REPORT ON

PRIORITIES IN THE EU FOR RISK ASSESSMENT IN THE NON-FOOD AREA

Part 1: ***Identification of areas of risk to be covered over the next 3 to 5 years***

Part 2: ***Recommendations of practical measures for the promotion of best practice for harmonised risk assessment by the non-food scientific committees***

Part 3: ***Identification of overlaps between food and non-food areas***

by

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EXECUTIVE SUMMARY

1. This report is the result of a three month scoping exercise conducted by the author over the period of July, August and September 2003. It covers a broad range of topics rather than attempting an in depth study on particular issues. The principal driver for this project is the recognition that the separation of food and non-food areas due to the formation of European Food Safety Agency provides an opportunity for a comprehensive reappraisal of the nature and use of scientific advice on human health and environmental issues by the EU. The aim is to characterise changes in the nature, scope and organization of risk assessment that are likely to be needed over the next few years. It must also be acknowledged that the proposed changes are against a background of general satisfaction with the work of the non-food committees and the quality of the support they have received over the past six years.

2. The principal themes addressed are:

   - identification of areas of risk to be covered over the next 3 to 5 years (Part 1);
   - recommendations of practical measures for the promotion of best practice for harmonised risk assessment by the non-food scientific committees (Part 2);
   - identification of overlaps between food and non-food areas (Part 3).

3. The information used for this report came from the following sources:

   - A search of the published and grey literature;
   - the findings from a survey based on a questionnaire, designed for this project;
   - interviews/discussions conducted with officials, scientific advisors, representatives from industry, national governments and NGOs;
   - analysis of the Opinions of the nine scientific committees administered by DG SANCO over the past six years.

4. As a consequence of these investigations the principal factors that are likely to influence an expansion of risk assessment have been identified as follows:

   - stronger enforcement of existing legislation;
   - further efforts to coordinate EU policies and initiatives for the protection of human health and the environment;
   - public concerns;
   - new developments in technology and other emerging issues.

5. It is anticipated that over the next three years the principal areas for risk assessment will be very similar to those at present. However, the total work load is likely to increase considerably due to a combination of further legislation and growing public concern. In addition to the establishment of robust mechanisms for meeting this demand, it is recommended that much more attention should be given to anticipating the potential human health and environmental impacts of new technologies and other emerging issues. In the past failure to be proactive on issues relating to human health

and to the environment, has had serious adverse consequences for the public acceptance of new technologies.

6. The author of this report concludes that it is vital that risk assessments are:

   - credible and convincing;
   - clear and consistent;
   - cost effective and current (i.e., up-to-date).

7. There is considerable public distrust over various aspects of risk assessment and risk management practices. This can only be counteracted by ensuring that all aspect of such work are of high quality, independent and open to public scrutiny.

8. The survey conducted for this report indicates strong support for the development of a close working relationship between the Scientific Committees working with DG SANCO and between these committees and Scientific Committees of other Commission Services (DGs) such as the Joint Research Centre (JRC) and European Union agencies. Two such organisations were highlighted for the development of close collaborations in the survey:

   - The European Food Safety Authority (EFSA);
   - The European Environment Agency (EEA).

   The report identifies ways in which further collaborations could function.

9. The survey indicates that the initial priority for the non-food Scientific Committees should be to establish an effective working relationship with the European Food Safety Authority because of the many potential areas of overlap. Stressors (agents, substances), where overlap occurs, may be classified as follows:

   - plasticizers and other substances present in plastic film, baking and wrapping paper (also found in toys, cosmetics and personal care products and occurring as environmental contaminants);
   - food contaminants, both chemical and biological. (They are also used widely in industry);
   - pesticide residues and natural toxins (also found in herbal medicinal products, cosmetics and other personal care products and textiles);
   - additives (also used in cosmetics and personal care products, in tobacco and by various other industries);
   - procedures for dealing with issues such as the evaluation of mixtures, identification of vulnerable groups in the population, identification and characterisation of emerging issues, application of non-animal tests, evaluation of processes, worker safety and environmental protection;
   - sharing of technical data;
   - determination of research priorities;
   - means used for stakeholder communication.

10. Insufficient, secure funding for scientific advice on risks (internal and external) is considered to be a major limiting factor in determining the range and thoroughness of assessments of risks from non-food stressors of concern in the future

Acknowledgement

The author is very grateful to the many individuals who have given their valuable time to answer questionnaires, take part in interviews and discussions, help in obtaining key documents and providing other administrative support.

1. INTRODUCTION

Since 1997 the organisation of scientific advice on the assessment of risks to human health and to the environment has been organised principally through the Directorate General (DG) for Public Health and Consumer Protection (DG SANCO). Although there has been general satisfaction with the way this advice was provided, in 2001 the decision was made to separate the risk assessment of stressors or agents in food from those of non-food stressors through the establishment of an independent European Food Safety Authority. This has provided the opportunity for the Commission to reconsider the nature and organisation of scientific advice necessary to facilitate a high level of protection of human health and of the environment in the European Community. A primary purpose of this report is to inform decisions on the nature and delivery of risk assessments in the non-food area.

The report focuses on the following themes:

- Part 1: Identification of areas of risk to be covered over the next 3 to 5 years;
- Part 2: Recommendations of practical measures for the promotion of best practice for harmonised risk assessment by the non-food scientific committees;
- Part 3: Identification of overlaps between food and non-food areas.

Discussion of the structure of the future scientific committees in the non-food area was not within the remit of this report.

The work was conducted over the period of three months, from 25th June to the end of September 2003. In view of the short period of time allowed for this work the report should be regarded principally as a scoping exercise rather than an in depth analysis of individual issues.

2. METHODOLOGY

There are many stakeholders in the EU who may influence the need for scientific advice in the area of the protection of human health and the environment over the next decade.

For the purpose of this study they have been categorised as:

- officials who, by the nature of their duties, are likely to require scientific advice from time to time;
- Commission staff involved in conducting or sponsoring research;
- scientists who currently provide advice to the Commission;
- senior officials in Member States involved in human health and environmental issues;
- specialists in key areas of technological development/emerging issues;
- members of the European Parliament;
- members of NGOs and trade unions;
- staff of trade associations and other industrialists;

- officials in other international bodies such as the World Trade Organisation (WTO), the World Health Organisation (WHO), and the International Labour Office (ILO).

Several hundred such individuals were identified (partly with the help of DG SANCO). In the short time available to complete this scoping project it was not possible to meet all of the stakeholders. Instead effort was concentrated on obtaining the views of stakeholders in the first three categories and testing their opinions.

This report draws on the following sources:

- Interviews conducted with Commission officials and members of Scientific Committees as well as other stakeholders (scientists and officials in several Member States, industry representatives, some members of NGOs) involved in either initiating requests for scientific advice, providing scientific advice or responding/affected by such advice. The use of Scientific Committees in the EU is shown diagrammatically in Figure 1.

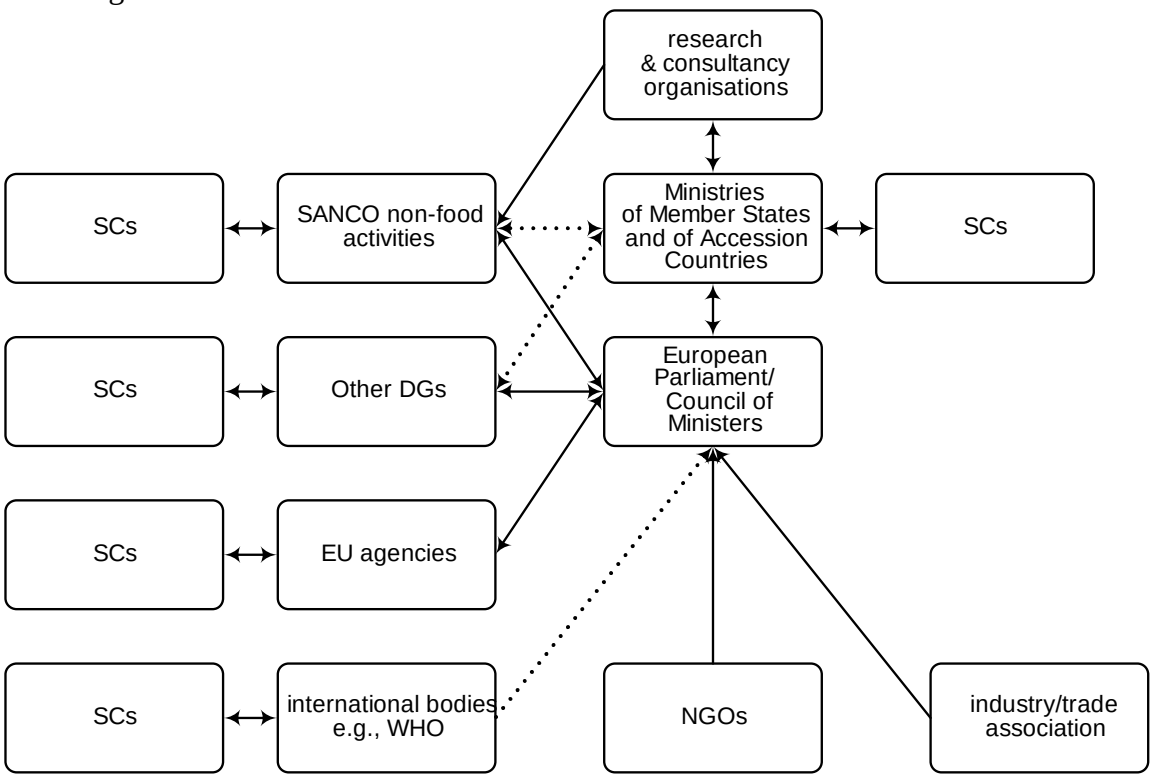

***Figure 1*:** **Stakeholders in Risk Assessments of Chemical, Biological and Physical Agents**

- In view of the rather short time period available for this investigation the number of such interviews was inevitably limited and in some cases involved small groups rather than one to one interviews. In total 89 individuals were interviewed. This number is too small to identify a "typical" view of a particular stakeholder. Instead, the aim was to cover a broad range of views while concentrating on those who are most actively involved in the risk assessment process.

- Analysis of the published literature. A wide ranging literature search was conducted using electronic search engines supplemented by hand searching of journals etc considered to be of particular relevance. Because of the breadth of issues pertaining to risk assessment, priority was given to the identification of emerging technologies and issues relating to the harmonisation of risk assessment.

- Evaluation of the Opinions of the non-food Committees over the past six years. Opinions from each of the nine Scientific Committees administered by DG SANCO were scanned to identify:

    - the range of topics addressed;
    - the areas of overlap;
    - gaps in coverage of agents/stressors;
    - the ways Opinions were expressed.

  An attempt was also made to identify the Scientific Committees in other DGs and EU Agencies. Further work is needed to establish a comprehensive list of these along with their mandates.

- Preliminary examination of Directives, White Papers and other publications of the EU and of its Member States. It proved to be very difficult to access all the key documents because many of them are not published in conventional form .

- Use of a purpose designed questionnaire (see Appendix 1). This questionnaire was distributed electronically and/or by hand to over two hundred and seventy individuals. Since no mailing list suitable for the purpose could be identified this had to be established de novo. Individuals were selected according to their role in risk assessments for the EU. The number of responses was 103. Many of the respondents did not wish their responses to be attributable.

- Examination of the structures used to integrate food and non-food risk assessment in the Member States and in countries outside the EU. The main source of information was from scientists involved in the risk assessment process in individual Member States.

3. IDENTIFICATION OF AREAS OF RISK TO BE COVERED OVER THE NEXT 3 TO 5 YEARS

As discussed in the two reports of the Task Force on the Harmonisation of Risk Assessment Procedures (Scientific Steering Committee (SSC), 2000; SSC, 2003), over the past twenty or so years, risk assessment has become an increasingly important source of information for risk managers in determining whether further regulation of specific products and processes (termed "stressors" for the purpose of this report) is necessary and important that procedures are in place to ensure that this advice is of the highest quality and timely. It is vital to characterise as far as possible the present and likely future needs for risk assessment This is the primary purpose of this chapter.

The main reasons for requesting an Opinion from any of the non-food Scientific Committees at present (and conceivably in the future) are the following:

a) legislative requirements;
b) policy issues;
c) new technological developments;
d) social trends;
e) public/political concern;
f) recent major incidents/accidents;
g) new data on known hazards.

It is therefore valuable to consider likely trends in these areas and how these may affect the future requirements for risk assessment and risk management.

3.1. Fulfilling legislative requirements

3.1.1. The Scientific Committees

The need to meet regulatory requirements is the most obvious rationale for the existence of the Scientific Committees.

3.1.1.1. The Scientific Committee on Toxicity, Eco-toxicity and the Environment (CSTEE)

The CSTEE is involved in the risk assessment element of a number of directives including:

- the existing substances regulation 793/93 under which it provides its Opinion on the risk assessment reports that are coordinated by the European Chemicals Bureau;
- the safety of toys 88/378/EEC and 88/379/EEC;
- restriction of the marketing and use of dangerous substances 76/769/EEC;
- the general product safety directive 2001/95 EC;
- classification, packaging and labelling of dangerous substances;
- phthalates 2003/113/EC, 98/485/EC, 98/815/EC;

- textiles and leather azodyes 2002/61/EC;
- asbestos 1999/77/EC;
- air quality 1996/62/EEC;
- water quality 2000/60/EEC, 76/160/EEC and 98/83/EC;
- waste 86/278/EEC.

New regulatory standards or strategies are being developed in several of these areas. Thus, the need for scientific advice is certain to increase. For example, the regulations that will follow from the White Paper on the EU chemicals policy (cf., the proposed new European system called REACH, for Registration, Evaluation and Authorisation of CHemicals[1]) will require some form of risk assessment for between 20000 and 80000 chemicals. It is also probable that the addition of a further ten Member States will lead to more requests for a scientific assessment of requests for derogations that involve health and/or environmental considerations. Further legislation on waste and soil contamination appears likely. Sustainability issues are also expected to become more prominent. The application of REACH following the implementation of the Chemicals Policy will also impinge on the formulation of many commercial and domestic products such as paints, cleaning agents, polishes, etc. Currently there is no independent scientific risk assessment of such products.

There are other product areas too which are poorly regulated at present where a continuing growth in the market appears highly likely. For example, odour improving/masking agents. It is a regulatory offence in some Member States already for an industrial/commercial facility to emit unpleasant odours. The use of chemicals to manage such odour emissions is therefore gaining in use. This parallels the increase use in domestic premises and public buildings.
The use of tobacco additives is a further area where regulation is needed. A recent survey in three Member States indicates that there are over 2000 such additives in current use.

