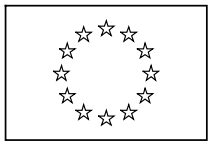

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

FINAL REPORT ON

SETTING THE SCIENTIFIC FRAME FOR THE INCLUSION OF NEW QUALITY OF LIFE CONCERNS IN THE RISK ASSESSMENT PROCESS

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 10-11 APRIL 2003

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1. INTRODUCTION, OBJECTIVES, JUSTIFICATION

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

The task force on the harmonisation decided to examine further whether quality of life considerations should be included in risk (benefit) assessment and if so how. It was felt that such an approach could be a way to take in account important concerns of the public and so to clear to some extent the risks, uncertainties, and the use of the precautionary principle. A working group was established to prepare a report on that topic taking in account that several other working groups are involved in defining other approaches for a harmonised quantitative risk assessment which are needed by individuals and bodies at different levels including EC and WHO.

An enlargement of the scope of the scientific assessment is proposed by including elements defining the **quality of life**. The framework of the areas to be considered in the quality of life assessment is provided by starting off from the health definition of WHO as "a state of complete physical, social and mental well being, and not merely the absence of disease or infirmity…" (WHO, 1992). As a consequence a wide range of traits need to be analysed. Apart from the classical medicinal, physical and chemical scientific areas, psychological, and social issues have to be dealt with. Cultural and economic analyses and last not least the ethical values, which can be different regionally and individually and which can even change in time are parts of the approach.

The analysis should not only take in account the usual objective risks but also the fact that a substantial part of the population is sensitive from a **perception** point of view to threats even from risks, which have not been shown to exist, but are only assumed or presented as hypothetic. Such a perception has a direct impact on the well being by its psychological component, but it can also have a psychosomatically induced physical health effect. One major reason for the perception of threats is that – admittedly - there is so far no consequent and systematic dealing in the scientific risk assessments with uncertainties that cover a wide range of evidence to non-evidence. Furthermore, the benefit –cost -risk – risk mitigation evaluation is a complex process, difficult to communicate. The role of the improved, fully transparent communication is therefore as important as the facts by themselves.

Interactions between scientific assessment, public communication and the resulting perception are major relevant issues in the quality of life evaluation. Topics that have found public interest in this

sense have been exposure to health hazards by chemical factors, safety of food and drinking water, natural and manmade poisons, infectious and non-infectious diseases, and new technologies, especially biotechnology. They include, also the welfare of companion animals, wildlife and animals in general, as well as the environment as a whole.

The importance of such an enlargement results from the idea that the risks are no more only coming from natural causes external to humans. New risks due to the human activities in particular those related to the technological innovations are nowadays very important and they are perceived in a very different way than the "natural ones". Humans are the cause and the target of those changes as they become judge and party. For examples the risks of accidents or pollution can result from the change of the transport means. The risks on health can result from the intensification of food production systems. The **endogenous** character of those risks versus the **exogenous** one makes more difficult their control and their sharing. That fact explains the ambivalent perception of the technical innovations, as they could not pretend always to improve the quality of life of humans. It results in a loss of confidence of citizens and consumers for science and decision-making.

It is worth also to consider that most of the innovations (including the economically important ones) can be produced following **autonomous** or **heteronomous** modes. For example, people can produce themselves all their food being responsible of the whole production system or alternatively they can also buy all those food in shops without taking care how they have been produced. People can try to keep in good health by having a hygienic life, exercising, and avoiding dangerous practises (alcohol, tobacco,..) but they can also ask professional therapists to take care of their health. That distinction is of particular interest in the public health area. René Dubos (1973) defines a **good health** as the "personal independent ability to control their life conditions, to adapt to accidental modifications of their environment and to refuse intolerable environments". The apprehension of new risks arising from our technological and anxiogenic civilization increases the heteronomous mode of health production to the detriment of the autonomous one. For example the provision of medical care for counteracting detrimental psychological conditions at work is the manifestation and the cause of a loss of autonomy (Dupuy, 2002). Those conditions damage health or produce threats due to the ability to face in autonomy the hazards of the environment. The distinction between autonomous and heteronomous modes is complementary to the definition proposed by WHO.

Moreover, the usual procedure in the scientific evaluation is to describe the ways to minimize the risks to the health. We propose a kind of dual approach aiming at **maximising the health**. That dual approach should take in account on one hand the endogen nature of the new risks and on the other hand the different ways the citizens and consumers perceive the risks, the costs and the benefits. Since their

combination determines the quality of life, for maximizing health this combination has to be attempted. The consumers, in parallel to the public safety actors, integrate those items to define their own feeding habits and prudent behaviour. Using that framework, it is clear that the assessors cannot provide a unique quantitative parameter from which using some threshold limit between the acceptable and the unacceptable can be drawn. One the contrary, that type of analysis should identify all the consequences of action or not action on a multidimensional basis. This report will include the public perception, not as a way to define the political issues but as an element of the quality of life of the public.

More than for other more classical risk analysis, those type of question addressed to the assessor by the manager is loaded with an **ethical background** and framed by **cultural values**. Those points should be made explicit prior to data collections and analyses in particularly for the quality of life assessment that relates to individual, collective and historical backgrounds.

Crude expressions of the probability and severity of an adverse health effect do not provide a complete picture of all the relevant useful information for the assessment, in particular they do not account for how individuals and decision-makers **value adverse and positive consequences** of individual or collective actions. There are at least two clearly distinct levels of analysis considered by the public, which could be reflected in the scientific assessments and managerial decisions, namely the **population** (general or subpopulation, e.g. children) and the **individual** levels. The consequences of action or no action have to be analysed for the individuals to build up their own choices. The managers can have a different **set of values** including the facts that all individuals they are dealing with are not considered the same (for example the children more than the others) and that economical or cultural values can be taken in account. All the stakeholders have to be taken in account making clear their own ethical choices and perception of the questions raised. As a consequence of those different view points the recommendations might be expressed in terms of relative perception of the risk, relative preferences, ethical choices or constraints. A variety of techniques and indicators has been proposed to incorporate the ethical values held by different stakeholders to the evaluation of risks, such as social-welfare, economics, disease-burden evaluations, elicitation of individual or societal preferences.

