)**	**(3) Excess Risk of Gatro-intestinal Illness[2] (prob. per person)**	**Disease Burden - Number of excess cases of gastrointestinal illness per year [=(2)x (3)x 52.9 million] (95% confidence interval)**	**Change in Disease burden between baseline year (1999) and improvement year (2001) (95% confidence interval)**
Mean	460 (313-607)	0.57 (0.39-0.75)	0.090	2.71 million (1.86 – 3.57 million)	0.75 million (0.52 - 0.99 million)
			0.065	1.96 million (1.34 - 2.58 million)	
Median	260	0.32	0.090	1.52 million	0.42 million
			0.065	1.10 million	

[1] In order to calculate the total number of episodes for use in the grossing up exercise, use can be made of either the mean or median episodes per person from Table 2. The median is used since it is less susceptible to outliers in the sample, whose effect will be greatly multiplied when grossing up estimates to the population level.

[2] The figures relate to risks related to swimming only, and may or may not be correct for other bathing associated water activities. Epidemiological evidence relating to other high exposure activities such as surfing, etc., is currently inadequate for a parallel figure to be established for these activities (WHO, 2001).

Although there is some degree of uncertainty associated with the disease burden figures, principally due to technical issues regarding the shape of the bacterial probability density functions associated with UK coastal waters and with the effect of prior population immunity impacts on illness (Hunter, 2000)

C Assessment of Economic Benefits from reducing the gastrointestinal disease burden associated with improvements in coastal bathing waters

The economic value of the reduction in disease burden associated with the risk of gastrointestinal illness from bathing is based on taking the above estimation of the change in the disease burden number of episodes of GI associated with swimming and multiplying by the willingness to pay to reduce an episode of GI from swimming. The willingness to pay (representing the measure of economic value) of reducing an episode of GI associated with swimming is based on estimates from a contingent valuation study.

Total swimming episodes calculation basis	**Change in Disease burden between baseline year (1999) and improvement year (2001)** **(95% confidence interval)**	**Mean WTP for avoiding one GI episode** **(95% confidence interval)**	**Economic value of Benefits associated with disease burden reduction in GI associated with improvement in bathing water**
Mean	0.75 million (0.52 - 0.99 million)	£17.32[2] (£12.51-22.15)	£12.99 million (£6.5 – 21.9 million)
Median	0.42 million		£7.27 million

[1] Based on evidence presented in section A and B

[2] Based on unpublished WTP contingent valuation study

ANNEX 4. Case Study on Air Pollution

1. Background:

The European Community has **Risk assessment for particulate air pollution**

Legislation in place that sets limit and target values for air quality with the objective of reducing and avoiding harmful environmental and health effects. The legislation builds on WHO guidelines for air quality in Europe and Commission working group's documents:

Council Directive 99/30/EC sets down limit values for PM_{10}: 50 µg/m3 for the 24-hour average and 40 µg/m^3 for the annual average.

Air pollution with particulate matter (PM) claims an average of 8.6 months from the life of every person in the European Union (EU), but Germans lose more: 10.2 months of life in the year 2000.

Current policies to reduce emissions of air pollutants by 2010 are expected to save 2.3 months of life for the EU population and 2.7 months of life for the population of Germany. This is the equivalent of preventing 80 000 premature deaths and saving over 1 million years of life in the EU; the corresponding figures for Germany are about 17 000 premature deaths and over 240 000 years of life (see Fact sheet EURO/04/05 of 14 April 2005)

Regulatory framework

Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe

Aim of risk assessment

Estimate burden of disease, mortality, costs of particulate air pollution on European population.

Protection target

According to national legislation; generally protection of health of the population from environmental damages is explicitly mentioned in most national constitutions.

2. Problem:

Hazard identification and dose-response relationship

WHO: air quality guidelines global update 2005: http://www.euro.who.int/InformationSources/Publications/Catalogue/20070323_1

"Research on PM and the interpretation of research findings on exposure and risk are complicated by this heterogeneity, and the possibility that the potential of particles to cause injury varies with size and other physical characteristics, chemical composition and source(s).The 2000 review *(1)* found evidence sufficient to link PM to a variety of adverse effects on mortality and morbidity, in both the short and the long term. It offered quantitative estimates of risks for selected outcomes, based on the epidemiological information. The epidemiological evidence is supported by an increasingly strong foundation of toxicological research"

The risk for various outcomes has been shown to increase with exposure, and there is little evidence to suggest a threshold below which no adverse health effects would be anticipated. In fact, the lower range of concentrations at which adverse health effects has been demonstrated is not greatly above the background concentration, which has been estimated at 3–5 µg/m3 in the United States and Western Europe for PM2.5. The epidemiological evidence shows adverse effects of particles after both short- and long-term exposures.