3.1.1.2. The Scientific Committee on Cosmetics and Non-food Products for the Consumer (SCCNFP)

The main activities of the SCCNFP stem from the obligation for prior consultation of the committee under directive 76/768EEC on ingredients and substances in cosmetics. It is anticipated that the level of work on cosmetics and other personal care products in response to further tightening of regulatory requirements will increase. It is noted that there are some 8000 cosmetic ingredients listed in the Blue List (2000) and even more in the INCI. Only about 5% of these have been evaluated for their effects on human health. Moreover, there are new directives, updating previous legislation on detergents and on biocides, which have still to be implemented.

[1] COM(2003) 644 final, 2003/0256(COD), 2003/0257(COD)

The SCCNFP must be consulted where regulations on alternative animal tests are proposed (76/768/EEC). It also has a role under the general products safety directive (2001/95/EC).

It is anticipated that the work in this areas will continue to increase as public concern heightens on the safety of various constituents. A major challenge in this area of risk assessment is the increasing problems in obtaining in vivo animal data that has to date provided the main source of information on hazards. This situation arises as a consequence of the decision by the Commission to ban in vivo testing for cosmetics. There are also gaps in the legislation on cosmetics that mean that some substances in widespread use. For example, aroma therapy oils and creams containing biocides are not adequately addressed at present.

3.1.1.3. The Scientific Committee on Medical Products and Medical Devices (SCMPMD)

The SCMPMD has no statutory role or regulatory responsibility for medical devices or medical products, responsibility for medicinal products being assigned to the European Medicines Evaluation Agency (EMEA). The EMEA has not to date been asked to look at the issue of blood safety per se, although it is responsible for the evaluation and supervision of blood and plasma medicinal products authorised through the Community's centralised procedure. The safety of medical devices is managed through “new approach” Directives that require notified bodies, designated by the Member States, to ensure compliance with certain essential requirements. The SCMPMD was consulted on medical devices from time to time under 93/42/EEC. A new directive on medical devices is nearing the final stages. This directive will give more emphasis to the health and safety aspects of such devices. The EMEA established the Working Party on Herbal Medicinal Products in 1999 as a forum for Member States. While herbal medicines continue to be licensed at national level, the Working Party provides common guidance to Member States on the interpretation of quality, safety and efficacy of these medicines within the context of EU pharmaceutical legislation. The Working Party also has a role to advise the European Commission, on request, in the context of the new EU legislation on herbal medicinal products.

3.1.2. Other possible areas for future legislation

There are several factors driving the need for further legislation relating to human health and the environmental effects of commercial products. These include:

- producing a more level playing field for industrial competition;
- a desire to encourage innovation in the EU in order to enhance its international competitiveness;
- consistency in legislation across different kinds of products and compatibility with WTO approaches;
- public, political and professional concerns.

It can be anticipated that, in response to public concerns, an ever-expanding group of consumer products will become the subject of regulatory controls, on the basis of health, safety and /or environment issues. Areas of concern, in regard to product safety, include substances added to textiles, furnishings, fabrics and building materials, especially the widespread use of dyes such as azodyes in consumer products (these range from textiles to finger paints and tattoos). The so-called smart/intelligent materials are also likely to need risk assessment.

A further issue is the need for some assessment of the environmental impact of most products, starting with medical products, cosmetics and other personal care products. It is noted that only one of the current non-food committees has expertise among its members on environmental issues.

Worker protection is also an area where some expansion of risk assessment activities is necessary. It is an anomaly that the CSTEE is required, by legislation, to consider worker protection issues while the SCCNFP is not. It is notable that while hundreds of thousand of people are employed in the beauty care industry across the EU, no formal assessment is made of their exposure to the products they use or the effects of these products.

The needs of the 10 Accession States may also add to the requirement for involvement of the Scientific Committees. However the nature and scale of such involvement is very uncertain at this time.

Overall it appears likely that there will be a progressively increasing demand for risk assessment in the domains of each of the three non-food Scientific Committees. The administrative arrangements that will ensure that this demand is met are not yet entirely clear. Thus there is a proposal that the risk assessment of industrial chemicals should be carried out within a new agency. It seems probable that such an agency would require a minimum of two years to be established. It is uncertain how medical devices will be assessed in the future.

3.2. Impact(s) of policies

Over the past decade, the EU has generated a plethora of policy papers impinging on human health and the environment. The flow of such documents is likely to increase. Unfortunately, until recently, too little attention has been given to the cross linking and consolidation of policy initiatives. Consequently, it is very difficult to achieve an overview of EU policy across the areas of human health and the environment. Perhaps, for this reason such an overview has not been published. This apparent lack of an integrated approach has resulted in:

- excessive compartmentalisation of activities;
- duplication of effort and;
- a failure of valuable initiatives to make their deserved impact.

A particular recent development of concern is an apparent increase in the use of hazard criteria as a substitute for risk assessment. This trend is appearing in both environmental risk assessment (persistence, biomagnification and toxicity (PBT)) and in the human health field (carcinogenicity, mutagenicity and reproductive affects, (CMR)). It needs to be widely understood that all agents /stressors are hazardous however they do not necessarily constitute a risk unless exposure is sufficiently high. PBT and CMR criteria are useful for some labelling purpose and for setting priorities for risk assessments. On their own however they provide an unsound scientific basis for ensuring public health and environmental protection.

Legislation has played the major role in promoting the protection of the environment in the EU. There are over 700 items of community legislation including more than 250 directives relating to the environment. The Treaty of Amsterdam provides the legal basis for the community environmental policy (Articles 174–176). The Treaty also makes sustainable development one of the EU's main objectives. This has yet to work its way through into specific activities involving the risk assessment of human health and /or the environment. In part this may be because the EU, under the principle of subsidiarity, only tackles environmental problems when it is in a better position to do so than individual Member States. This separation also tends to inhibit an EU under integration of environmental protection measures.

There is relatively little public health legislation essentially because of the limited legal competence.

Moreover there are differences in view about the scope and meaning of public health. In some definitions, public health incorporates protection of workers—in others, worker health is seen as a separate issue.

The Decision establishing the New Programme of Community Action on Public Health sets out the programme's objectives as:

- improvement of information and knowledge for the development of public health policies;
- enhancement of capability to respond rapidly, and in a co-ordinated fashion, to public health threats;
- promotion of health and prevention of disease by addressing health determinants across all policies and activities;
- in so doing, the programme will contribute towards:

    a) ensuring a high level of human health protection in the definition of all community policies and activities through the promotion of an inter-sectoral and integrated health strategy;
    b) tackling inequalities in health, even those linked with environmental factors, such as housing; and
    c) encouraging cooperation between Member States.

The EU has moreover, produced a separate strategy paper on health and safety at work (COM(2002)118 final). The stated objectives of this strategy are:

- a continuing reduction in occupational accidents and illnesses;
- mainstreaming the gender dimension into risk evaluation (NB the gender dimension does not appear from the Opinions of the Scientific Committees to be given much emphasis at present);
- prevention of social risks;
- enhanced prevention of occupational illnesses;
- taking account of demographic changes in terms of risks, accidents and prevention;
- taking account of changes in forms of employment, work organisation arrangements and working time and of the size of firms;
- analysis of new or emerging risks.

Close coordination of worker protection and public health policies would be particularly useful since it is the combined impacts of work and non-work situations, which are important to ensure a high level of public health.

A distinction is also often made in various EU and international policies between consumer protection, environmental health and public health. From a logical standpoint, consumer health is a sub-set of public health. A diagrammatic representation of the relationship between the various EU policy documents discussed above is given in Figure 2.

The EU consumer policy is indicated in the Treaty of Amsterdam (Article 153 (129a). This states that the community shall contribute to the health, safety and economic interests of consumers. Article 95 (105a) emphasises the role of scientific evidence, both at the EU level and at the national level in the evaluation of proposals concerning health, safety and environmental protection measures. It also recognises that the right to health and safety protection is one of the five basis rights of the consumer. The Amsterdam Treaty allows Member States to adopt more stringent measures to protect the health of their public as long as they are compatible with the Treaty (in particular are not used as a trading barrier).

The situation for environmental health is more complex: some use the term to mean a combination of human health and environmental protection while others consider it to describe the environmental cause of adverse effects only on human health.

Environmental health is better described as ‘a European environment and health strategy’ as in the recent Communication from the Commission (EC 2003). It appears, however, that this definition excludes traffic and domestic accidents even though these are a major cause of prolonged injury or death. The term ‘environment and health’ should strictly be used to cover direct contributions to adverse health effects in man other than those that can arise from contact with consumer products. It should also cover indirect effects of the environment on human health. On this logic, a third sub-set would then be genetics and health. There is a similar lack of clarity on the use of the term ‘environmental protection’. It has recently been proposed

that this term should not include domestic and farm animals. For issues concerning such species, the term 'animal health' should probably be used. (SSC 2003).

The progress in human health policy is towards an evidence-based health policy. This would make the strategies used to identify best practice much more compatible with those of risk assessments relating to consumer health and environment and health.

A strong emphasis on an evidence-based public health policy in the EU should also facilitate international cooperation. This is essential to meet the growing inter-nation dependency, the worldwide health inequalities and the rapidity with which infectious diseases can be transferred from one country to another. (Murray and Frenk 2001, Kickbusch 2000, Rowley 2002).

A new development is the move to establish additional EU independent Agencies that are intended to have an important responsibility for risk assessments. The European Food Safety Authority (EFSA) was the first of these but there are plans for a new Chemicals Agency (COM (2001) 88 final), and a European Centre for Disease Prevention and Control[2]. Others are under discussion. At present it is difficult to gauge what the impacts these proposed agencies will be on the need for external scientific advice and how it will be obtained.

The recent strategy on environment and health (2003) seeks to achieve the following objectives:

- to reduce the disease burden caused by environmental factors in the EU;
- to identify and to prevent new health threats caused by environmental factors;
- to strengthen EU capacity for policy making in this area.

This is in line with another very important and over-arching policy paper on the establishment of a European Research Area[3], to which the Sixth Framework Programme for Research and Technological Development (FP6)[4] is linked.

[2] Proposal for a regulation of the European Parliament and of the Council Establishing a European Centre for Disease Prevention and Control (COM/2003/0441 final – COD 2003/0174).

[3] "Towards a European research area" - COM (2000)6 - 18 January 2000

[4] http://europa.eu.int/comm/research/fp6/index_en.html

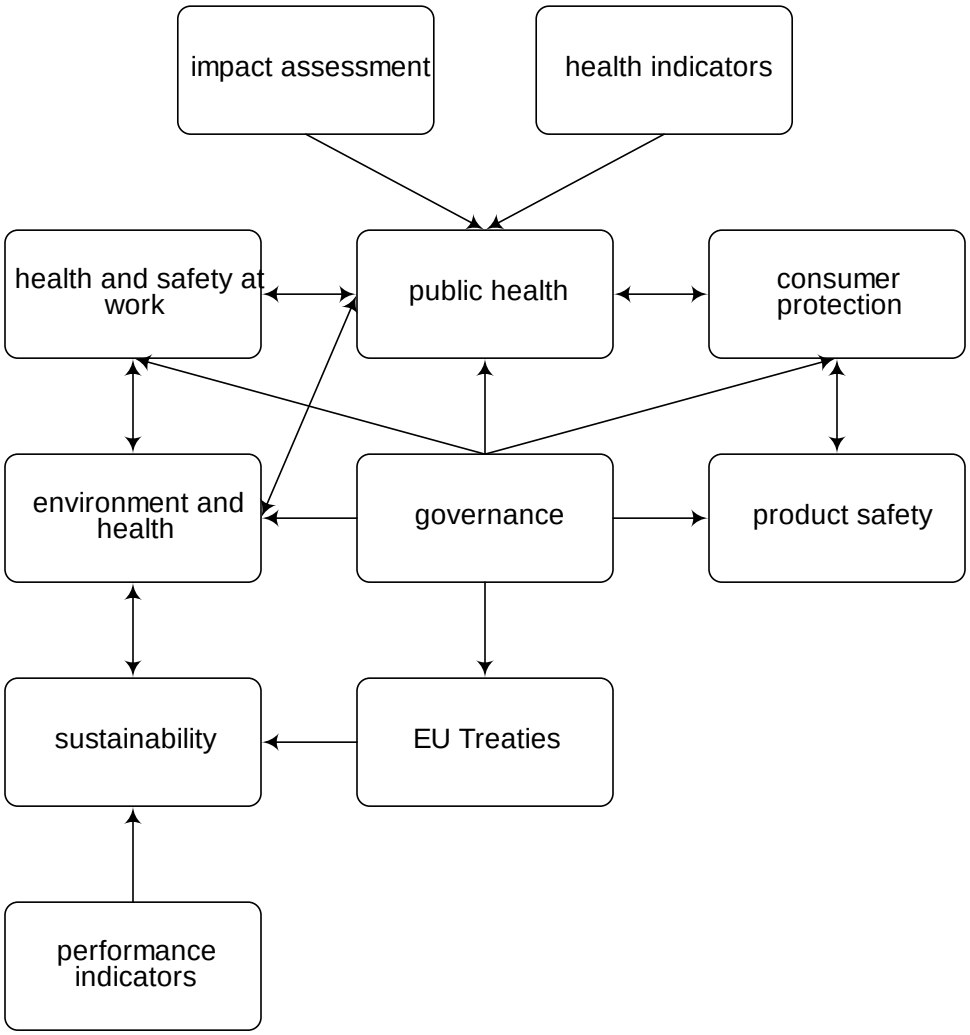

***Figure 2*:** **Relationship between Recent, EU Policy Documents on Human Health and Environmental Protection**

This White Paper incorporates and extends previous Community action programmes on: pollution-related diseases (decision 1296/1999 of the European Parliament and the Council), and on health promotion and health monitoring (decisions 645/96/EC and 1400/97/EC). These are consolidated in the public health (2003-2008) plan (decision 1786/2002/EC). The White Paper also touches on a range of other relevant policies including, food safety legislation, recommendations on electromagnetic fields, tobacco control, health impact assessment guidelines and radiation protection. The White Paper should also be considered in the context of the separate environmental health action plans (NEHAPs) of individual Member States.

Monitoring and surveillance are essential elements of any public health improvement programme.

The European Community Health Indicators Project (ECHI) has developed a framework for the development of harmonised environmental health indicators. It covers outdoor (ambient) air quality, housing, the drinking water supply, the sewage system, ionising radiation, noise, workplace exposures and accidents and social and cultural environment indicators. To date the outcomes of this project do not seem to have been integrated with other activities in the Community concerned with risk identification.

A harmonised and integrated approach is needed for identifying, characterising and dealing with risks from processes as well as products. In January 2003 the Commission launched an 'integrated impact assessment tool' to facilitate the identification of health impacts of projects, policies and strategies not primarily meant to affect health. This is intended to be an aid to policy makers in preparing new initiatives. This tool needs to be considered alongside the traditional techniques in risk assessment of processes such as HAZOP, fault tree analysis, HACCP).

Areas that are anticipated to become a much more important part of the EU risk evaluation framework over the next few years include:

- a specific requirement to assess the risks to children (White Paper on a European Environment and Health Strategy 2003);
- increasing recognition of the need to consider the impacts of exposure to mixtures of stressors (SSC 2003);
- evaluation of the persistence of chemical and biological materials under the range of environmental conditions that occur in the expanded Community;
- the incorporation of sustainability criteria (COM (2001) 53 final).