As a zero-risk and absolute safety can hardly be achieved or proven for any issue, a major question is the acceptability both for minor established risks as well as for potential low risks not fully accessible to quantitative risk assessment due to uncertainties. What is acceptable for risk assessors and risk managers must not necessarily be acceptable to those parts of the human population who are susceptible to threats. The attempts to deal with this issue by comparative evaluations are usually not successful. Acceptability, however, increases if the consumer sees a personal benefit from this type of risks (e.g. the use of genetically modified organisms in medicine as compared to agriculture).

The **societal process of the appreciation and assessment of risk** does not necessarily make use of a rationale, technically-informed procedure, but the judgement is rather based on a personal impression, which may derive from a limited, unstructured set of information, using a set of qualitative attributes rather than a quantity (Chevassus-au-Louis, 2000). Subjectivity takes over objectivity of the procedure when the risk is not measurable and only expressed as not measurable uncertainties. The scientific process of risk assessment more and more tends to be formally structured and subjected to standardised, rational, and scientifically accepted rules and procedures. On the contrary risk perception is not dependent of a formalised scheme of evaluation but greatly results from a number of subjective variables. Those are linked to the different individuals, their level of education, their natural and social environment, even their ethical and political believes, and last not least their physical and mental health status. This evaluation is a process which to be able to end up with a **cost benefit analysis** need to assign negative or positive values to those different items. However not all questions can be subjected to a cost benefit analysis and for example it can be accepted that ethical concerns are more especially expressed when something should not be the object of a trade-off because it would result in a decrease in **human (or animal) dignity**.

As a consequence of these complex processes and interactions between scientific facts and perceptions the answers are very complex and difficult to solve without explaining the social and economical issues, for examples:

- Physical health effects on few individuals or on sensitive groups of the human population due to the minor, real risks, can be accepted by risk managers following a risk benefit evaluation based on population averages.
- Physical health effects can result in the human population, or in some groups, due to non-established, perceived risks without scientific evidence of causation. Possibly, for this type of effects, risk sources are exchangeable.
- Effects on mental well being following the perceived threat can be important.

The economic part of the first two types of effects can be included in **cost –benefit evaluations**. The valuation of the effects on well being, especially concerning minorities in the human population, is an ethical issue to be dealt with by the society in case of conflict.

The quality of life can also include **environmental components**. A good quality of life requires a proper quality for the surrounding environment, and since the first industrial development in the 19th century, it was clear that human activities might lead to environmental consequences. If not controlled, they could affect quality of life; and therefore, environmental managers should take care of this aspect.

"We believe all citizens have an inherent right to the enjoyment of pure and uncontaminated air and water and soil; that this right should be regarded as belonging to the whole community; and that no one should be allowed to trespass upon it by carelessness or his avarice or even ignorance" (Massachusetts Board of Health, 1869).

Over hundred years ago, a Board of Health adopted this resolution recognising the environmental component of Human Health control. The current level of environmental degradation in large areas of the world has enhanced this concern.

During the 20th century, a significant part of industrial development moved in circles, creating and solving problems by technological development: "We first polluted the rivers and later developed specific technology for treating river water and produce safe drinking water". Obviously, from a "restricted" concept of health this should be enough, but **sustainable development** requires further actions. The Water Framework Directive offers a clear example of that question. The aim of "good ecological status" in all European waters is fully in line with the goal of a proper quality of life: "our environment must not only be safe, but also good". Voluntary activities of companies introducing "green accounts" or "environmental profiles" are initiatives for reducing impacts below legal requirements.

Environmental protection has usually considered three main goals:

- Protection of human health from environmental exposures,
- Protection of natural resources such as fisheries, landscape, forest, soil, water, etc., which are essential for human development,
- Protection of other species.

There are often conflicts between the development of human activities and environmental protection. To assess those effects it is considered important to distinguish between **intended** and **non-intended** changes. Agriculture offers a good example where that distinction is useful. European landscape has undergone an in-depth modification over the last 2000 years, in order to getting agricultural land, essential for food production. The environmental impacts associated to the transformation of natural areas into agricultural lands could be seen in most cases as much higher than those associated to the use of agro-chemicals. However, citizens establish clear distinctions between both impacts, the former are considered as intended, assumed as inherent to the land use, and therefore accepted. The later are considered non-intended and treated with suspicion. The reasons for that suspicion are mistrust in the chemical industry resulting from the lack of transparency in decision making in the past. Strict regulations have been developed for minimising the associated non-acceptable risk. Thus, the authorisation of pesticides under Directive 91/414/EC requires that the used patterns are

not assessed as representing an unacceptable risk for non-target populations although it is clearly recognised that most of these populations will be severely affected physically during the usual crop harvesting.

In conclusion, environmental status is a component to take in account in a quality of life assessment, although not all environmental impacts are considered equally important.

2. RISK PERCEPTION AND QUALITY OF LIFE

2.1 THE STARTING POINT: THE RISK CONCEPT

Risk means different things to different people. For instance, risk is defined as exposure to a hazard, as chance of some adverse outcome, such as death or the contraction of a particular disease. In economics, risks are viewed as opportunities whose returns are uncertain.

Yates and Stone (1992) define risk in a more general way. They propose three critical elements of risk:

- The type of potential loss
- Significance of the loss
- Uncertainty of the loss

The potential loss could be physical (including the physical consequences of health problems), psychological, social, cultural and financial. It is clear that the more significant a type of loss is the greater the risk is. However, the significance of a loss might vary for different people or different groups of people. Thus, what is a major loss to one person might be a minor loss to another.

The uncertainty of risk is often defined as likelihood of the loss. However, there is another possible view: Uncertainty may refer to the category of the loss itself. In some situations we face uncertainty about what the type the loss might be.