Example:

Table 1: WHO air quality guidelines and interim targets for particulate matter: annual mean concentrations

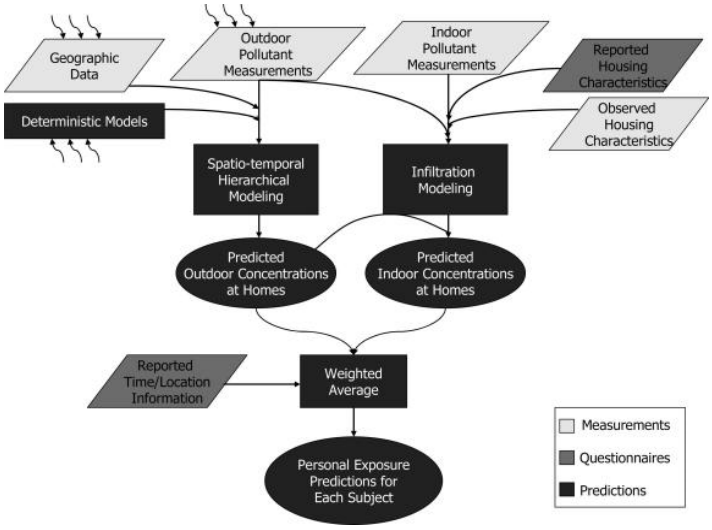
	($\mu g/m^3$)	$PM_{2.5}$ ($\mu g/m^3$)	Basis for the selected level
Iinterim target-1 (IT-1)	70	35	These levels are associated with about a 15% higher long-term mortality risk relative to the AQG level.
Interim target-2 (IT-2)	50	25	In addition to other health benefits, these levels lower the risk of premature mortality by approximately 6% [2–11%] relative to theIT-1 level.
Interim target-3 (IT-3)	30	15	In addition to other health benefits, these levels reduce the mortality risk by approximately 6% [2-11%] relative to the -IT-2 level.
Air quality guideline (AQG)	**20**	**10**	These are the lowest levels at which total, cardiopulmonary and lung cancer mortality have been shown to increase with more than 95% confidence in response to long-term exposure to $PM_{2.5}$.

3. Risk assessment

a) Exposure assessment

While most studies used in WHO guidelines are based on general population related exposure averages, new development has used modelling based on different data sources (e.g. emission inventories, road traffic density) and immission data from all available measuring stations. Based on addresses and detailed small area related air pollution distribution data, subjects' address history, GIS models, personalized exposure histories can be compiled and thus allow much more precise estimates of personal exposure which can then be linked to specific health effects. In addition dispersion modelling approach has recently been developed as an alternative for assigning individual exposure indices based on both physical and stochastic processes. It is seldom used because detailed emission and meteorological data are required.

One example is given in the graphic below: (*Environ. Sci. Technol.*, Article ASAP DOI: 10.1021/es8030837)



b) Hazard-effect estimates

Hazard effect is generally expressed in terms of increase in mortality in the general population with increasing air pollutant levels (see table 1 and 2 above), hospitalisation rates and different other health outcomes (ranging from respiratory symptoms, lung function, haematological and cellular parameters to heart rate variability and atrial fibrillation) are also linked to short and long term pollutant exposures. It is important to distinguish short term exposure effects, which occur most obviously during high pollution episodes, but have clearly been shown on lower levels in numerous time series studies, and effect of long-term exposure, which is the continuous exposure to pollutants especially urban populations are experiencing.

c) *Risk characterisation, risk assessment*

Risk is most often expressed in terms of number of additional deaths, hospitalisations, days with increased medication per additional 10 µg/m^3 short or long-term exposure. These risk estimates generally stem from observational population studies. Obviously experimental studies are only possible in a limited environment (chamber studies) with limited exposure and exposure time. Also these studies are in most cases restricted to healthy young adults.

As population based studies do not show signs for thresholds of health effects, the results are communicated as dose-response relationships. The majority of studies' finding suggest a linear increase of health deterioration with increasing pollutant levels.

4. Uncertainty analysis

"There are several uncertainties and limitations involved in using epidemiological evidence for quantitative assessment. A key assumption is that the relationship between air pollution and health effects is causal. The likelihood of causation is strengthened when: (*a*) epidemiological results are replicated by similar findings in different studies with variable underlying conditions; (*b*) multiple health outcomes appear to be affected in a consistent and coherent manner; and (*c*) the results are supported by either toxicological or controlled studies on humans. There are several methods for expressing the underlying uncertainty in HIA estimates. The level and range of uncertainty can be expressed descriptively and qualitatively through the use of confidence intervals, through sensitivity analysis of the more important assumptions and through the use of expert judgement and subjective probability exercises "(WHO, 2005).