A further issue for the future, that may or may not involve new legislation, is the frequency with which risk assessments are revisited. There is no legal requirement at present for a review of existing risk assessments in the non-food areas. In view of the increasingly higher levels of protection of public health and of the environment, demanded by the public, and the continually evolving nature, which underpins the science for risk assessment, it would be appropriate to introduce such a review at least every decade (with the option to review any stressor promptly if a new cause for concern is identified).

A general aim of legislation is to replace chemicals causing concern with safer chemicals. This strategy is exemplified by the REACH proposals. To promote this strategy a basis for risk comparisons, will need to be established. This is important for stakeholder understanding. To date, it has largely been excluded as a formal aspect of risk assessment of individual chemicals/products. A wide adoption of risk comparisons could have a substantial effect on the work of the Scientific Committees.

Inevitably, many other aspects of EU policy have implications for human health and the environment for example transport policy, energy policy, waste management policy. Mechanisms to assess the impacts of combinations of policies need to be developed. A

further important consideration is the impact on the EU of policies developed by WHO, USEPA, WTO, OECD .

3.3. Influence of new technological developments

The number of technological developments with the potential to impact on human health and/or the environment is considerable. In the past, typically, interest in possible health and environmental impacts has only occurred once the technologies were in widespread use. This is no longer acceptable to the public, as is evident from the public and political reaction to the introduction of genetically modified agricultural crops. In the future, much more effort will be required to anticipate at an early stage in their development, possible impacts of new technologies, in order that their benefits can be realised while minimising any effects to human health and to the environment.
The EU has also a number of activities considering various aspects of the impacts of technologies in particular DG Research programmes such as the New and Emerging Science and Technology (NEST) programme, JRC activities and COST programmes and the activities of various other EU funded research centres. More integration between these initiatives is needed.

It is important for the future of technological developments that potential adverse impacts they could have on human health and/or on the environment are identified at an early stage and measures taken to avoid or ameliorate such problems. The consequences of not doing so may include public alarm leading to the distrust of the technology or to damage to human health and/or to the environment which is difficult to reverse (see, for example, EEA 2001). A continuing dialogue between those at the forefront of promoting the new technologies with experts in human health and the environment is necessary to avoid such outcomes. A full evaluation of the potential impacts of these technologies is a very time-consuming process and well beyond the scope of this project. Nonetheless, an indication of some of the issues for particular technologies that are likely to have a major impact on the citizens of the EU can be given.

These technological developments also raise particular questions regarding containment of adverse impact on workers. It is notable that a number of very different technologies have one feature in common namely the potential for self replication (nanotechnology, biotechnology, computing science, robotics). This inevitably heightens public concern.

3.3.1. Biotechnology

From a societal perspective this area is dominated by public and political concerns about risks from genetically modified organisms or the products from these in food. (Pardo *et al* 2002). However, biotechnology developments are likely to lead to the development of many new non-food products too (Rowley 2002). Among these are likely to be:

- use of plants to produce drugs and other specialty chemicals;
- tailor-made microorganism strains for particular bio-remediation purposes. This potentially could be on a large scale as Europe tries to recover large areas of land, which have been contaminated over the past 200 years. Moreover, the EU faces a major challenge to find an alternative safe way of dealing with municipal solid waste (MSW) as a consequence of the decision to progressively reduce the amount of MSW going to landfill and incinerators. The use of biotechnology offers a valuable prospect of achieving this goal;
- replacement of existing synthetic polymers with those derived from plants.

Each such application requires a specific risk assessment.

3.3.2. Nanotechnology

Nanotechnology is an umbrella term, which describes technological developments at the sub-micron level. The EU, the USA and many national governments have separately identified nanotechnology as a priority area for research because of its potentially major commercial and strategic implications (Lane 2001). In the biomedical field to date, nanotechnology has been focussed on two potential applications: drug delivery systems and biosensing. It has the potential for example to detect diseased cells in situ, to deliver drugs to specific sites in the body and to allow the development of skeletal implants, which are much stronger and lighter than those currently available. It is difficult to find current research on the possible adverse effects of the outputs of this technology. However, it is well known in the public health field, that inhalation of submicron particles can cause severe effects on both the respiratory and cardiovascular systems of susceptible individuals. At present only the potential advantages of injecting particles of this size range into the blood stream appear to be discussed.

There are interesting proposals too for the application of nanotechnology for environmental problems. For example, the use of nanoparticles of iron to clean up contaminated soil and ground water (Wei-xian Zhang 2003).

Concerns about nanotechnology have already become the basis for at least one novel, *Prey*, by Michael Crichton (2002). It is therefore important that a scientific assessment of the potential health and environmental risk is conducted in the near future for each type of application before public concerns are heightened

3.3.3. Mass electronic communication systems

Electronic communication systems continue to expand at a very rapid rate. An increasing number of epidemiology studies report some biological changes from excessive exposure to electromagnetic radiation. The effects from mobile phones and mobile phone transmitters are already areas of public concern. The link between subtle biological changes and possible health and environmental implications need to be scrutinized carefully to distinguish between effects that are 'physiological' (and may be even beneficial?), those which may be considered undesirable and those where the human health and/or environmental consequences are probable. Two particular issues that will need to be addressed are:

- risks from exposure to multiple sources of EMF because the range of sources is increasing. The development of electronically controlled home environments and the increasing amounts of time people spend indoors are important aspects of this issue;
- effects of combinations of exposure to physical stressors and chemical/biological stressors. (For example, chemical emissions from personal computers combined with EMF exposure and poor body posture).

3.3.4. New materials

In the past, new materials were often used to replace existing ones by building industry, manufacturers of textiles, fabrics, furnishings and even medical devices with only a cursory examination of the health and environmental impacts of the new material. This was the case with replacing asbestos with man-made mineral fibres. In future it is important that a proper comparative risk assessment is conducted before any substitution is embarked on. Not only should the health and direct environmental consequences be examined thoroughly but some form of life cycle analysis should also be conducted to gauge the indirect consequences. From a human health perspective much more attention needs to be given to possible allergenic/sensitisation effects in individuals who may be in frequent contact with such materials.

An interesting new development is the introduction of smart/intelligent materials for a variety of purposes. These materials are intended to monitor the condition of the product or person they surround. Some types of such materials may release chemicals if the monitoring reveals that a change in the conditions would be beneficial. A thorough understanding of the possible health risks of such materials is appropriate.

3.3.5. Robotics

The public views robotics as a rather narrow range of applications. However, the potential applications of robotics are very broad and include surgical devices, remote handling of hazardous materials and labour saving devices. There are obvious health and safety considerations (such as physical accidents involving robots). Other concerns have

also been expressed ,such as dispersal of hazardous materials and electromagnetic radiation emissions.

3.3.6. Non- fossil fuel energy sources

The sources of fossil fuels in Europe are limited. Moreover, there is increasing recognition of the global consequences of the combustion products of such fuels on human health and the environment. Direct toxic effects and indirect ones arising through damage to the ozone layer and through global warming are of importance. There is great interest in developing alternative sources of energy. Insufficient attention has been given so far, to the idea of establishing a robust framework that addresses the human health and environmental impacts of each option. This would serve as a base for comparative purposes.

3.3.7. Use of markers for product tracing and authentication

Individual manufacturers may add chemical or biological markers to their products in order to identify their authenticity. To date, the use of such markers is very limited but the potential for growth in this market is enormous as manufacturers attempt to counteract the counterfeiting of their products. The EU has accepted the application of markers to control the illegal use of diesel oil intended for heating purposes. It has been argued that because relatively small amounts of substances are added there is no risk to either human health or to the environment. However, if this practice were to be extended widely, this would not necessarily remain the case. It would not be appropriate to use tonnage manufactured, as a cut-off point below which the risk assessment of such marker types is not required. Addition of markers could become a legal requirement for some products where sourcing is considered to be an important issue.

3.3.8. Greater use of recycled materials

Commitment to sustainability is a major driving force for the recycling of waste of all types. Recent directives on landfilling and on incineration limit the amount of municipal solid waste that can be disposed of by these routes. Alternative means of treating municipal solid waste may not remove contaminants, such as metals or persistent organic chemicals (dioxins, PCBs, and brominated flame retardants). Therefore there is a risk of the accumulation of such contaminants in materials subjected to multiple recycling . How products are treated at the end of their useful life should become an important aspect of the evaluation of the risks they engender (see EU sustainability policy). This is not the case at present.

The above list of emerging issues is not comprehensive. Further discussions are needed to identify others. It is proposed that regular meetings are held involving all the key stakeholder to discuss potential human health and environmental impacts of emerging technologies.

3.4. Social and health and environmental trends

The human health and environmental situation in Europe is continually changing. It is valuable to understand the nature of these changes, the principal causative and exacerbating factors and the trends over time. It is not possible to consider all the societal, health and environmental impact trends in this report.

3.4.1. Societal trends

3.4.1.1. Progressive urbanisation

Human and environmental hazards include: increased exposure to vehicle generated pollutants, higher demands for energy generation and water, reduced manpower for the rural/agricultural environment with consequent further changes in agricultural practice.

3.4.1.2. Increased longevity

The EU is faced with both an increasing population of the very elderly and public expectations of higher quality of life. Human health issues include: longer period of exposure to chronic pollutants, greater use of various drugs, greater vulnerability of the elderly to environmental stressors, and greater dependency on medical devices.

3.4.1.3. New addictive recreational drugs

No toxicity studies are carried out for most drugs of this nature. The animal models for predicting addiction are poor. In order to provide an informed public health advice in this area an understanding of the risks involved is essential.

3.4.1.4. Increased self medication with 'natural' remedies

This reflects a trend among the public to favour alternative means of ensuring their health rather than conventional medicine practices. Issues include: inadequate knowledge of toxicological properties, great variability in the content of active agents in the preparations, possible interactions with conventional drugs.

3.4.1.5. Changing nature of the workplace

Across Europe there is a trend for high technology manufacturing, office and home working. Issues include: prolonged exposure to indoor environments (as well as the interior of motor vehicles), insufficient knowledge about the nature of this exposure and the interaction between chemical, biological and physical components in this environments.

3.4.1.6. Growing emphasis on a sustainable environment at work and at home

Issues include: increasing exposure to recycled materials (which might have higher levels of contaminants), more tightly sealed environments with reduction in air exchanges (See also v).

3.4.1.7. Expanding use of mono-culture in agriculture

Issues include: impacts on biodiversity, increasing potential for environmental contamination through persistent use of the same agricultural agents.

3.4.1.8. Threat of bio-terrorism

There are concerns about both the acute human health impacts, and deliberate chronic contamination of the environment.

3.4.1.9. Global economy

The growth of the global economy means that large number of the population may be exposed more or less simultaneously to a new product. It is therefore imperative that all such products are adequately assessed for their possible impacts on human health and on the environment. This is often not the case at present. Rapid transport of goods and people provide the potential for the quick spread of illness. Very rapid response strategies must be in place to meet this threat.

3.4.1.10. Simultaneous exposure to an increasingly complex range of stressors

This is a major issue of concern because it is a very common situation and yet only rudimentary knowledge exists of its significance in health terms. A framework needs to be developed to enable important interactions to be identified and managed.

3.4.2. Human health and environment trends

Set out below is a list of some conditions that appear to be on the increase along with the likely causative /exacerbating factors. A particular need is to identify vulnerable groups in the population and to identify the causes of their vulnerability.

3.4.2.1. Allergic and auto-immune diseases

Environmental stressors are believed to be the primary cause of the increase in these conditions. However, the principal causes of this increase have not yet been properly identified. The contribution of auto-immune changes to various common human diseases is not well researched.

3.4.2.2. Antibiotic resistance including human and animal pathogens

Implications include the loss of effectiveness of valuable antibiotics for human use and animal use and possible environmental impacts.

3.4.2.3. New pathogenic microorganisms including zoonoses

As well as the rapidity with which human diseases can be transferred between countries, recent experiences with Bovine Spongiform Encephalopathy (BSE) and Severe Acute Respiratory Syndrome (SARS) indicate the potential for new zoonoses to transfer between animals and between animals and man. It must be anticipated that identification of new zoonoses will continue to occur from time to time in the future.

3.4.2.4. Fertility reduction in humans and environmental species and cancer of the endocrine organs

There is a particular interest in the role of endocrine disrupters in promoting these effects. It should not bee assumed however that that the sole cause of these effects is exposure to endocrine disrupters

3.4.2.5. Effects of chronic stress

There is a general increase in mental health problems in the western world. One aspect of this is chronic stress which is increasingly common workplace related condition, with a very profound societal and individual impact. It is uncertain whether physical, chemical and/or biological stressors can contribute to this condition.

3.4.2.6. Musculo-skeletal problems

The increase in musculo-skeletal problems involving the upper body has been attributed in part due to work associated activities such as prolonged work with personal computers. It is uncertain what factors influence this condition other than body posture and psychological factors.

3.4.2.7. General hearing loss

The increase appears to be in part to be related to continual exposure to sound including loud music from various electronic devices. Other factors that promote hearing loss are not yet certain.

3.4.2.8. Chemical sensitivity

An increasing number of the population claim to be highly sensitive to one or more chemicals in consumer products. Little is known about the reason for this condition. There are unverified suggestions of the similarity between ‘chemical sensitivity’ and addiction.

3.4.2.9. Domestic and traffic accidents

These remain one of the principal causes of death and chronic morbidity across the EU. An increasingly elderly population will almost certainly increase the number of such accidents. This will result in an enhanced use of medical devices.

3.4.2.10.Loss of biodiversity

The full implications of changes in the balance of are rarely fully understood. A better understanding of the pint at which reversible changes become irreversible is particularly important.

3.4.2.11.Impacts of global warming and damage to the ozone layer (climate change)

The impacts (both direct and indirect) from these phenomena are potentially very wide ranging for both human health and for the environment.

3.5. Public and political concerns

Public and political perception of risk can be very different from the risk assessment as carried out by scientific experts. There is a large volume of literature on this subject (See Royal Society, 1992; Earle and Cvetkovich, 1995; Renn, 1997; National Research Council, 1989). The EU is currently completing its policy on governance, which addresses this issue, and how it could be addressed. Scientists have to appreciate these differences in views and to consider the extent to which some resolution of these differences is possible.

Important elements to the bridging of gaps between scientists and the public are:

- building public confidence in the objectivity and trustworthiness of the scientists. This is vital for the independent Scientific Committees;
- more effort by scientists to understand the nature of the public concerns in relation to each particular hazard and to address them.

These issues are discussed further in Part 2.

A further aspect is how increasing ‘market forces’ will affect the demand for risk assessments and who will conduct them.