2.2 QUALITY OF LIFE RELATED RISKS

Usually in the risk assessment tradition, the risks of the quality of life are more especially related to economic, aesthetic, and equity impacts, as well as effects on cultural and community identity and on the individual well being. Thus a specific subset of potential losses is especially focused.

In the medical tradition, quality of life has a slightly different, but comparable meaning. The issue is the importance or interest of outcomes for the patients. Especially in the field of public health intervention studies, outcomes may be classified as surrogate, clinical and patient relevant. Only the latter refer to quality of life aspects.

According to a definition of National Health and Medical Research Council (NHRMC 2000, 24) :
Surrogate are laboratory measurements or physical signs used as substitute for a clinically meaningful endpoint.
Clinical outcomes tend to be defined on the basis of the disease being studied, for example, cancer, ulcer, and infection.

Patient relevant outcomes are the ones that matter to the patient. They need to be outcomes that patients can experience and that they care about.

Quality of life risks are subsets of risk that matter especially to people. They are strongly related to risk perception. The risk perception approach acknowledges that the final issue of any risk assessment is the impact on people's life as experienced by the people.

2.3. RISK PERCEPTION

In risk perception research, the term 'risk perception' is used to describe attitudes and intuitive judgements about risk (Slovic 1992). In a broader sense, however, risk perception often also includes more general evaluations of and reactions to risk (e.g. regarding the acceptance or mitigation of risk). We will confine our overview to cognitive determinants of perceived risk.

Although the first studies on risk perception go back to the early sixties (e.g. Bauer 1960; Slovic 1962), the concept of 'perceived risk' became prominent only since the mid-seventies with the seminal work of Slovic, Fischhoff and Lichtenstein (Fischhoff, Slovic, Lichtenstein, Read & Combs 1978; Slovic, Fischhoff & Lichtenstein, 1977, 1980). Two problem areas motivated their work: people's 'non-rational' adjustment to natural hazards such as floods and public controversies about the risks and acceptability of modern technologies. Common to both problem areas was the observation that people often responded to risk in a seemingly irrational way - at least from the viewpoint of many experts.

Building on Simon's concept of *bounded rationality* (Simon 1955) and Tversky and Kahneman's work on *cognitive heuristics and biases* (Tversky & Kahneman 1974), Slovic and his co-workers argued that those faulty perceptions of risk could be explained as a result of the cognitive limitations of human beings (Slovic, Fischhoff & Lichtenstein 1977). These cognitive limitations were also held responsible for people's opposition to modern technologies, in particular nuclear power, which according to scientific risk assessments should have been regarded as safe, or at least acceptable, technologies compared to other risks, e.g. from sports activities or lifestyle, which people were obviously willing to accept without complaint.

However, it soon turned out that other aspects than misjudging probabilities might be of even greater importance for the perception of risk. In reaction to a paper by Starr (1969), Slovic and his co-workers introduced a new methodological approach to investigate risk perception, which is now often referred to as the '*psychometric paradigm*' of risk perception research.

Slovic and his co-workers proposed the *expressed preference* approach, which uses questionnaires to ask people directly about perceptions of risk (Fischhoff *et al.* 1978; Slovic, Fischhoff & Lichtenstein 1980, 1985). In these questionnaires people were asked to rate the risks associated with various sets of

hazardous activities, substances and technologies, such as nuclear power, pesticides, bicycles or sunbathing. Also, judgements were recorded about other hazard characteristics which were hypothesized to account for risk perceptions, such as voluntariness of risk, its controllability, knowledge about the risk, dread associated with risk, and so on.

Multivariate analysis of the relationships between these variables showed that many of these risk characteristics were highly correlated and could be reduced to two or three factors that explained most of the variance of the judgements. Most important was the factor that represented characteristics that were related to the severity and dreadfulness of the hazard, such as dread, lack or distrust of controllability, non-voluntariness or concern for future generations ('dread risk' factor). A second factor comprised knowledge-related characteristics such as whether the risk is observable, known and new ('unknown risk' factor). While the 'dread risk' factor was strongly correlated with perceived risk, the 'unknown risk' factor showed only a weak association with perceived risk.

The important message from the psychometric studies on risk perception is that for most lay people, risk is more than some combination of 'size of damage' and 'probability of damage', which are the core parameters of the technical concept of risk (Kaplan & Garrick 1981). This had a strong impact on the research and application of risk communication and risk management (National Research Council 1989; Kunreuther & Slovic 1996).

2.4. PERCEPTION OF THE ENVIRONMENT

The perception of environmental impacts in the surrounding environment produces a significant reduction in the quality of life. A heavily polluted river is a cause of concern for all citizens. However, perception patterns are different among urban and rural populations. Urban populations are basically concerned on the possibility for enjoying a pure environment during free-time activities. Rural populations develop their activities in close contact with the surrounding environment. Therefore they are most concerned on a proper sustainable development, where sustainability does not only considered environmental impacts but also economic development.

However, in both cases their perception of environmental impacts has serious discrepancies with the scientific assessment. The focus in ecotoxicological assessment is the effect/risk on the structure and functioning of the ecosystem. The assessment is complex, requires sophisticated tools, and has serious difficulties for a proper risk communication.

Some environmental changes are easily observable, and therefore perceived by citizens as either positive or negative. This perception is not always in line with the scientific evaluation of expected environmental impacts. For example, fish or bird kills are easily observed and perceived as very

negative, although in same cases has no or only minor consequences on populations and ecosystems. Changes on invertebrates, microorganisms, etc. cannot be observed without a proper assessment, and therefore are not perceived as environmental impacts by citizens even when they are so dramatic that they will result on significant alterations of the communities and ecosystems. Finally, some strongly negative impacts can be perceived as positive changes, for example, in an eutrophic system, a heavy chemical impact destroying all populations will be associated to an increase in the water transparency, which can be perceived by not specialists as an improvement in water quality when in reality it is associated with the acute lethal concentrations of a chemical.