All statistical analyses give 95% confidence intervals. In addition there are numerous studies (especially for short term effects) showing similar findings in different countries and at different pollution levels. This might add to the argument of a causal relationship.

However there are fewer studies on effects of long-term exposure, as these require a different, more demanding design (cohort studies) and a long follow-up.

SCHER 2005: *"The SCHER agrees that there is increasing epidemiological evidence that $PM_{2.5}$ may be related to adverse health effects especially in susceptible populations and vulnerable groups. However, there is currently a lack of knowledge on the exposure-response function for adverse health effects in Europe. However, it is SCHER's opinion that there may be risk for $PM_{2.5}$ which needs to be limited. If an air quality standard for $PM_{2.5}$ is decided upon, it is SCHER's opinion, that the scientific basis for the use of a PM2.5 standard would be surrounded with uncertainties and gaps in knowledge for the European situation*".

5. Risk assessment advice to risk managers

WHO gives in the guidelines examples on health impact for different levels of pollutant exposure. This should help local, national, or international authorities to decide on the legal limits they want to introduce (see table 1).

6. Risk Management

Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe

http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:152:SOM:EN:HTML

Determination of requirements for assessment of concentrations of sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM10 and PM2.5), lead, benzene and carbon monoxide in ambient air within a zone or agglomeration

Particulate matter (PM_{10}/$PM_{2.5}$)

	24-hour average PM_{10}	Annual average PM_{10}	Annual average $PM_{2.5}$ (1)
Upper assessment threshold	70 % of limit value (35 µg/m^3, not to be exceeded more than 35 times in any calendar year)	70 % of limit value (28 µg/m^3)	70 % of limit value (17 µg/m^3)
Lower assessment threshold	50 % of limit value (25 µg/m^3, not to be exceeded more than 35 times in any calendar year)	50 % of limit value (20 µg/m^3)	50 % of limit value (12 µg/m^3)

(1) The upper assessment threshold and the lower assessment threshold for $PM_{2.5}$ do not apply to the measurements to assess compliance with the $PM_{2.5}$ exposure reduction target for the protection of human health.

7. Monetarisation

Example from: http://ec.europa.eu/environment/enveco/air/pdf/betaec02a.pdf.:

BeTa (the Benefits Table database) has been developed by netcen, part of AEA Technology, to provide a simple ready reckoner for estimation of the external costs of air pollution.

Example of calculation:

- The dispersion models, combined with GIS data on population distribution, provide an estimate of exposure for rural France of:
- 336 person. µg per m^3 per tonne of PM2.5 (see 'Further data', below).
- The exposure response function for PM2.5 acute effects on respiratory hospital admissions shows that there are:
- 3.46x10-6 (0.00000346) respiratory hospital admissions for every person. µg/m^3.
- Multiplying these figures together provides an estimate of:
- 0.00116 respiratory hospital admissions for each tonne of $PM_{2.5}$ released.
- Each hospital admission is valued at €4,320.
- Multiplying this by the number of cases per tonne emission (0.0016) gives an estimated externalityof:
- €5.01 for effects on respiratory hospital admissions per tonne release of $PM_{2.5}$ in rural France

RURAL Marginal external costs of emissions in rural areas, year 2000 prices

	SO_2 €/tonne	NO_x €/tonne	$PM_{2.5}$ €/tonne	VOCs €/tonne
EU-15 average	5’200	4’200	14’000	2’100

URBAN Marginal external costs of emissions in cities, year 2000 prices

Urban results for NOx and VOCs are taken to be the same as the rural effects, given that quantified impacts are linked to formation of secondary pollutants in the atmosphere (ozone, nitrate aerosols). Given that these take time to be generated in the atmosphere, local variation in population density has little effect on the results.

Urban externalities for PM2.5 and SO2 for cities of different sizes are calculated by multiplying results for a city of 100,000 people by the factors shown below. Results scale linearly to 500,000 people but not beyond. These results are independent of the country in which the city is located. Once results for the cities are calculated, nationally specific rural externalities should be added to account for impacts of long range transport of pollutants.

	$PM_{2.5}$ €/tonne	SO_2 €/tonne
City of 100,000 people	33,000	6,000
Population Factors		
500,000 people	5 times	5 times
1,000,000 people	7,5	7,5
Several million people	15	15

Literature

Council Directive 99/30/EC

Fact sheet EURO/04/05

Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008

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SCHER, 2005: Opinion on New evidence of air pollution effects on human health and the environment.

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