3.6. Incidents and accidents

DG SANCO Scientific Committees were minimally involved in anticipating and advising on the management and monitoring of and/or learning from major incidents and other emergencies. Usually, during an incident all the efforts are directed towards crisis management. It is important as soon as possible during an incident to have independent

observers recording events. After the incident the emphasis is on finding a culprit and, as a consequence, the cause(s) of the incident become of secondary importance. However, the lessons learned should be embedded in the risk management culture.

3.7. New scientific findings on known hazards

Science is continually evolving and new discoveries are made. Among the few predictable outcomes of research is the detection of substances of current concern in new environmental compartments, and of chemicals of uncertain origin in the human body. To some extent it is possible to prepare for such developments through scenario exercises.
Priorities in the area of human health and environmental protection need to be established. The EU framework programmes of DG Research are designed to facilitate this at the EU level. Unfortunately, the coordination of this research with that of Member States remains poor. The independent Scientific Committees have had the opportunity to contribute to the identification of such areas. However, the principal vehicle for this was through the DG SANCO Scientific Steering Committee (which no longer exists). It is necessary to ensure the continuity of advice to DG Research and other DGs that fund research on the impacts of non-food stressors on human health and on the environment.

There should be a linkage too between outcomes of such research and the reviews of the relevant risk assessments.

3.8. Funding issues

In order to increase the scientific advice to meet the challenges discussed above additional funding will be required. For some products such as medicinal products an assessment fee is already charged bur for most it is not. The fee approach may be a rational one but it is difficult to apply where:

- the same stressor is used by a number of companies;
- the concern is about environmental contaminants such as dioxins;
- the industry producing a particular category of product is deemed to be important to the EU but is unable to afford to pay for an assessment.

There is a danger that evaluation of important risks may be delayed or even shelved through lack of funding support for appropriate risk evaluations.

The response from the questionnaire indicated the following order of importance (based on percentage of respondents rating on agent as of high importance) for risk assessment for various agents:
industrial chemicals> environmental pollutants> pesticides> medical devices> personal care products> household products>EMF> building materials> fabrics.

3.9. CONCLUSIONS

Key factors that are likely to influence the need for scientific advice on risks to human health and the environment have been identified as: legislative requirements and policies, rate of introduction of new technologies and/or major expansions in the use of existing technologies, societal, health and environmental trends, public and political concerns, international pressures for harmonisation and global cooperation, advances in scientific understanding, and occurrence of major incidents and accidents.

Table 1: A Semi-Quantitative Assessment of Substances for Risk Assessment (in numbers of chemicals)

industrial chemicals*	40–70 000
cosmetics components	8–10 000
tobacco additives†	>2000
medical devices	>2000
drinking water contaminants	>2000
pollutants in ambient air	>4000
indoor air pollutants	>4000
chemicals in other consumer products	uncertain
chemicals emitted from waste facilities	>1000

*Many of these substances are found in the consumer products and other sources.

†Excludes consideration of combustion products.

A semi-quantitative assessment of the number of chemicals for which a risk assessment is needed is given in Table 1. This excludes consideration of the many biological materials that also should have a risk assessment.

It is not possible to quantify the impacts of the above substances further without a more detailed examination of the relative importance of each of them. This is beyond the scope of this work. Nonetheless, in some areas there are already indicators of the order of magnitude of activity involved. On the basis of the work set out in this report a steady rise in the need for scientific advice on the risks is predicted, particularly in the following areas:

- cosmetics and other personal care products;
- industrial chemicals;
- chemical products for domestic use such as detergents, soaps and biocides;
- dyes and other additives in an increasing variety of consumer products, in frequent contact with skin;
- environmental pollutants (indoors and outdoors);
- devices emitting electromagnetic radiation;
- products created by geno-technology;
- non-prescription health remedies;
- medical devices.

It is anticipated that legislation will be introduced for the assessment of many consumer products and that this assessment will include both environmental impacts and worker protection issues.

It is recommended that a transparent system is developed for setting priorities for risk assessments.

4. RECOMMENDATIONS OF PRACTICAL MEASURES FOR THE PROMOTION OF BEST PRACTICE FOR HARMONISED RISK ASSESSMENT BY THE NON-FOOD SCIENTIFIC COMMITTEES

4.1. Providers of scientific advice

The use of external scientific advice by the Commission Services, in respect of human health and environmental issues, has increased substantially over the past decade. In part this is because scientific advice is viewed as generally objective and consistent with time. As a consequence scientific advice is among the most trusted opinions by the public. Scientific advice on health and the environment may be required for:

- risk assessment of individual stressors/agents (which may or may not involve development of standards);
- impact assessment of 'processes' of various kinds (both generic and specific);
- evaluation of the effectiveness of risk management options;
- strategic and/or detailed evaluation of new issues or issues of increasing importance;
- actions to be taken to control/reduce the impact of /learn from and therefore prevent emergencies /major incidents ;
- development of data gathering/monitoring and surveillance procedures and/or the interpretation to be placed on trends uncovered by these;
- research priorities and programmes.

In practice, there is considerable overlap between these domains and, therefore, an individual scientist may be involved in providing the Commission with advice in several domains.

Scientific advice may be provided by:

- members of staff of the Commission Services (including its research centres and agencies);
- employees of government departments of Member States;
- research institutes of Member States;
- commercial consultancy companies;
- university-based scientists providing advice directly or through the aegis of Scientific Committees;

- scientists belonging to a variety of other organisations often nominated or chosen for this role by national governments.

Many considerations influence the selection of the source(s) of scientific advice on the protection of human health and the environment. These include the nature of the expertise required (depth and breadth), the availability of the expertise, accessibility of the relevant information, costs, transparency, and last but not the least, credibility with third parties.

Since 1997, during the BSE crisis, the Commission has given increasing importance to the requirement that its scientific advice is not only expert but also independent and that the advice provided is accessible to all the stakeholders. The Commission has placed particular emphasis on the use of Scientific Committees comprising high level experts who are seen as independent of commercial and governmental interests. The advice of independent Scientific Committees is of particular value where:

- the issues are of high public/political concern;
- there is disagreement among Member States on the interpretation of the underlying science;
- of a broad multidisciplinary nature;
- there is insufficient readily accessible expertise available from within the Commission services;
- there is a need for a demonstrable separation of risk assessment from risk management;
- new issues are involved that require a thorough understanding of the current state of the science.

Demonstrable independence and objectivity is a growing issue particularly for the public and NGOs. While individual scientists cannot always be entirely objective, objectivity can be maintained by a committee as a whole, as a consequence of the diversity of experiences, knowledge and outlooks within each committee. (Parascandola, 2003).

Although, in principle, ad hoc committees could provide advice on each of these aspects, there are clear benefits in using a well-established committee. For example, it takes time to establish trust among all the potential stakeholders (who include Commission officials, the public and politicians, industry, NGOs), to develop efficient working procedures. Moreover, there is a likelihood of a much greater commitment to meet the deadlines set by the Commission.

Three Scientific Committees covering non food topics were established by DG SANCO in 1997 and are still continuing with their work:

- the Scientific Committee on cosmetics and non-food products (SCCNFP);
- the Scientific Committee on medical devices and medical products (SCMDMP);
- the Scientific Committee on toxicology, ecotoxicology and the environment (SCTEE).

The chairmen of these three committees, along with the chairmen of five food committees and eight independent members, comprised the Scientific Steering Committee, which coordinated the work of all the Scientific Committees across food and non-food areas. Typically the detailed work of Scientific Committees has been conducted through working groups (working parties, task forces) appointed by each main committee to deal consider specific issues in depth. The composition of these working groups in the case of the SSC and the CSTEE often includes external experts. In contrast external experts are rarely used by the SCCNFP.

With the formation of the European Food Safety Authority (EFSA, EC 2002) this formal coordination of the work of all the Scientific Committees involved in human health and environmental issues has been lost. In addition, the informal communication between non-food and food scientific specialists is greatly reduced. This is very unfortunate because many human health and environmental issues span the food and non-food areas. It has been recognised that there is a need to ensure continuing cooperation between the non-food and the food areas. To this end a new unit, unit D5 has been established in DG SANCO to ensure an effective interface with EFSA. Liaison between scientific committees will be facilitated by the SANCO Risk Assessment Unit on a day-to-day basis.

All these forms of advice are valuable for particular purposes. It is important that the procedures for appointment of individuals and organisations to give advice is seen to be open and be drawing on the best available expertise and not be perceived as prejudiced.

The current method of appointing members of the Scientific Committees is generally regarded as appropriate. However, the survey results indicate that more attention needs to be given to ensuring that this selection is based solely on the criterion of expertise.

It is not feasible for Scientific Committees to embrace all the necessary expertise in sufficient depth to address all the issues that they are required to tackle. It is not sufficient to rely on the expertise of a single member of the committee. Appointment of external experts is therefore essential to ensure the criterion of quality (credible and convincing) is fulfilled. The process for selecting individual external experts to participate in working parties appears to be less satisfactory. The survey shows that this process is not transparent and is often on the advice of one individual. It is recommended that the Commission Services draw up a list or establish a panel of experts in each of the relevant disciplines. This can be achieved through a call for expression of interest combined with the process for the appointment of committee members. Working groups would then be expected (wherever possible) to use members drawn from the approved and published list/panel. Apart from being a transparent process the establishment of such a panel would provide a useful initiation for younger scientists who could become committee members in the future. At the same time it might be appropriate to establish a sub-panel of experts who would be willing to become involved promptly if a major incident occurs.

Thought needs to be given to the title of such experts (e.g., appointed scientific expert to the EU in the field of toxicology, ecotoxicology, etc.).

A number of the respondents felt that the Scientific Committees should be described as Scientific Committees of the European Union rather than of DG SANCO. Employers are prepared to allow their staff to be members of Scientific Committees because of the prestige attached to the participation in the Commission activities. Strictly committees are already appointed by the commission

This is therefore an issue of perception. Nonetheless it needs to be addressed.

4.2. The organisation of advice

It is not within the remit of this report to propose an organisation structure for the delivery of scientific advice. However it is appropriate to consider some of the key factors that might inform the choice of structure. The criteria should include:

- efficient use of scientific expertise. This is very important because of the relative lack of experts in key areas. For example, is it really necessary that each committee has its own specialists in disciplines such as immunotoxicology? There is also a risk that over reliance on a single specialist on a committee may lead to some Opinions that are in reality one persons view on an issue (see below). Consideration should be given to grouping expertise in scarce disciplines to a single committee. This committee would then act as a source of expertise in this domain to the other non-food committees;
- comparable work loads for each of the main committees;
- avoidance of significant overlap of remits;
- flexibility to respond to changing priorities;
- mechanisms to address potential differences of Opinion between Scientific Committees;
- fitting with EU regulatory requirements and policy initiatives that are likely to demand risk assessments;
- satisfaction of potential members of committees with the organisation;
- understanding by those outside the system(other stakeholders);
- matching the delivery of risk assessments of major organisations with which close collaboration is needed.

4.3. The tasks of Scientific Committees

The process of risk assessment and its application is under continual close scrutiny by industry, national governments, Non Governmaental Organisations (NGOs) and other international bodies. The author of this report recommends that risk assessments should be:

- credible and convincing;
- clear and consistent;
- cost-effective and current.

These criteria might be described as ‘the three double C rules’ (or TDC rules) for risk assessment.

Up till now the emphasis in the European Union has been on ensuring that risk assessments are credible and convincing. This is because of evidence from various surveys that public confidence in risk management of a number of important issues is rather low.

To try to improve this confidence the Commission has placed responsibility on academic/non-industrial experts to carry out risk assessments on matters relating to human health. These scientists are expected to be both independent of the risk managers and have no potential conflict of interest in the outcomes of the risk assessments with which they are involved. The Commission has also tried to adopt measures to make the process of risk assessment and its outputs more open and transparent.

Rather less attention has been given to ensuring that the outputs of risk assessments are clear and unambiguous to all the stakeholders. In general, Opinions of Scientific Committees are not edited to ensure that the meaning is clear to both scientists and non-scientists. It helps public confidence if Opinions are consistent over time. This is more challenging for a number of reasons. Firstly, scientific understanding of a particular data may change with time and, secondly, the scientists examining may have different opinions.

The need for risk assessments to be cost effective appears not to be a general criteria at present. It will, undoubtedly, become increasingly important in response demands for risk assessments of an ever-increasing number of stressors. The real costs of conducting risk assessment should be recognised . The survey indicated that attention should be given to matching the level of sophistication of risk assessments to the risk management options available. It is proposed that a staged approach to human health risk assessment is introduced, as is the case for many environmental risk assessments.
Mechanisms also need to be put in place to ensure that risk assessments are current (up to date). If an issue arises the public will not be reassured to find out that the last time it was assessed was a decade or so previously!

The survey identified that the key issues in the conduct of a risk assessment by the Scientific Committees are:

- the increasing need for transparency throughout the process;
- ensuring a very high and consistent scientific standard;
- clarity (both for scientists and other stakeholders) about the precise outcomes of the risk assessment;
- a harmonised approach between different Scientific Committees to avoid apparent ambiguities in assessments and to facilitate collaboration between committees where practicable;

- reducing unnecessary duplication of work both between EU scientific committees and with other national and international scientific committees. RAs carried out by one scientific committee need to be readily utilizable by other committees.

The increasing sophistication of the risk assessment process and the likely increase in the number of risk assessments in future will mean extra resources. Universities and research institutes might not be willing to increase the time their staff spends working for the EU. This problem has to be tackled in another way.

For example:

(1) By increasing the number of scientists, who have the relevant expertise, employed by DG SANCO. Their role would be, in particular, to produce draft reports for the Scientific Committees. Thus, the time of the external experts will be used more efficiently. The possibility of the Commission hiring academic scientists for short periods or time to carry out these tasks should be examined. This approach could have the added benefit of identifying future committee members.
(2) By the introduction of a staged approach to risk assessment. In some cases the risk assessment required from a risk management point of view may be quite basic and a sophisticated answer is not necessary.
(3) By the development of a reliable data base. At present, for many questions committee members are expected to perform their own (unpaid for) literature searches
(4) Through giving much more careful attention to the framing of questions to Scientific Committees and ensuring that their implications for risk management are fully understood by committee members. (This issue is discussed further below.)

The solution, probably, can be found in a combination of the above approaches.

4.4. Public perception considerations

There is a burgeoning literature on the issues surrounding the perception of risk by the public and the reasons why perception of risk may differ from the estimate of the actual risk by scientific experts. It is beyond the scope of this report to address this issue in any depth. Differences in views between the public and the scientists may be of two types:

- stressors that scientists consider to be of relatively low risk but become a particular focus of attention and sociopolitical activity in society (social amplification see, for example, Renn 2003). Recent examples include BSE, SARS, and Genetically Modified Organisms (GMOs);
- stressors that experts consider to be an important risk but which the public has less concern about . Examples include smoking and radon exposure.