2.5. THE IMPLICATION FOR THE RISK ASSESSMENT

Risk assessment could be conducted in a broad perspective:

- Besides classical endpoints in risk assessment such as reproductive toxicity, mutagenic and carcinogenic effects, qualitative risk characteristics should also be incorporated in risk assessments because dread associated with a risk is a stress factor that might impair health.
- Furthermore, in cases where the knowledge about the risk potentials is inconclusive, the risk assessors should be attentive to quality of life risks such as community identity, equity and aesthetic issues. It could be that these aspects matter to people too and ignoring relevant issues means to invite a controversy.
- Quality of life risks should be considered from the beginning of the risk assessment process. Especially in the scoping phase, risk assessors should take the opportunity to explore qualitative characteristics of the risk. Therefore stakeholder involvement is essential.

The risk perception research provides tools to measure those characteristics. Therewith risk assessors are in the position, to consider quality of life aspects in the risk assessment process.

3. THE IMPORTANCE OF THE COMMUNICATION FOR THE QUALITY OF LIFE ASSESSMENT

The goals of the communication are to describe risks and benefits, to conduct a fair and factually oriented debate about different types of actions, and to find solutions to conflicts between stakeholders. It would be a mistake, however, to believe that all these goals could be achieved just by supplying information about risks. In fact, success depends on each of the following building blocks:

- The quality of the relationship between those involved,
- The design of the information,
- The shaping of the dialogue.

Without this foundation, risk communication is, at best, just a patchwork, and at worst, ineffectual. How difficult risk communication might be depends from the complexity of the risk issues.

The first level is to **provide factual, scientific information** to the public. It is the duty of the risk communicator to explain the assessment tools and results and to clear the uncertainties in a way that the public may develop a better understanding of the risks. In terms of substance, the aim is to communicate facts and knowledge. It is important:

- to convey information about the type of issue concerned, to clear and minimize differences in the ways of looking at the issue,
- to provide tools for evaluating the risks and benefits, for answering the questions, and for dealing with objections.

This requires both high scientific expertise and the ability to translate technical information in a common sense language.

The second level of the communication deals with **participation and conflict**. Risk communicators should create a culture of fairness and mutual understanding. All stakeholders should be empowered to express their views. In social terms, the aim must be to enhance the quality of the relationship between all those participating in the communication, i.e. to develop the social climate for talking to each other. This means that perception patterns, images and self-images must develop in a way that helps to establish a foundation for proper understanding and productive debate. As long as communication is characterized by distrust and hostility, no objective discussion is possible at all.

The third level deals with different worldviews, social values and concepts of "good life". This is the case, when "quality of life" is a part of the risk assessment and the search for appropriate risk management options. Here, neither scientific expertise nor discursive competence and openness are sufficient. The main issues are trust and social responsibility. It is at the relationship level that the crucial interpretation patterns evolve, on the basis of which information about quality of life assessment is perceived and understood. It is at this level that the signals are set for the direction the communication is going to take.

A systematic approach to that communication consists of six steps. The first three steps lay the foundation for the subsequent steps of implementing communication on quantitative risks and uncertainties:

1. The first task is to establish the basic situation: What is the type of quantitative risks and uncertainties in question and what is the key information that has to be communicated?

2. The next step is to identify the audience for the communication, including their positions, perspectives, and interests. Who do we need to communicate with and why? Another important aspect is "How?", in other words, what form of dialogue should be chosen?
3. Following this, the next task is to carry out an assessment of the level of trust that the other stakeholders have in the communicator.

Once these questions have been addressed, the core messages of the communication effort have to be defined. These should cover all the information that is important for understanding and assessing the risk:

4. The social contexts in which people perceive the quantitative risks and uncertainties play an important role here. The aim is to minimize the difference between the expert assessment and the way people view it.
5. Only when this has been achieved can quantitative information on quantitative risks and uncertainties be conveyed.
6. The final step is to select risk comparisons suitable for illustrating the quantitative information on quantitative risks and uncertainties.

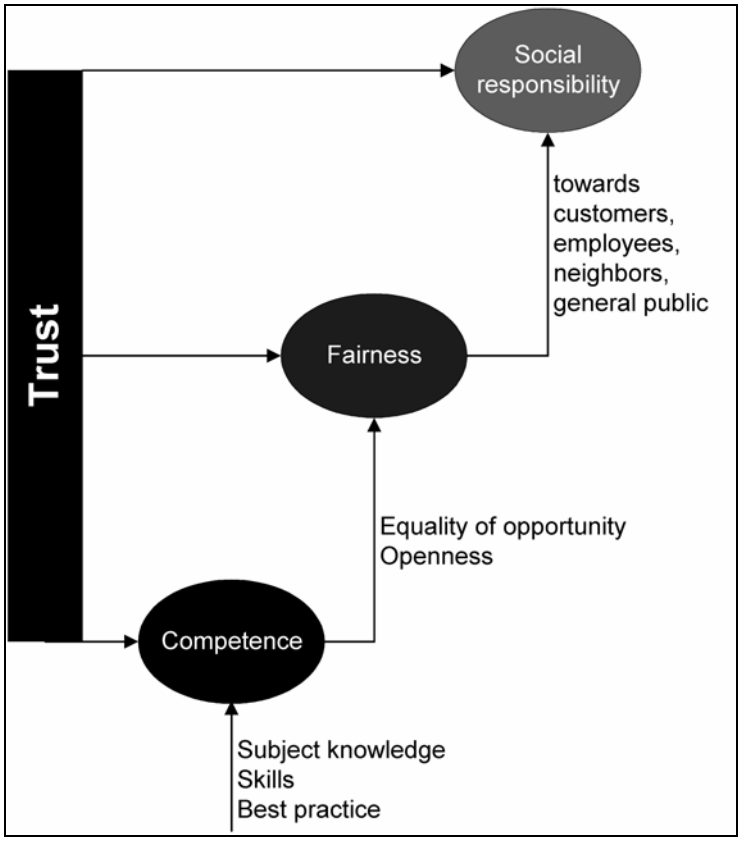

Figure 1: Elements for the risk communication

Key elements for the risk communication:

Discussions and decisions in the context of risk issues are interdisciplinary and must be tackled across boundaries of expertise for an intensive exchange of ideas.