As part of the social amplification process certain categories of stressors may become 'stigmatised' . This has occurred with GMOs, bovine somatotrophin, steroid growth hormones. Terms such as 'chemicals' and 'radiation' are now almost automatically associated with being dangerous, toxic or deadly. The concerns may be magnified by a perceived inequitable distribution across the population. The literature indicates that recurrent failures in risk management arise ,in part, from inability of risk managers to recognise the complexity of a modern society. Lack of transparency and openness, a failure to consult interested parties and to respond adequately and in a timely manner to public concerns will damage trust of the public in the risk assessment process. Trust underlies confidence and, if this is shared across community, credibility of the risk assessment is achieved. It is very evident that it is much easier to destroy trust than to build it. Renn, Kasperson, Slovic and others identified five attributes of trust:

- competence (appropriate expertise);
- objectivity (assessments that are free from bias);
- fairness (all points of view acknowledged);
- consistency (assessments consistent over time);
- faith (a perception of goodwill).

It is important to take these concepts on board in addressing the issue of how to achieve and maintain confidence in risk assessments. The starting point in meeting the concerns of the public should be:

- an examination of current practices to ensure that Scientific Committees achieve consistent high standards over time and are easily understood by all the stakeholders;
- harmonisation to stop confusion in the minds of stakeholders when different Scientific Committees in various organisations arrive at different conclusions about the same/similar stressors.

4.5. The need for harmonisation

There are many players involved in the process of risk assessment. For historic reasons the risk assessment activities of each organisation are largely or entirely independent although individual scientists are often involved with more than one organisation. A more harmonised approach is highly desirable for a number of reasons:

- to aid the understanding of risk managers and other stakeholders who may need to examine different risk assessments on the same or related stressor from one or several Scientific Committees. This is the most pressing of the reasons why harmonisation should be implemented now rather than delayed;
- to enable the work done by one scientific body to be utilised, without unnecessary duplication of effort, by other risk assessors who are concerned with the same stressors or processes;
- to facilitate the comparison of risk from different products or processes that could be used for the same or similar purposes. This is particularly relevant where substitution is being considered;

- to ensure that the overall risk from multiple sources of exposure to the same stressor can be properly evaluated;
- to simplify the training of future risk assessors;
- to assist the integration into the EU of Accession Member States with their own practices for evaluating and managing risks;
- to achieve a common strategy in the use and interpretation of new methodologies;
- to establish a shared procedure, regarding emerging new technologies and the health and environmental questions. This needs to be at an early stage before widespread public concern has developed.

The need for an agreed strategy in DG SANCO, for harmonisation of risk assessment has become more crucial because of the recent decision to separate food and non-food risk assessments from April 2003. Another consideration for the future is the establishment of other Agencies of the EU that have risk assessment as an important part of their activities.

4.6. Mechanisms for achieving harmonisation

The following factors have been identified by the survey as the most important ones , which are likely to improve the confidence of the general public and politicians in risk assessment:

- public communication;
- increased collaboration between bodies involved in risk assessment;
- more transparency in the risk assessment process;
- an accessible database for risk assessments;
- ensuring the expertise of the risk assessors.

In reality many of these factors overlap. However, for the sake of clarity they are addressed below as separate ones. This inevitably means some limited repetition of discussion.

4.7. Public communication

Outputs should aim to be clear and unambiguous.
The language used in many scientific Opinions often lacks clarity when read by non-scientists. The lack of clarity takes several forms: too much technical language, inconsistency in terms to describe the same thing, too many caveats, gaps in information because committees assume knowledge which the reader may not have. Variations in the terminology used, was identified in the first report of the Task Force on the Harmonisation of Risk Assessment Procedures (2000) as a significant barrier to the further harmonisation of the work of the Scientific Committees. More importantly it is a source of confusion for stakeholders: In particular:

- the variation in terms used to describe the same situation. This is of particular importance for terms that are used to describe the nature and/or the magnitude of a

risk. Thus, in the report 18 different terms were found to describe de minimus risk. Terms need to be selected for each level of risk;
- difficulties can be encountered in the translation of committee Opinions into the various European languages, a situation that will be exacerbated as the number of Member States increases.

In the second Harmonisation of Risk Assessment Procedures Task Force Report(2003) it was recommended that, the Translation Services should be asked to advise on this issue. Once this has been accomplished Scientific Committees would be expected to use these terms in describing risks. This proposal needs to be progressed.

How to explain uncertainties is a further major communications challenge in terms of public confidence. As indicated above, some individuals welcome expression of uncertainty as a sign of honesty, while for others it may enhance their distrust of the information provided.

At present no formal expression of uncertainty is used by any of the Scientific Committees. Instead standard 'safety' factors are used. These factors are probably better described as uncertainty or default factors. If such practices are to continue the magnitude of the factors ought to be based on the extent of uncertainty involved.

"Uncertainty" is defined as the gap between scientific valid knowledge and the complete ultimate scientific evidence. The various forms of uncertainty need to be described separately:

- data gaps;
- measurement errors/unreliability (see Appendix 2);
- difficulties in extrapolation between use of substances/products, different species;
- conceptual and/or modeling difficulties.

It may be appropriate to establish an editorial sub-group in Scientific Committees to ensure consistency in presentation. It is recommended that:

- for each Opinion a summary in layman's language is produced;
- a harmonised terminology is achieved;
- a format for expression of uncertainties is established .

4.7.1. Ease of access to opinions

In principle Opinions are easily accessed through the website. However, as noted in the survey, for those who are not familiar with the system the site is not easy to find. For example, the web site address is 50 letters long. Most of the data used by individual committees is also inaccessible both to other committees and to the public.

It is recommended that:

- a simplified website address is provided and widely publicized;
- the web site is cross- linked to other relevant web sites of the Commission and its agencies;
- additional means are found for the dissemination of information on Opinions that are likely to be of particular public interest;
- the role of members of committees is defined, when communicating with the media.

There is no well-established process for stakeholders to obtain further details that underlie an Opinion of interest to them. Nor is there any defined mechanism for dialogue. This was identified in the survey as a barrier to trust.

It is recommended that:

- further data is provided to support an opinion;
- a mechanism for dialogue between stakeholders is established.

4.7.2. Bench marking of risks/risk comparisons

The expression of risk in absolute terms may raise unnecessary concerns among the members of the public and is not very helpful to the risk manager. Means need to be developed that are robust scientifically and accepted by stakeholders. Two possible approaches were identified in the survey:

- bench marking of risks against known and understood standards;
- comparison of risks and benefits.

Past attempts to benchmark risks have often failed to impress the public because voluntary risks are compared against involuntary ones (see, for example, Morgan et al 2000).

Despite these legitimate scientific concerns risk comparisons are of increasing importance in considering suitable substitutes for stressors that are deemed to constitute an unacceptable risk. The risk comparison of the original source with the substitutes should be available prior to management actions. A particular aspect in comparative risk assessments should be to compare the uncertainties.

It is recommended that:

- work is carried out to develop a framework for bench marking. This must start by considering the failure to be accepted of previous unified scales of risk (see, for example, those used by the nuclear industry);
- broad descriptive categories of risk are used e.g. minimal risk (see above).

4.8. COLLABORATION BETWEEN BODIES INVOLVED IN RISK ASSESSMENT

There is an increasing number of bodies around the world involved in risk assessment with differing structures and range of activities (see, for example, Hornbeek 2000) These can be grouped as follows:

- Scientific Committees within DG SANCO;
- EU agencies;
- organisations of experts in other DGs in the Commission Services;
- organisations of experts in individual Member States and in accession states;
- organisations of experts in candidate members states;
- organisations of experts participating in international bodies such as WHO and OECD;
- organisations of experts from non-EU countries.

The number of such organisations is probably in the hundreds. Currently the links even between the remaining Scientific Committees in DG SANCO are rather limited. The rationale for collaborating with selected organisations includes:

- a consistent and prompt response, particularly to issues of high public/political concern;
- providing a rapid and appropriate response to major incidents which includes the gathering of data to ensure that lessons from each such incident are learned;
- sharing of relevant information.

The survey has not identified existing effective mechanism for such collaboration. Indeed in most Member States a somewhat rigid compartmentalization of activities takes place (largely for historic reasons). For the reasons listed above the development of links with selected organisations should be embarked on as a priority.

Two types of link can be envisaged:

- links between officials in the public health division of DG SANCO with officials in the other organisations;
- links between the scientific advisors to both organisations.

It is proposed that initial priority be given to clarifying the current links between the various units in DG SANCO and other organisations. The next priority must be to establish in the revised structure for scientific advice in DG SANCO effective interactions between its own committees.

The survey identified strong support for the establishment of formal and effective links with the JRC and a number of Agencies of the EU. In order of importance these were:

- the proposed chemicals agency;
- EFSA;
- European Environment Agency;
- European Medicines Evaluation Agency;
- the proposed centre for diseases control.

Of particular note is that at least 50% of all respondents felt that formal links with each of these agencies was of high importance for the risk assessment activities administered by DG SANCO. There is a number of mechanisms by which a link could be developed and maintained, including:

- appointment of a correspondent in each relevant organisation;
- appointment of common committee members for key committees/working parties;
- annual stakeholder meeting with representatives from all the relevant organisations;
- committee(s)/working parties meetings at the Centre of each relevant organisation;
- invitation to representatives from the relevant organisations to attend committee meetings;
- setting up of common task forces/workshops for tackling major shared issues;
- regular attendance of members of the committee/secretariat at key conferences;
- linking of web sites.

These proposed mechanisms are not mutually exclusive. The most effective means of linkage may vary between organisations or more than one mechanism may be appropriate.

It is recommended that:

- priorities for linkage are identified. In the first instance the number for practical reasons needs to be small;
- discussions are held to identify the next steps in achieving collaboration with each of these organisations;
- a pilot scheme is set up with EFSA (see below for further discussion).

4.9. MORE TRANSPARENCY IN THE RISK ASSESSMENT PROCESS

This issue has already been discussed above. While the Opinions of scientific committees are available to all stakeholders the actual process by which these Opinions are produced is not subject to any external scrutiny. This may not remain acceptable to the public in the future. Potential ways of improving this transparency are:

- provision of more detailed documentation on how each Opinion is arrived at. One aspect of this is the separation of the reports from the actual Opinion (see Appendix 2);

- attendance/participation at certain meeting of outside observers;
- appointment of lay members to committees;
- provision of opportunities for stakeholders to present evidence and have it discussed at some meetings;
- use of an external auditor system(s) It is noted that external auditing of activities is an increasingly common procedure to ensure satisfactory performance (e.g. Manela and Moxley 1999);
- stakeholder participation at specific stages of the process;
- annual presentation of the work of the committees at an outside forum(s);
- guidelines are developed for the operation of the Scientific Committees and these are widely disseminated.

It is recommended that:

- the various approaches to improving transparency are considered and discussed with key stakeholders;
- one or more pilot projects are set up to test the actual benefits and difficulties;
- guidelines setting out the operating procedures of the Scientific Committees are devised and widely disseminated.

4.9.1. Improved interface between risk assessors and risk managers

An important aspect of the risk assessment process is to demonstrate independence of the risk assessors while ensuring that the work they conduct is clear, appropriate and timely from a risk management point of view (see above and appendix). To achieve this, the survey identified that dialogue must take place between risk assessors and risk managers. These need to be transparent in order to satisfy possible concerns of other stakeholders. There is also a need to establish 'good practice' in the risk assessment process.

It is recommended that:

- a procedure is put in place to ensure that proposed questions put to Scientific Committees by risk managers are discussed with a member of the committee and its scientific secretary prior to the formal request for an opinion;
- the good practice guidelines are developed and adopted (see Appendix 2).

4.9.2. Accountability of the risk assessment system

At present the committees are only accountable to DG SANCO officials. This may be a significant factor inhibiting trust of the public to the Scientific Committees. There are various ways (see, for example, Boote et al 2002) in which the public accountability could be developed:

- an annual report, followed by a meeting with stakeholders;
- an open meeting for all stakeholders (e.g., the European Parliament, Member States, consumers and their representatives, industry, etc.);

- an external auditing system;
- allowing stakeholders to observe selected meetings of the committees.

It is recommended that:

- ways are identified in which accountability could be enhanced. This process should involve discussions with key stakeholders;
- pilot scheme are put in place to test accountability procedures.

4.10. COMMON ACCESSIBLE INFORMATION USED FOR RISK ASSESSMENT

Establishment of a comprehensive and validated data base is increasingly necessary. Even among the scientific committees of DG SANCO information seen by one committee is often not systematically available to other committees. Ideally, such a database would be developed by a partnership of several of the organisations identified above. The availability of such a database if accessible to those with a legitimate interest could decrease the number of animal experiments and lead to improvement in the extrapolation of results (structure activity relationships) between related stressors.

It is recommended that:

- the current position regarding existing data bases is reviewed;
- criteria for a common data base are developed in conjunction with other interested parties;
- priority is given to the development of a readily utilizable database (NB with the imminent introduction of the REACH scheme starting such a database is extremely important and urgent).

4.11. ENSURING THE EXPERTISE OF THE RISK ASSESSORS

The criteria for the selection of Scientific Committee members are well defined by the Commission services as:

- a high level of current expertise in a relevant discipline;
- demonstrable independence from the primary stakeholders particularly industrial organisations;
- able to give sufficient time to the Scientific Committee;
- acceptance that part of the work is confidential.

In addition, there are other less defined criteria such as the need to: draw expertise from all Member States, cover a spectrum of opinions and approaches, achievement of a balance of disciplines, ability to work in a team.

The Second Harmonisation of Risk Assessment Procedures Task Force Report (2003) identified a number of new developments in risk assessment that should be incorporated in the process in the future namely:

- integration of human and environmental information;
- identification of sensitive groups of the population;
- assessing the impact of simultaneous exposure to multiple stressors;
- quality of life criteria;
- quantitative risk assessment.

In the appointment of members of the new committees consideration should be given to the need to have expertise in the above areas.

Consistency of views between experts

As noted above, public concern is heightened, not surprisingly, when different committees arrive at different judgements on the same or very similar stressors. The survey conducted for this Report indicates that the main reasons for this situation are differences in the:

- form of question asked;
- different data bases used;
- regulatory considerations;
- committee culture and approaches by individual experts particularly if they are the sole expert, in a particularly critical field, on the committee.

Inconsistency in views in a specific area can sometimes arise in the same committee. Where this occurs it is vital that an explanation for the apparent discrepancy is given. Such inconsistencies need to be minimised without suppressing the occasional need for different views to be made apparent on an issue. This is best dealt with as a minority opinion (see Appendix 2).

A recent very disturbing development identified in the survey is the use by some EU committees of hazard data as a surrogate for the assessment of risk of individual substances and products. This is occurring both in environmental risk assessment i.e. use of PBT data (persistence, biomagnification and toxicity as indicated in the technical guidance document on marine risk assessment) and in human risk assessment i.e. use of CMR data (carcinogenicity, mutagenicity and reproductive effects).

Continuation of this approach will simply fuel the public perception that if a chemical causes a dreaded effect such as cancer it should be banned regardless of the levels of exposure. The foolhardiness of such an approach can be evaluated by examining the repercussions of the so-called Delany Clause (sometimes referred to as the “Delany Amendment”) of the 1958 Food, Drug, and Cosmetic Act in the USA.

It is recommended that:

- further analysis is carried out to characterise the causes of discrepancies in published opinions;
- a procedure is established of rapidly identifying previous opinions in the EU and in Member States on the same issue;
- regular expert workshops are conducted on areas where a common approach to interpretation of data is considered to be particularly important;
- induction courses are provided for all new Scientific Committee members;
- hazard criteria are not substituted for risk assessments.

4.12. DEVELOPING EXPERTISE FOR THE FUTURE

There is a diminishing number of academic scientists in a number of the key disciplines of risk assessment, as confirmed in the survey. It is likely that this trend will continue.

This is a paradoxical situation because the demand for risk assessors is high and certain to increase in the future. Industry will be forced to compete for the services of risk assessors in order to meet its obligations under the REACH framework. The Commission should consider how it could develop the high quality risk assessors that it will need in the future rather than assume that if they are needed they will be readily available.

It is recommended that:

- a manpower planning exercise is conducted in Member States in the areas (which are increasing- see above) that make up the field of risk assessment. This is a post graduate activity that also involves some research training (NB: it is not a suitable field for undergraduate courses);
- procedures are put in place in the Commission to develop risk assessor skills through the initiation of short course training programmes. These could be provided by calling on the services of a number of current and past Scientific Committee members;
- a panel of experts to the Commission Services is established (see above). Their services would be used not only to help in risk assessments but to develop and round their skills in a broader context of risk assessment methodologies.

It is important to try to link these activities. These issues also need to be borne in mind in considering manpower planning and training. This is a further issue where collaboration between organisations involved in risk assessment needs to be developed.

Overall recommendations:

- the current status of work in these areas in the Commission is assessed. The risk assessment unit of DG SANCO should be represented in their further development;
- the priorities for extension of current risk assessment practices are identified and a strategy is put in place to phase them in.

4.13. CONCLUSIONS

Risk assessment procedures and working practices need some modification to ensure:

- a better understanding by the public of how they are used;
- greater consistency;
- more efficient use of resources.

Harmonisation of procedures has been identified as a key measure to attain these objectives.

Priorities for harmonisation identified in this investigation are the establishment of:

- formal links between organisations that have a major involvement in conducting risk assessments. The survey conducted for these investigations emphasized the need for collaboration with a number of Agencies of the European Union;
- transparent guidelines for the working practices of Scientific Committees;
- procedures to ensure that Scientific Committees' Opinions are clear and consistent over time;
- means of introducing greater stakeholder involvement;
- standardisation of means of describing the magnitude of risks.

High quality independent and transparent scientific advice is viewed as crucial to retaining public confidence in the procedures for assessing risks.

A re-examination of current practices and procedures is needed to ensure that thy are consistent, justified by current scientific understanding, readily understandable and take into account the legitimate concerns of the key stakeholders.

In conducting this re-examination due account must be taken of the substantial body of work on public perception of risk and of the factors that can contribute to the amelioration of concerns. The immediate step is to ensure that the members of committees are recognised experts in their field and that the range of expertise reflects the full mandate of each committee.

5. IDENTIFICATION OF OVERLAPS BETWEEN FOOD AND NON-FOOD AREAS

HISTORICAL BACKGROUND

Ensuring effective collaboration between the food and non-food areas in terms of risk assessments has been identified as very important by many respondents to the questionnaire.

Prior to 1997 scientific advice on food and non-food areas was spread across a number of DGs in the European Union. There was very little interaction between external experts in the different committees concerned with human health and environmental protection. Following the BSE crisis, risk assessment was brought together under DG XXIV, the predecessor of DG SANCO. An organisational structure, involving eight task-specific Scientific Committees and an overarching SSC was established.

This structure, in principle, allowed overlap and gaps between non-food and food areas to be considered and acted on. In practice these interactions were limited at the scientific steering committee because issues relating to BSE and Transmissible Spongiform Encephalopathy (TSE) dominated its agendas. However, some key overlapping issues, not relating to BSE and TSE, were considered by the SSC including:

- harmonisation of risk assessment procedures;
- antibiotic resistance;
- genetically modified organisms;
- emerging issues;
- animal waste disposal;
- transmissible infective agents.

In addition, the Scientific Steering Committee, because its membership included the chairman of each of the eight committees, provided a forum for the identification of stressors of common interest. In a number of cases, this lead to the establishment of joint working parties to pursue common stressors.

In 1999, a review was carried out (at the behest of the Commission), to re-examine the way that scientific advice on health issues was provided (EFSA 8-12-99[5]). This examination was carried out by three senior members of the SSC ('the three wise men'). They took evidence from a number of individuals. Their report concluded that further development of the system for scientific advice was needed because:

- The Treaty of Amsterdam stated the need to include health issues in policy making at the European Union level.

- There is a very wide differences in social and environmental conditions such as diet and smoking habits across the EU. This situation will be exacerbated because among the Accession States there is in general a greater burden of ill health than among the current Member States.

- There is a continual public concern about issues associated with health alongside the diminishing public confidence in both government and scientific analyses and actions because of a perceived bias. The current system of advice appears to the public to be remote and isolated from public and parliament scrutiny.

[5] http://europa.eu.int/comm/food/fs/sc/future_en.html

- Industry developing novel products finds that the present system for evaluation is very cumbersome.

- The organisation of scientific advice could be provided through a number of alternative models however the most appropriate model would be a single organisation covering both food and public and (environmental) health issues.

- There is a major need for an effective monitoring and surveillance programme.

- The importance of providing scientific advice that is independent, transparent of excellent quality and capable of being understood by non-experts, by Parliament, Member States and industry as well as by the Commission was stressed.

The SSC endorsed these conclusions unanimously (April 2000).

This advice that the risk assessment of food and non-food areas should remain integrated was not considered to be vital by the decision makers. Instead a decision was made by the European Council and by the European Parliament to establish the European Food Safety Authority (EC 178/2002). Thus, a formal separation of the risk assessments of food and non-food stressors took place. It is notable that in the all Member States food and non-food risk assessment activities are separated either largely or completely. This, in part, reflects the tradition that food was dealt with as part of agricultural policy.

Various other authors have called for a more integrated approach to public health issues in general (Legemaate, 2002).

The conclusion of the 'three wise men' that a major strengthening of the EU surveillance and monitoring is needed will be partly implemented through the proposed European Centre for Disease Prevention and Control.

The issues of transparency of advice and stakeholder involvement have been addressed above (see section 5.9). The primary reason why collaboration is necessary between the food and non-food areas is that consumers are exposed to many individual chemical and biological agents in both food and non-food products. From a health perspective it is the overall exposure to these individual agents that is important rather than the increment from a particular source. The question, therefore, arises as to how this holistic need in risk assessment can be achieved?

The following factors need to be taken into account in order to identify how to proceed:

- the brief of EFSA;
- to identify and characterise areas of significant overlap between the risk assessment responsibilities of EFSA and those of DG SANCO and elsewhere in the Commission for non-food risk assessments;
- to draw attention to other differences resulting from the separation of food and non-food and to outline mechanisms by which these overlaps and gaps may be addressed.

5.1. THE BRIEF OF EFSA

The definition of non-food is determined entirely by the definition of food. Since this study is focussed on the EU, it is appropriate to use the definition of food used to establish EFSA.

5.1.1. Definition of food (article 2 of EC/178/2002)

"Food" includes drink, chewing gum and any substance including water, intentionally incorporated into the food during manufacture, preparation or treatment. It includes water after the point of compliance as defined in article 6 of directive 98/83/EC.
The definition of what is included in "food", is further clarified by an examination of the brief of its scientific committee, and those of the eight scientific panels established by EFSA:

- The Panel on food additives, flavourings, processing aids and materials in contact with food

  This panel is responsible for safety in use of food additives, flavourings, processing aids and materials in contact with food: associated subjects concerning the safety of other added substances and questions related to the safety of processes.

- The Panel on additives and products or substances used in animal feed

  This panel is responsible for safety of the animal, the user/worker, the consumer of products of animal origin, the environment and to the efficacy of biological and chemical products/substances intended for deliberate addition/use in animal feed

- The Panel on plant health, plant protection products and their residues

  This panel is responsible for safety of plant protection products for the user/worker, the consumer of treated and products and the environment and plant health

- The Panel on genetically modified organisms

  This panel is responsible for the safety of genetically modified organisms as defined in Directive 2001/18/EC such as micro organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed including their derived products.

- The Panel on dietetic products, nutrition and allergies

  This panel is responsible for dietetic products, human nutrition and food allergy and other associated subjects such as novel foods.

- The Panel on biological hazards

  This panel is for assessing the risks from biological hazards relating to food safety and food borne disease, including food borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management.

- The Panel on animal health and welfare

  This panel is responsible for all aspects of animal health and animal welfare, primarily related to food producing animals including fish

- The Panel on contaminants in the food chain

  This panel is for assessing contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues of non authorised substances not covered by another panel.

- The Scientific Committee

  This committee deals with questions on multi-sectorial issues falling within the competence of more than one panel and on issues which do not fall within the competence of any of the panels.

5.1.2. Definition of non-food

The term non-food includes all the stressors, specifically excluded in the remit of EFSA. "Food" in terms of the remit of EFSA does not include:

- medicinal products (within the meaning of Council Directive 65/65/EEC and 92/73EEC);
- cosmetics (within the meaning of Council Directive 76/768/EEC);
- narcotic or psychotropic substances (within the meaning of the United Nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic substances 1971);
- tobacco and tobacco products (within the meaning of Council Directive 89/622/EEC);
- plants prior to harvesting;
- live animals (unless they are prepared for placing on the market for human consumption).

5.1.3. Other considerations important to the identification of areas of potential overlap

The role of EFSA in terms of risk assessment activities as set out in Articles 22 and 23 of Regulation 178/2003, can be summarised as follows:

- to provide scientific advice and scientific and technical support for the Community legislation in all fields which have a direct or indirect impact on food and feed safety;

- to provide independent information on all matters within these fields and communicate on risks;
- to provide Member States with the best possible scientific advice;
- to promote and coordinate the development of uniform risk assessment methodologies in the food area.

It follows from the above remit that risk assessment in the food area is more or less exclusively concerned with the ingestion by humans of chemical and biological agents that are added to raw or processed plant and animal products or are natural components or contaminants of such products. There are, however, three areas where the task is broader:

- environmental impacts of agents used to control pests of various kinds or facilitate animal growth (feed additives);
- protection of workers handling these agents;
- risks to non-food products and to the environment from GMOs.

There appears to be no explicit remit to consider the protection of the very large number of workers who are employed in the food processing and catering industries in respect of exposure. However, these workers are also consumers.

5.2. AREAS OF OVERLAP BETWEEN FOOD AND NON-FOOD

Areas of potential overlap can be classified as follows:

- exposure of consumers to the same or similar chemical /biological agent present in food and non-food products;
- impacts of the same or similar chemical/biological agents on workers, the environment and/or on domestic animals;
- strategies in risk assessment e.g., how to evaluate the impact of mixed exposures, identification of vulnerable sub groups in the population, characterisation of emerging issues;
- research needs;
- mechanisms for interacting with stakeholders.

5.2.1. Exposure of consumers/the public to the same chemical/biological agent present in foods and non-foods

In the non-food area the emphasis is on exposure by other routes than ingestion. In particular, by inhalation and dermal exposure. There is also a much greater emphasis on protection of the environment.

Nonetheless, the non-food area risk assessments also include consumer exposure by the oral route to a wide range of chemical and biological agents. For example:

- prescribed and over-the-counter medicines, including herbal preparations and recreational drugs;
- substances/products put into the mouth such as toothpaste's, mouth washes, breath improvers;
- tobacco products, such as cigarettes and chewing tobacco;
- children toys, teething rings, dummies which are put in mouth by young children;
- dental implants and fillings, false teeth;
- lipsticks and lip balms;
- substances present in ambient air that are inhaled and, subsequently, swallowed , for example coarse particulate matter;
- many other materials that come in contact with the mouth ranging from the end of pencils and pens to contaminants on hands.

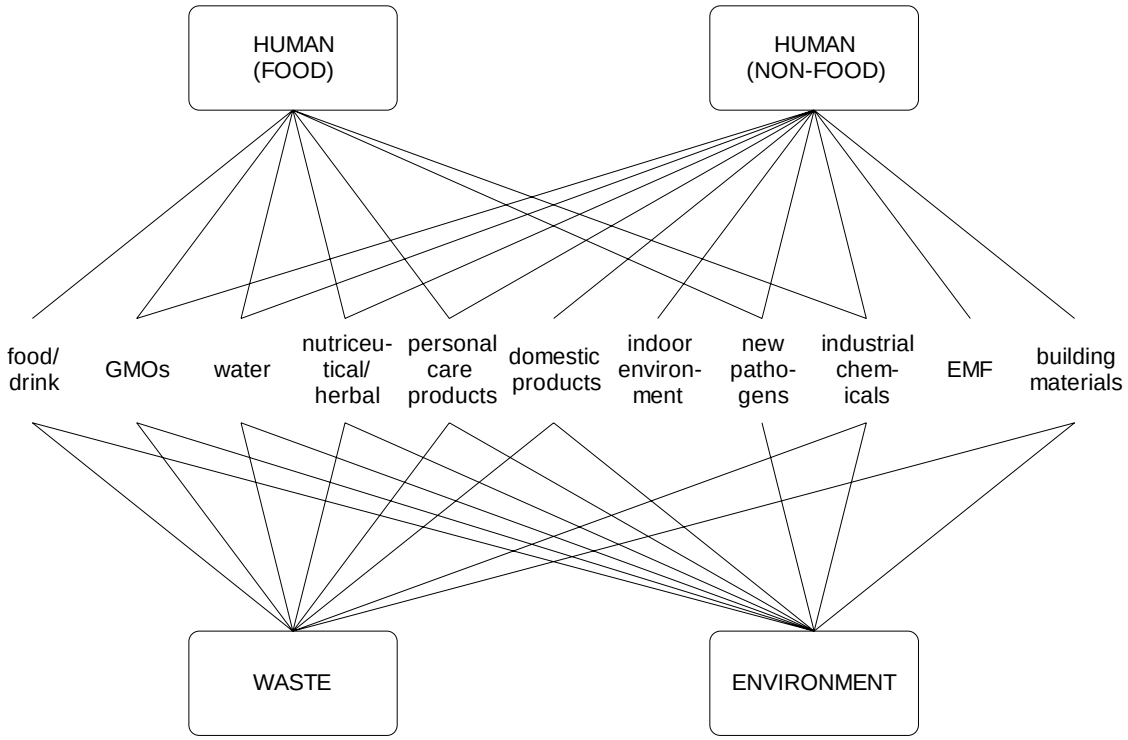

***Figure 3*: Interactions between Food and Non-Food Areas**

The first stage in identifying such agents has been to scan the Opinions of the nine DG SANCO Scientific Committees to identify the product types (see also section 5.9). Five major categories have so far been identified:

5.2.1.1. Food contact materials

These include plasticizers such as phthalates, citrates and adipates plus chemicals found in baking and wrapping paper. For most of these materials exposure of consumers is also likely in one or more of the following products: children toys (of particular importance are the toys that young children can put in the mouth), cosmetics and personal care

products, various kinds of medical devices including blood bags, non-food packaging, clothing (particularly recreational clothing), furnishing fabrics . These substances are also found widely as environmental contaminants, which raises questions both about indirect human exposure and environmental impacts.