Risk Communicators should be aware of and remember the different risk perspectives and take them into account in their risk communication efforts.

An equally intensive reconciliation of opinions is essential in order to understand the complex correlations involved and to be able to make "acceptable" decisions and take "appropriate" actions.

Risk communication aiming in consumer trust as outlined in the above graph depends on a positive appraisal of the competence, fairness, and social responsibility of the partners in the communication process. Without such a positive appraisal, risk communication is bound to fail. As the EUROBAROMETER publications clearly demonstrate it is not only competence regarding facts, but the inclusion of the competence in ethical/moral challenges that drive consumer trust.

4. ANIMAL QUALITY OF LIFE

That part has been introduced because of the public concern about the welfare of the animal. It is also of interest but because of the interest of the comparison between the ways that question of the quality of life are handled in animals and humans.

All the animals under the human control are involved in those assessment including the experimental, farm, and companion animals. However large differences can be found in the way to treat the different types of animals depending on their uses despite the fact they are basically the same animals with the same physiological and psychological backgrounds. Animals from some species can be considered to deserve a higher concern than others. In particular, concerns on animal quality of life are restricted to vertebrates, and within vertebrates, to mammals and birds. This partition has not a scientific equivalent in the environmental arena, as the relevance of the change depends upon the ecological consequences. It therefore focuses on the ecological role of the population, including recovery and redundancy, and on the final consequences on biodiversity, independently of the affected organisms, from mammals to microorganisms. All these aspects are species and/or community specific, while the public is concerned only by some species.

That concern has increased recently and this is at least partly due to the new management practices which increased the constraints on the animals. Large groups, poor indoor environment, low social stability are common characteristics of those systems. Some production systems are perceived by the public as a cause of unnecessary suffering for the animals.

Several **definitions of Animal Welfare** exist, for example:

- The welfare of an animal is what is achieved when it is in harmony with its environment and with itself, both physically and psychologically (Lorz, 1973).
- The welfare of an animal is its state as regards its attempts to cope with its environment and its health and feelings are part of this state (Broom and Johnson, 1993).

Animal welfare concerns physical and psychological suffering. Welfare deals with a lot of concepts: needs, freedom, happiness, coping, feelings, suffering, pain, anxiety, boredom, stress, health (Broom, 1996). Even if we are using the same words as for describing the human feelings, the major difficulty of that welfare analysis is to avoid **anthropomorphism**. What is important for the animal cannot be decided from what we could feel if we were in their situation, or from our empathy. It can only be defined by observing the animals. Those definitions are very similar to the human ones. In particular they include the psychological and social components and the ability of the subject to predict and control its environment.

It is then necessary to have tools to measure how the animals really react in the environment where they are living. The analysis of welfare implies the study of a **large range of biological criteria**. Three main categories can be defined physical health, physiology and behaviour:

Physical health: the environment where the animals are raised should not cause high mortality and morbidity. Any effect that lowers the ability to resist abiotic or biotic adverse effects (decreases of bone strength, or immunosuppression for example) results in a poorer welfare of the animals. However, only relative values can be obtained comparing different environments or types of animals.

Physiological traits: any alteration of the normal functions of the animal is considered as potentially harmful for the animals. That alteration can be measured by a change in production. *Low growth and reproductive problems* can be indicative of difficult conditions. However, too high production can also have detrimental effects on other aspects of the welfare of the animal. When such a modification, often presented as a *functional pathology* is observed, it is necessary to control that it can be the cause of sufferings before concluding that it lowers the welfare of the animals. Levels of *hormones* (cortisol, catecholamines, opioids) are used for assessing the extent of *stress* or the difficulty to cope with the challenges.

Behaviours of the animals give a lot of information for a welfare analysis. It is the main way for the animal to express its feelings. Those studies aim at understanding how the environment can modify the mental representations of the animals and their affective and emotional status. Different analyses can be done. It is possible to compare the activities of the animals under a constraint to the one without that constraint to detect changes of the *time budget* and of the *rhythms* and the appearance of *abnormal activities* (stereotypies, apathy, aggressiveness). It is also possible to study the *preference* for any item of the environment (floor, space, social partner,...). The preferences are analysed by giving the animals a choice between various items. The price the animal is ready to pay to obtain some resource can also be obtained.

The different measures described above do not react in the same way to the constraints. When a constraint causes an increase in mortality it is usually construed as detrimental for the welfare of the animals. However, if the constraint does not cause any detrimental consequence on the physical health it is not sufficient to decide that the environment is good for them. The more sensitive tool is usually behaviour that will change when a constraint is imposed much before the other ones.

The other point is that some parameters can give contradictory conclusions. For example, keeping animals individually impairs the ability of the animals to develop a normal social life but may allow better control of disease and hence can lower mortality and morbidity. As a hierarchy between the different measures of welfare is difficult to define, care must be taken when contradictions between the different indicators exist.

The constraints that can be imposed on the animals at the farm level are abiotic, e.g. the temperature, ventilation, floor,.. or biotic, e.g. the food, social environment. Within a species several factors can modify the **ability of the animals to cope with their environment**. Very important *genetic variabilities* exist but the previous experience of the animals is also of major importance. For example prenatal stresses and environment during childhood have been described to be important.

The issue of animal breeding targeted to meet commercial requirements and disregarding in some cases the animal well being or even its physical health is an issue requiring a lot of attention.