5.2.1.2. Accidental food contaminants

A large number of potential food contaminants may be identified including; heavy metals, dioxins and PCB's, polycyclic aromatic hydrocarbons, acrylamide, flame retardants, fluoride, detergents, various micro organisms and their products. There are many non-food sources of these agents. For example, emissions from combustion plants such as power stations and incinerators, vehicle exhausts, municipal solid waste. In addition, some contaminants are part of a non-food product, for example lead in water pipes, candles, car batteries.

5.2.1.3. Plant materials

Traces of pesticide occur widely in vegetable matter for human consumption. Fungal contaminants may also arise. Plant materials have a variety of non-food uses, however, that may result in additional exposure of the consumer. These include: clothing herbal medicinal products, personal care products including cosmetics and textiles. Additional exposure may occur through the environment.

5.2.1.4. Animal materials

Traces of veterinary medicines may be present in meat products. A number of these biologically active substances are also used as human medicines. This is of concern in respect of antibiotic resistance and drug allergies (see section 4.4.2).

5.2.1.5. Additives

Foods may contain many types of additives, which range from flavouring, colouring and aroma enhancers to processing aids. Many of these agents are also used in cosmetics and personal care products, in over- the counter medicines, in tobacco products and various industrial processes. For example benzoic acid, sugar substitutes, various dyes.
An analysis of the Opinions of the former Scientific Committee on Food over the past six years indicates some common grounds with the activities of current non-food committees for almost fifty percent of the Opinions. Other former committees on food appear to have common issues with the non-food committees. This overlap occurred both for the risk assessments for individual agents and also for various methodological issues.

5.2.2. Impact of the same or related agent on workers, domestic animal and /or the environment

Historically, the only areas relating to food that have been subject to risk assessment for their worker and environmental impacts have been pesticides and growth promoters. It is

noted that the disposal of food waste has a considerable effect on the environment. For each agent where there is overlapping use in the food and non-food areas some consideration of worker exposure and of possible environmental impacts would be appropriate. A phased approach to assessment of such agents might be used. The first phase could be based on a simple algorithm to identify the importance of embarking on a more detailed evaluation.

5.2.3. Strategies in risk assessment

The process of risk assessment is very similar for food and non-foods. The Harmonisation of Risk Assessment Procedures Reports of the SSC identified a number of important evolving issues:

- the assessment of the risks from the simultaneous exposure to a number of stressors;
- characterisation of at risk groups in the exposed population;
- the need for early identification of emerging issues;
- incorporation of quality of life factors into the risk assessment process;
- weighting to be given to in vitro hazard data.

It is important that there is a harmonised approach to these issues between EFSA and the Commission. The mechanisms by which such harmonisation could be achieved are discussed (see section 5.6).

5.2.4. Research needs

As there are many common elements in the risk assessment process in the food and non-food areas it is likely that there will be a number of shared research priorities. In view of the limited resource available for research, it would be appropriate to seek agreement on research priorities relating to risk assessment.

5.2.5. Interacting with stakeholders

Common means for food and non-food issues of communicating with stakeholders could enhance public confidence in the information conveyed. This topic will be discussed in the third report.

5.3. NEED FOR A MORE INTEGRATED APPROACH BETWEEN FOOD AND NON-FOOD RISK ASSESSMENTS

The DG SANCO Interface Unit has a key role in managing the interactions between EFSA and the Commission. The link between the risk assessment activities of the two organisations is expected to be handled on a practical basis by the DG SANCO Risk Assessment Unit.

A number of Member States have been approached by the author of this report for information on the mechanisms they use to ensure a common approach for food and non-food issues that are closely related. From the preliminary replies it is apparent that such formal mechanisms appear to be poorly developed in most if not all Member States. This is compensated for to some extent, particularly in the smaller Member States, by the use of informal grapevines and individual scientists to provide advice in both non-food and food areas. There is very little information in the published literature on this topic. There are three very recent papers (Banati, 2003; Hobbs *et al.*, 2002; and Knight *et al.*, 2003) that make some cross comparisons on the management of food safety and have some reflections on the non-food areas including public health, but these are mainly set in a historical context.

5.4. CONCLUSIONS

Many areas have been identified for which close collaboration between the EFSA Panels and Scientific Committee and the Scientific Committees of the Commission in risk assessment related activities would be very beneficial. It can be concluded that it is commonly the case that the same stressor (chemical or biological agent) is addressed by both the Scientific Committees concerned with food and committees concerned with non-foods.

Further work needs to be conducted to develop recommendations on how this collaboration can be best achieved without having an adverse effect on the independence of either EFSA or the non-food Scientific Committees administered by the Commission.

6. BEYOND RISK ASSESSMENT

Risk assessment is an evolving field both in terms of the depth of scientific understanding but also in the breadth of themes that are covered. See, for example, Tukker (2002) and Part 1 of this report. It is probable that risk assessment will broaden in the near future (see Figure 4):

- to include benefits as well as risks;
- to embrace socioeconomic and other factors (i.e. human impact assessment);
- to consider elements of sustainability and life cycle analysis.

The progression of the risk assessment process is set out in the following diagram.
Currently the risk assessment for human health is normally addressed completely separately from that of the environmental risk assessment. Support for the integrated risk assessment for a substance (where data generated for human risk is used to assess environmental risk and visa versa) is growing (WHO 2002). There are several recent EU discussion papers advocating human impact assessment. This would involve the addition of socio-economic factors to those traditionally used in risk assessment. The Scientific Steering Committee also recommended such a progression in the report on the Harmonisation of Risk Assessment Procedures (2003).

Conclusion

It is recommended that an evaluation is made of how these developments could affect the requirement for expertise on the Scientific Committees.

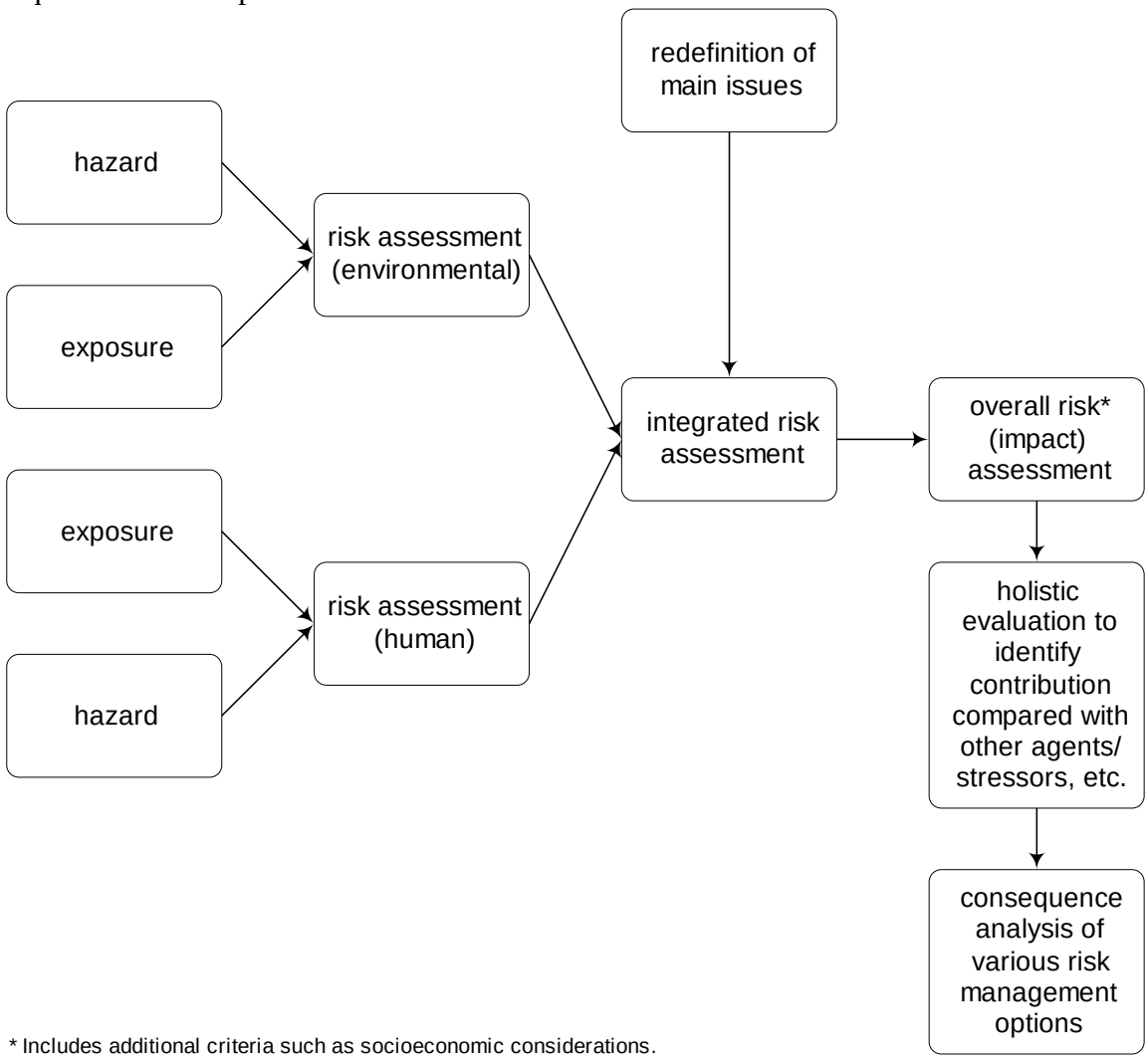

***Figure 4*: Beyond Risk Assessment**

7. SUGGESTIONS FOR IMMEDIATE FURTHER WORK

1. Identify the key contacts in Member States and Accession States in order to establish an effective network for future long-term collaboration. The work in this report on this topic was necessarily very preliminary.

2. Carry out further discussions with stakeholders to quantify better the relative importance of each area for risk assessment identified in this report. This should inform the work load for the proposed new Scientific Committees

3. Complete the guidelines for the working procedures for the new Scientific Committees and identify the information requirements for the induction workshop(s)

4. Develop a more integrated approach between the risk assessment activities and those centred on other aspects of public health in the EU

5. Complete the work to identify all the scientific committees in the EU with an involvement in the non-food area. The aim of this is to identify committees with which some form of further collaboration would be highly desirable.

6. Meet with the Scientific Committees of EFSA, EEA, and EMEA to discuss their views on how collaboration should be facilitated. (NB: it is important that all the ideas are not seen to be coming from Scientific Committees managed by the Commission.)

7. Identify the priorities for the development of harmonised exposure assessment in the non-food area.

8. RECOMMENDATIONS

Based on the scoping work conducted for this project a number of recommendations for action related to greater harmonisation and coordination are made. These recommendations have been separated into two categories:

a) recommendations proposed for an immediate action (within the next three months). The author considers progress in these areas very important preferably before the new non-food Scientific Committees are set up;
b) recommendations where an action should be initiated during 2004 (Medium term).

8.1. IMMEDIATE ACTIONS PROPOSED

- To ensure that the new structure proposed for the Scientific Committees Scientific Committees in the non-food areas facilitates collaboration on issues that span the mandates of two or more committees. This requires early recognition of common issues.

- To develop a mechanism or mechanisms for formal collaboration between the scientific committees/panels of EFSA and those covering non-food issues, in order to ensure that areas of overlap (see below) are dealt with appropriately.

- To explore how similar links might be established subsequently with the European Environment Agency and with the JRC.

- To arrange a meeting with appropriate representatives from Member States to discuss how information in the non-food area pertaining to risk assessments can be shared and unnecessary duplication of effort avoided. This meeting should aim to establish mechanisms by which long-term collaboration, through a sustainable network, can be achieved.

- To develop a guideline for the operation of the Scientific Committees to ensure that their procedures are transparent, harmonised and effective. This guideline should include the interactions between the independent risk assessors and commission officials, and proper relationship with other stakeholders. An appendix to this report could, with further work, become such a guideline.

- To arrange an induction workshop for the members of the new committees, along with key officials, to be held as soon as members are appointed.

- To use the call for expressions of interest in membership of the new Scientific Committees as the opportunity to establish a panel of experts that can be drawn on to contribute to working parties etc of the Scientific Committees.

- To identify an individual in the risk assessment unit of DG SANCO to be responsible for the implementation of these recommendations.

8.2. MEDIUM-TERM ACTIONS PROPOSED

- To establish formal links with other bodies in the non-food area with whom collaboration on risk assessment issues is considered to be very useful and initiate approaches to them. A list of such bodies is provided in this report.

- To initiate a series of annual meetings involving Scientific Committee members, key officials from the commission and its agencies, plus other invited participants to identify emerging issues and how they should be tackled. It may be appropriate to address general issues and specific themes in alternate years.

- To require Scientific Committees to produce an annual report of their activities. This could be linked to a subsequent meeting with stakeholders.

- To introduce a procedure for an independent scientific audit of committee activities as means of enhancing public trust in their work.

- To set up a small working group of risk assessors and officials to follow up the recommendations of the Reports of the Harmonisation of Risk Assessment Procedures Task Force, which was published in 2003.

- To bring together all interested parties in the EU to discuss how a common, validated data base of hazard and exposure information can be established and further developed, which is readily accessed for risk assessment purposes.

- To carry out pilot schemes to assess the most effective and trusted methods for stakeholder involvement in the work of the Scientific Committees.

- To introduce short non-technical versions of Scientific Committee opinions for the public information that are consistent in style across all Scientific Committees.

- To examine the efficiency of the process for obtaining and utilizing scientific advice by the EU, how it is rewarded and acknowledged, and identify means to ensure availability of sources of such advise in the future.

- To build up a comprehensive list of stakeholders and their interests.

- To develop an algorithm for the transparent identification of priorities for risk assessments.

- To review the resource requirements (including expertise needs) for the extension of the risk assessment process so that the risk assessment includes socioeconomic and other considerations.

- To review the role of the non-food committees in assessing environmental impacts and effects on workers producing or using commercial non-food products.

- To assess the resource implications of adopting these recommendations to ensure that they can be supported.

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10. APPENDIX 1 - QUESTIONNAIRE

This questionnaire has been commissioned by SANCO to determine their aims for the future. We consider your input to be of utmost importance and are very grateful for your time.