Depending on the ethical position taken, the minimal requirements asked for the animals can vary largely from a deny of any duty of humans towards the animals to the " Animal rights " defenders' position which leads often to vegetarianism. However, most of the scientists assume that humans have at least a duty to avoid any *unnecessary suffering* of the animals and that they should provide an environment for the animals which assures a minimal standard of welfare. However the limits are difficult to define as absolute values. For example "*any unnecessary suffering*" implies a trade-off between the sufferings of the animals for the future benefit of human or other animals. A cost benefit analysis is then done with on one hand the benefit of specific environmental conditions for the animals and on the other hand the benefit of constraints on the animals for the human health (suffering for experimental animals) or wealth (cost of the housing for example). As a consequence the same level of suffering of a rabbit will be more acceptable if in a sound experiment for trying to cure a disease in the future than if it is to gain more money in a farm. However, depending of their perception of the problem some people or stakeholders can claim that on ethical ground not negotiable minimal conditions should be provided to the animals.

Basic differences between the quality of life analyses for humans and animals exist. Animals especially those living in farms have not a great opportunity to choose their environment and the farmers can choose animals for specific environments. Then the animal welfare is simpler than the human quality of life and the distinction autonomous vs. heteronomous, as the exogenous vs. endogenous are not so relevant. However even with that simple question the maximisation of animal welfare ends with a combination of different parameters (health, freedom, sociality) that need to be weighted. The values given to the different parameters, in addition to the ones given to the benefit for the humans, have to be combined for taking a decision.

5. QUALITY OF LIFE ASSESSMENT

5.1 PSYCHOSOMATIC HEALTH IMPACTS

There is clearly a two-way link between psyche and soma, and an impact of the environment, particularly when it is stressful on the soma? The consequence is that the stress may affect the quality of life both by increasing the occurrences of functional diseases and by decreasing the psychological status.

A number of studies provide clues that psychosocial factors contribute significantly to the pathogenesis and expression of coronary artery disease (CAD) and have an impact on human immune function. The evidence is composed largely of data from animal experiments (Villemain, 1989).

Epidemiological data relating CAD risk to 5 specific psychosocial domains (Rozanski et al, 1999): (1) depression, (2) anxiety, (3) personality factors and character traits, (4) social isolation, and (5) chronic life stress are less convincing because of contradictory findings that might be explained by the difficulty in assessing the degree of psychological distress in large scale surveys. There is also suggestive empirical evidence indicating some causal relationship between work stress and CAD risk.

Relationships between psychosocial factors and immunity have been investigated for several diseases, including cancer, acquired immune deficiency syndrome, and autoimmune diseases (Leary, 1990).

Anecdotal evidence suggest that elderly people might be much more affected by a given type and level of stress than younger people.

However, the available evidence is not strong and consistent enough to allow quantitative risk prediction for a given situation generated by a stress. More studies should be done to assess the effect of stressful situations on quantity and quality of life, including the sudden awareness that one is exposed to a particular risk factor.

5.2 STRENGTH OF DATA AND QUALITY OF LIFE ASSESSMENT

Quality of life is specific of each individual

Quality of life is defined multidimensionally. One or more of the components are related to autonomy, and are largely generic. At least one other dimension is specific for each individual (it has been called "subjective" by reference to the subject (Gerin et al, 1992). How large is this dimension is unknown. Its stability across different individuals or groups of individuals is unknown. However, from anecdotal observations it is likely to be quite variable. This means that quality of life assessment is individual or, at least, group dependent. An individual has her or his own life goals. The same hazard may well have opposite consequences on quality of life of two individuals. In addition, one risk factor may be detrimental for a dimension, and beneficial for another one. An example is given by disease conditions that impaired autonomy in all patients. It can improve somewhat the well being of some of them because their family does take more care of them but it can impair their well being if their loss of autonomy is perceived as fundamental.

Therefore, any conclusion as to whether a factor has a significant or an insignificant impact on quality of life might not be true if another group is considered.

Available quality of life scales

There are hundreds of quality of life scales (www.qolid.org). They are used in clinical research, and particularly in an attempt to assess the therapy effects on quality of life. Most of those scales, if not all, are more functional status scoring instruments than true quality of life investigating tools. The shift from the "subject" based quality of life to a more generic approach is likely to have been caused by the difficulty of the former.

Two issues

From the above considerations, it comes that for assessing the strength of data for correlating risk perception or risk exposure with the quality of life, two issues should be of concern:

1) The type of questionnaire used: Many questionnaires, particularly those that are disease specific (e.g. for arthritic or heart failure patients) focus on functional autonomy. They essentially do not pay attention on the psychological and specific aspects of the quality of life of the subject.

2) The stability of the results across different groups exposed to a potential hazard: Since most of the questionnaires used to explore the relation between a certain disease and the quality of life investigate somatic functions or the direct consequences of impaired functionality, they are generic and thus yield relatively stable results across different subgroups. When subject specific dimensions are looked at, this is apparently no longer true (Gerin et al, 1992). Whether it would be possible to identify patterns of reactivity to a given hazard is still open.

Future research in the domain of risk assessment and quality of life, should consider two types of development which should be developed sequentially:

a. A generic scale of evaluation of quality of life accounting for all the relevant dimensions.

b. A specific scale allowing evaluating the impact on quality of life of the awareness for an individual to its exposure to a hazard.

6. CASE STUDIES

6.1 Pesticides

Scientific background

The presence of hazardous (toxic) chemicals in water, soil, air, or food items can have negative consequences on human health. The effects depend on the toxicity (intrinsic hazard) of the chemicals, the sensitivity of the individuals, and the level of exposure. Product safety will finally depends on the combination between the exposure and the effect of all chemicals found in the food, water, soil or air, accounting also for synergistic effects.

The scientific community has developed several tools for estimating, on a quantitative basis, the expected danger, which is usually addressed using risk terms: the likelihood of the adverse effects to occur under certain circumstances. These risk assessments are currently a basic tool in the process of decision-making, and in some cases, such as for pesticides, must be conducted as part of the authorisation process.

Pesticides are frequently used in modern agriculture, and therefore, the pesticide regulation considers scientific assessments related to the safety of these products for human health and the environment, including specific assessment for residues in crop items and food products, contamination of water, soil, effects on non-target organisms, etc.

An alternative agriculture, usually named organic farming, is gaining increasingly importance. These agricultural practices avoid the use of pesticides and other man-made chemicals, while the use of

"natural products" is promoted. There is a claim that products obtained by organic farming are not only more environmentally friendly but also safer than the others.

Avoiding the use of a particular chemical is expected to avoid (or at least significantly reduce) the exposure to this particular chemical, but not to others that could be used to replace that product or which can appear when it is not more used. Distinctions between the origins, man-made versus natural, cannot be scientifically based. In fact, several natural toxins are among the most toxic known chemicals.

Furthermore a clear distinction has to be made based on the mode of action of a chemical. For example no effect threshold can be assumed for genotoxic carcinogens as even very small quantities may lead to the development of cancer at a later point in time. On the contrary for all other chemicals toxicity thresholds are assumed that can be estimated from the available information.

The perception of the problem

Citizens make clear distinctions between chemicals according to the kind of chemicals and the reasons for exposure.

- In the case of pharmaceuticals, individuals are ready to experience some toxicological consequences (secondary effects) if they are compensated by expected immediate benefits of the treatment to their health.
- In addition to carcinogens, pesticides are probably one of the best examples of chemicals perceived as particularly dangerous by the general public.

The presence of pesticides in food and water has received significant attention by the media, citizens associations and NGOs. It has been considered that the general public has more concerns regarding the presence of pesticides than for other chemicals. Therefore, the European Commission and Member States have adopted particular measures on the basis of the Precautionary Principle. They have taken political decisions for pesticides that are not only and exclusively based on risk assessments.

Usually, the concern is expressed for the chemical category as a whole, without distinctions. So, citizens are concern about all carcinogens, and the perception does not distinguish between genotoxic and non-genotoxic carcinogens. Similarly, the political decisions based on perception include all pesticides, although the toxicity range for these products covers several orders of magnitude.

Inclusion of perception in risk assessment and risk management

In general, management decisions are based on the outcome of the risk characterisation, applying scientifically sound evaluations whenever possible. However the concerns of the public for the exposure to low levels of pesticides have produced new decision-making strategies.

Two different options can be mentioned, labelling and special procedures for decision-making. Labelling is a general measure to give citizens the possibility of choosing among different options. A food produced without the use of pesticides can be marketed with labels indicating its origin. Names

such as “ecological” or “biological” agriculture are commonly used in the legislation. These denominations are not scientifically based but depend on a political definition.

Mostly, these production systems focus on avoiding the use of man-made chemicals. The general perception is that natural products are safer than the ones produced following the industrial procedures. From a toxicological perspective this difference has however not been validated. On the contrary, several “natural” toxins are reported among the most toxic chemicals in the world and several of the most problematic pollutants, including certain metals, PAHs, etc. are found in nature. The replacement of a chemical pesticide by a plant extract will obviously reduce the amount of residue of that pesticide, but it does not necessarily produce a safer product.

Most regulatory decisions on chemicals follow the conclusions of a risk assessment. However, some regulations on pesticides have applied the Precautionary Principle to follow the specific concerns of citizens on pesticides. A clear example is the regulation on the level of pesticides in drinking water. In the 70s, a political decision was taken to reduce to “zero” the presence of pesticides in drinking water, independently of their toxicities. However a “zero level” is neither achievable and cannot be assessed. As a consequence the “zero level” was transformed in an analytical level of 0.1ug/L, which was considered to be the limit of detection for the techniques used at that time.

At the same time it was decided that this rule should not generally apply to all other chemical substances in drinking water (e.g. minerals). For those substances specific maximum levels in drinking water have been established following a toxicological evaluation.

The developments of analytical methods have not yet modified those limits. Nowadays, in particular after a substantial European research investment, pesticides can be detected in drinking water much below 0.1ug/L but their presence is still considered as acceptable if that limit is not exceeded. From a risk characterisation perspective, this decision basically means that the safety factor used is inversely proportional to the toxicity: the most toxic pesticides get a lower margin that the less toxic pesticides. In theory, the safety factor used for a very toxic pesticide can be even lower than the one used for general chemicals.

Consequences of public perception on quality of life

The use of these types of decisions can lead to opposite results than expected. Until now, this problem has not been identified regarding Human Health assessment but it has been analysed from an environmental perspective. Using the Precautionary Principle the drinking water criteria for pesticides were included as reference value for groundwater contamination. Directive 91/414/EC adopted a level of 0.1 ug/L as the maximum acceptable concentration in groundwater, independently of the toxicity of the pesticide to living organisms. Several pesticides show toxicity to aquatic organisms at concentrations lower than this value, and therefore this criteria, which initially was adopted as an additional precaution, is at the end of the process less protective for the environment and the human than the scientifically based risk assessment.

A similar example for the consequences of public perception on quality of life is the regulation of the presence of pesticides in marketed infant food: The value set for marketed infant food is below the value which could be achieved in home-made food when using normal food ingredients from the markets with "accepted" levels of pesticide residues.

The use of the precautionary principle for decision-making instead of a scientific risk assessment is a political decision. However, specific tools must be implemented to guarantee that the decision process does not lead to scientific inconsistencies, and particularly to a lower level of protection than the one expected. As it is always stated, that precautionary principle should be used for a limited amount of time, allowing the scientists to develop tools to allow evaluating the risk instead of remaining under uncertainties.

The use of exposure limits is not necessarily safe, and the scientific society is concerned about the generalisation of these limits within the EU regulation, not only for pesticides, but also for other chemicals such as pharmaceuticals.

An exposure limit, with no information on the toxicity of the chemical, can never be considered safe enough. Obviously, the public concern can request a higher margin of safety, achievable using additional application factors or fixed limits. But methods to demonstrate that this decision is really safer than the standard risk analysis must be implemented in all cases.