When you have completed the questionnaire a Freepost envelope is enclosed for its return

Thank you

1. What is your main area of responsibility?

	Area
1) Policy making	☐ 1
2) Policy implementation (management)	☐ 2
3) Scientific research	☐ 3
4) Consultancy	☐ 4
5) Seeking changes in policy in NGO	☐ 5
6) International	☐ 6
7)	☐ 7
8) Industry association	☐ 8
9) Producer	☐ 9
10) Others, specify.....	☐ 10

2. How many years have you been involved in this area?
Please tick box.

Less than 5 yrs ☐ 1 5-10yrs ☐ 2 11-15 yrs ☐ 3 16-20 yrs ☐ 4

21-25 yrs ☐ 5 more than 25 yrs ☐ 6

3. Do you see any need for major changes to be made in the organisational structure of the non-food Scientific Committes of SANCO? **Please tick boxes**

3.1 Scientific Committee on Toxicity, Ecotoxicity and the Environment

yes	no	don't know
☐ 1	☐ 2	☐ 3

3.2 Scientific Committee on Cosmetics and non-food products intended for Consumers

yes	no	don't know
☐ 1	☐ 2	☐ 3

3.3 Scientific Committee on Medical Products and Medical Devices

yes	no	don't know
☐ 1	☐ 2	☐ 3

4. Which in your opinion are the five most important areas for SANCO Scientific Advisory Committees in terms of protection of public health and the environment in the next two years? Please grade them on the scale of 1 to 5. 1- being the most important.

Please grade five boxes only

1. Industrial chemicals (restricted consumer exposure) ☐ 1
2. Household cleaning products ☐ 2
3. Personal care products ☐ 3
4. Cosmetics . ☐ 4
5. Medical devices ☐ 5
6. Toys. ☐ 6
7. Fabrics, furnishing and clothing ☐ 7
8. Building materials ☐ 8
9. Non-ionising radiation devices ☐ 9
10. Others, specify..... ☐ 10

.....

5. Which in your opinion are the five most important areas for SANCO Scientific Advisory Committees in terms of protection of public health and the environment in the **next five-seven years**? Please grade them on the scale of 1 to 5. 1- being the most important.

Please grade five boxes only

1. Industrial chemicals (restrictded consumer exposure)	☐ 1
2. Household cleaning products	☐ 2
3. Personal care products	☐ 3
4. Cosmetics .	☐ 4
5. Medical devices	☐ 5
6. Toys.	☐ 6
7. Fabrics, furnishing and clothing	☐ 7
8. Building materials	☐ 8
9. Non-ionising radiation devices	☐ 9
10.Others, specify.....	☐ 10

.....

6. Which of the following agencies in your opinion should the SANCO scientific advisory committees have formal collaboration with?

Please tick the yes or no box for each .

	Yes	**No**
European Env. Agency	☐ 1	☐ 2
European Food Safety Authority	☐ 1	☐ 2
European Medicines Eval.Authority	☐ 1	☐ 2
European Chemicals Agency	☐ 1	☐ 2
European Agency for Disease Control	☐ 1	☐ 2
Joint Research Centre	☐ 1	☐ 2

7. Are there other Agencies/Committees for which you feel the SANCO scientific advisory committees should collaborate with?

8. What are the priorities, in your opinion, to improve the work of the SANCO Scientific Committees?

Please tick all boxes which apply

1. Draft reports from the Secretariat ☐ 1
2. Improved access to data ☐ 2
3. Broader range of expertise on Committees ☐ 3
4. Better remuneration of the members ☐ 4
5. Stakeholder access to meetings ☐ 5
6. Published time-scale for each question ☐ 6
7. Published rationale for each question ☐ 7
8. Others, specify ☐ 8

9. Which of the following do you think need to be introduced into the current risk assessment procedures?

Please tick all boxes which apply

1. Combining human health and environmental risk assessment ☐ 1
2. Ethical factors ☐ 2
3. Standardised terminology ☐ 3
4. Risk/benefit analysis. ☐ 4
5. Quality of life criteria. ☐ 5
6. Others, specify ..... ☐ 6

10.

Please tick one box for each statement.

	Agree	Disagree	Don't Know
1)	☐ 1	☐ 2	☐ 3
2) A decrease in .. .	☐ 1	☐ 2	☐ 3
3) Cause conflict between the within the practice.	☐	☐ 2	☐ 3 1
4) Increase in consumer..... concerns about their health.	☐ 1	☐ 2	☐ 3
.	☐ 1	☐ 2	☐ 3
5) Increase of perceived risk factor for consumers	☐ 1	☐ 2	☐ 3
7) Increase awareness of consumers about..... .	☐ 1	☐ 2	☐ 3

.

Thank you very much for completing this questionnaire, please return it within the shortest time possible in the freepost envelope provided (no stamp required).
If you are interested in feedback and the outcome of survey, please fill in your name below and we will be delighted to send you details.

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11. APPENDIX 2 - GUIDELINES FOR THE OPERATION OF THE SCIENTIFIC COMMITTEES

(this appendix is an adaptation of parts of the Report of the Task Force on the Harmonisation of Risk Assessment Procedures (2003).

11.1. INTERACTIONS BETWEEN RISK ASSESSORS AND RISK MANAGERS

Some of those interviewed have challenged the assumption that the most important interaction to consider is between risk assessors and risk managers. Their view was that exclusion of other stakeholders (Consumer organisations and other NGOs) contributed to public distrust of the Risk Assessment (RA) process and to social amplification of the risks (see above). The survey identified the following recommendations:

- a much higher involvement of other stakeholders, such as NGOs, governmental officials in Member States, and industry representatives;
- information is given in the form, which reflects the "real world";
- various pilot studies for involvement of all the stakeholders are tried out.

The author of this report recommends that an effective mechanism(s) of interaction between risk assessors and risk managers is agreed before other stakeholders are added. In respect of the risk assessment process it is suggested that this mechanism should comprise the following stages:

(a) The first step should be led by the managers and would be devoted to defining the term of reference. this may involve other stakeholders. These terms of reference should be given to the risk assessors, so it is clear to them what the important items are.

The risk profile should then be determined by the risk assessors. From this profile it will be possible to define a question for a scientific committee or for several committees (depending on the scope of the question).

At present if several committees are involved in providing the answer to a question, each committee establishes a working group. The author proposes that a joint working group is established rather than two separate ones in these circumstances.

(b) The second step is to ensure that risk managers are present throughout the actual risk assessment. However, the autonomy of the committee during this process must be maintained.

(c) The last step for the managers is to encourage the stakeholders to comment on the report, and, in particular, on the Opinion of Scientific Committees. The author recommends that RAs of particular public interest are available on the Internet for

comment prior to a final Opinion being arrived at. This would allow having a feedback from the people who are interested in the particular issue.

The survey conducted for this report shows a strong need for better understanding of public values by risk managers and risk assessors to enhance the usefulness and acceptability of risk assessments. In principle, it is of benefit to involve the stakeholders from the very beginning and to have clear feedback from them.

11.2. ENSURING GOOD PRACTICE

Criteria to demonstrate good practice are commonly applied to the collection and use of data (good laboratory practice, good clinical practice) and to the management of organisations (e.g. ILO 9001).

The findings from risk assessments from the Scientific Committees of DG SANCO are available. How specific risk assessments were conducted may be less clear to those who are not members of the specific committee. Committees should aim to provide sufficient detail that their work could be amenable to external auditing. It is appropriate therefore to try to establish criteria of Good Evaluation Practice.

The increasing pressures for full transparency in the risk assessment process requires the development of a consistent and clear procedure that include all the sources of data that have been used and any important limitations of accessibility of potentially significant data and the weighting given to individual data sets and the rationale for this.

Good practice parameters might include specification of:

- the availability of suitable information on how the data was derived;
- the quality of the experimental work which includes whether the work was conducted included according to GLP, GCP, etc.;
- the scientific standing in the field of the authors and their perceived independence;
- whether the findings are consistent with the available literature in the field.

Means need to be developed to show how these parameters have been used in the selection of key data and in the rejection of any substantive submissions. One possibility is the introduction of a simple scoring system for the weight placed on each data source.

An issue that needs more attention is how assessment of false positive results and false negative results (type 1 and type 2 errors) are defined and whether the approach to each is even handed (see, for example, Needleman 1995). Gee (2003) makes out a strong case for giving more attention to attempting to identify false negatives.

Further work is needed to examine how these criteria might be weighted and/or others introduced.

11.3. THE ROLES OF SCIENTIFIC COMMITTEE AND WORKING GROUPS

Scientific Committees should continue to have the responsibility for establishing, where necessary, a Working Group (s)(WG) . A WG may have one of two roles:

- to evaluate a report provided by the Commission;
- to produce its own report, based on their own information and/or information provided by the Commission.

For both purposes the Scientific Committee should set the WG's terms of reference and the chairman of the WG should be appointed from among the Scientific Committee members. The current practice is that some WG's comprise only members of the Committee, whereas other WG's comprise mainly external experts. Inevitably, the balance of internal to external members will influence the interactions between the WG and the Scientific Committee.

The author of this Report recommends that an agreement is reached, at an early stage , between the committee and each of the WG(s) on:

- source data to be utilised;
- structure of any report;
- time scale to produce the required report.

11.4. RELATIONSHIP BETWEEN AN OPINION AND THE SUPPORTING REPORT

As stated above, Opinions are produced by Scientific Committees, whereas reports may be generated by outside bodies or Scientific Committee working groups. Under these circumstances problems may arise because of differences in methodologies and practices. The survey conducted by the author indicates that there is a considerable concern about the lack of transparency in this process.

The Opinion and the Scientific Report, although closely related, for some purposes may be used separately. Scientific Committees may draw on information not covered in the report in reaching their Opinion. The author of this Report recommends that each Opinion should be based on the relevant Scientific Report. In drafting both documents it should be assumed that, for various purposes, the Opinion and the Report might be utilised separately. Opinions should typically be quite short (1-5 pages). It is recommended that, where possible, the Opinion and the report be published simultaneously.

It is essential that scientific reports are based on the best available scientific data. High quality reports, in addition to being valuable for a specific purpose raise the status of the discipline of risk assessment.

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

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

The Scientific Report should, wherever it could be of value to those outside the relevant committee, be prepared on the assumption that it will be published in an appropriate form. Reports published on the Internet following review and acceptance by a Scientific Committee may be considered to be peer reviewed. However, it is acknowledged that in many cases the format may differ from the procedure used by existing scientific journals. It is recommended that the principal author(s) names are included in the Report. This measure is consistent with encouraging a high scientific standard and making participation in working groups more attractive to non-members of the Scientific Committees in that it would provide much more tangible professional recognition of the authors for the work they carry out. It will also aid transparency and help to reduce duplication of effort by different committees. It is recommended that a short synopsis of each Opinion is also provided in non-technical format that can be readily understood by the general public. For this purpose DG SANCO should consider providing editorial support by professional science communicators.

11.5. SOURCES AND CONFIDENTIALITY OF INFORMATION

This Report recommends that a clear formal distinction is made between a full literature search on the agent/substance/stressor under consideration and the information provided by Commission Services. It is also useful to identify whether or not individual stakeholders were invited to submit information to the Scientific Committee. All sources of information must be cited by Scientific Committee along with the rationale for excluding particular data sources from consideration.

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

11.6. EXPRESSION OF MINORITY OPINIONS

From time-to-time genuine significant differences arise in committees on the interpretation of scientific data. Where these differences cannot be resolved by extensive

discussion, they should be expressed in a minority opinion to ensure transparency. It is also important for risk managers to appreciate that in some cases there are differences of view.

Currently, minority opinions of Scientific Committee members must be included in the scientific Opinion but the author is only identified with his consent. It is recommended that the scientific basis for the viewpoint be attached in an appendix. This Report recommends that in instances of serious disagreement a formal vote of the Scientific Committee is conducted and the results of this vote are published.

11.7. RECOMMENDED FORMAT FOR OPINIONS

This Report recommends the structure of a Scientific Opinion to be as follows:

For the Opinion (i.e.: Committee's position)

a) Title
b) Terms of Reference and statement on sources of information available
c) Brief background
d) Summary of key issues
e) Conclusions and recommendations
f) Key words
g) References including cross references to other relevant opinions by Scientific Committees
h) Appendix (to include declarations of interest if relevant, alternative opinions, statement on sources of information available).

For the Scientific Report

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

11.8. OTHER ISSUES THAT SHOULD BE ADDRESSED IN THE GUIDELINES

- conditions under which deviations from normal practice, e.g., late acceptance of unpublished data should be noted;
- suitable independent external expertise drawn on where there is insufficient expertise on a particular important issue in the committee itself;
- all possible conflicts of interest of committee members are identified;
- any communication of members of the committee with stakeholders during the risk assessment is logged and explained;
- timeliness against pre-agreed targets;
- clarity of expression of the Opinion along with the clear identification of uncertainties in the Opinion;
- ease of use by risk managers;
- evidence of significant contributions from a number of committee members;
- all key statements appropriately referenced;
- consistency with other Opinions of the same committee and of other committees where it is not the case reasons should be given;
- details of any calculations used provided.

11.9. RESOURCE IMPLICATIONS.

Implementation of guidelines of this nature will inevitably involve the allocation of additional resources. It is unreasonable to expect that the additional burden should fall on the scientific experts. Consequently the requisite resources to implement and sustain these guidelines will need to be provided by the commission services.

12. APPENDIX 3 – GLOSSARY

BSE	Bovine Spongiform Encephalopathy
CMR	Carcinogenicity, Mutagenicity and Reproductive effects
COST	European Co-operation in the field of Scientific and Technical Research
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DG ENV	Directorate General for Environment
DGs	Commission Services
DG SANCO	Directorate General for Health and Consumer Protection
ECHI	European Community Health Indicators Project
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMEA	European Agency for the Evaluation of Medicinal products
EMF	Electro-Magnetic Field
EU	European Union
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMOs	Genetically Modified Organisms
HACCP	Hazard Analysis and Critical Control Point
HAZOP	Hazard and Operability method
INCI	International Nomenclature of Cosmetic Ingredients
JRC	Joint Research Centre
MEP	Member of the European Parliament
MSW	Municipal solid waste
NEHAPs	National Environmental Health Action Plans
NEST	New and Emerging Science and Technology
NGO	Non Governemental Organization
OECD	Organisation for Economic Co-operation and Development
PBT	Persistence, Biomagnification and Toxicity
PCBs	Polychlorinated Biphenyls
REACH	Registration, Evaluation and Authorisation of Chemicals
SACs	Scientific Advisory Committees of Commission Services
SARS	Severe Acute Respiratory Syndrome
SCCNFP	Scientific Committee on Cosmetics and Non-food Products for the Consumer
SCMDMP	Scientific Committee on Medical Products and Medical Devices
SSC	Scientific Steering Committee
TSE	Transmissible Spongiform Encephalopathies
TDC	The three double C rules for risk assessment
USEPA	U.S. Environment Protection Agency
WG	Working Group
WHO	World Health Organization
WTO	World Trade Organization

J. Bridges
November 2000