Regulatory decisions should be based on solid scientific basis and decisions on labelling should include a realistic assessment of the intentions of the label and of its perception by the general public.

The consumption of a particular product lays on the individual consumer freedom. However, there is a clear responsibility from risk assessors and decision-makers for creating a clear and transparent network for risk communication. There is an obligation to inform in a proper manner on the reliability and uncertainty of the level of risk assumed as acceptable during the authorisation of pesticides and other chemicals, but also, to clarify all the issues as for example that "natural" does not mean safe. A sound risk communication is particularly relevant when labelling is included in the management process. Labelling should be related to reality. If a product has been produced without using pesticides, the label should identify this fact, and only this fact, without giving the impression that the product is free from (all) chemicals. Such an assessment should provide all information about potential hazards and impacts for the public and for the decision makers to take decisions.

6.2 BSE

The scientific background

The Bovine Encephalopathy Spongiform (BSE) disease raised many questions during the last ten years. It seems now highly likely that the new variant of Creutzfeld-Jacobs (nvCJ) disease is due to the ingestion of products from bovines that are developing the BSE disease. From the beginning of the epidemic to the 2001 autumn, 118 human cases have been diagnosed including 111 in Great Britain, five in France, one in Italy and one in Ireland. The extent that will reach the outbreak is still difficult to

forecast and very different previsions are still valid. It seems however likely that the total number of diseased people will fortunately be limited.

The aim of that text is not to comment on the tragedy for the diseased people and for their relatives but we want to point out on others possible effects on humans. The question we want to address is if it will not be possible to enrich the risk analyses by including them. Consumers and industry people can be concerned by the question.

BSE developed on cattle mainly from the ingestion of contaminated meat-and-bone meal. The epidemic starting from Great Britain developed in most of the European countries. Between 1987 and 2001 about 184000 heads of cattle developed the disease. Several hundred thousands were destroyed in the different European countries. The detection is linked with the destruction of the animal and often of its whole herd. A whole set of regulations has been published in order to limit and stop the epidemic.

The perception of the problem

Three main components can characterize the episode:

- The risk has been out of the control of the consumers and of the industry people. Others risks as for example smoking or driving are known and, to some extend, accepted. That is not the case for the vCJ that is linked to the consumption of beef products. Consumers had not perceived any risk before the beginning of the crisis and had consumed often a lot of products before knowing the risk they where exposed to.
- The risk is still partly unknown. The probability to develop the disease is not well assessed and it seems even that it differs between people.
- The number of concerned people is large. Most of the people will have eaten some beef during the last years and have given those products to relatives and friends.

Inclusion of perceived risk in risk assessment and management

The “mad cow” crisis has consequences on almost every people. Its genesis and its development were the result of several actors (media, public, political decision-makers, industry stakeholders, scientists). The crisis has sometime been described as a “collective psychosis”. It results in a high tension in the public calling feeding habits into questions. Those feeding habits are well known to be an important part of the social life. As a result beef consumption is probably now negatively perceived. The collectivity was able to manage the crisis but it was not possible to avoid the tensions in the public that probably resulted in a lower quality of life.

Consumption of risk products is not the only cause of discomfort. Even if that preoccupation is not so strong, a large proportion of the public is concerned about the welfare of the animals. Some people stop consuming meat. However, most of the people keep their food habits while being concerned about the suffering they could indirectly provoke. Everybody is aware of the destruction of thousands of animals. It concerns not only the sick ones but also healthy ones because of their age or

herd. The sacrificial character of that practice has been probably emphasized by the other epidemics, classical swine fever and other foot and mouth disease.

It is also necessary to wonder on the consequences of the crisis on the industry people. The reduction of consumption still present and which peaked at 40% for some periods had a large impact on the economy. It strikes all the industry including the people from suckling herds that had very few sick animals. A main concern is however to question about the consequences on the farmers of the detection of a sick animal in their herds. Farmers have historical and affective relationships with their animals. The character unfair, and perhaps infamous, of the situation has probably large consequences on the psychology of those farmers and on their behaviours. It triggered probably the hiding of cases to avoid all those consequences

Most of those risks have not been taken into account in the scientific assessment of the risk as they are mainly related to psychological factors.

Consequences of the public perception of the problem on Quality of life

The public has been involved a lot in the "mad cow crisis" issuing from an unforeseen factor that changed a lot the scientific paradigm. They have seen the dreadful impact of that terrible nervous disease by watching the television. Most of the people have concern about that issue for themselves and for their relatives. However it is difficult to assess the exact consequences of that concern. Risks are mainly consequences of the perception of the different people of the situation and they are of psychological nature. Due to the episode, quite a lot of very important aspects of the life of the people are under question including their feeding habits but also their relationships with the animals. They have to be further analyzed in the future to complete the quality of life analysis.

6.3 ElectroMagnetic Field (EMF)

The debate on possible health effects of EMF exposure started in the 70s of the last century. Since then, several studies have investigated a wide range of possible adverse effects. In the 90s the concern shifted from power lines (ELF EMF) towards mobile communication (RF EMF). Nowadays, the RF EMF controversy becomes more and more heated all over Europe.

Scientific background

Most scientists conclude that EMF risks below the EU recommended limits seem to be rather small, if they exist. Some critics assume that possible effects of RF EMF on humans might occur even at very low doses (non-thermal effects). They refer to an increase of brain tumour, changes in the brain metabolism, effects on blood pressure, and subjective perception. On the one hand, a large scientific review conducted by WHO (Munich, November, 1996) concluded that there is no convincing evidence that exposure to RF EMF shortens the life span of humans, induces or promotes cancer. On the other

hand, the same review underlined that further research is needed to draw a more comprehensive picture of EMF health risks, especially about possible cancer risk from exposure to low levels of RF EMF.
The predominant scientific issue is the interpretation of so-called "biological effects at non-thermal levels". Two citations may demonstrate the range of the views:

"Data on human responses to high-frequency EMF that produce detectable heating have been obtained from controlled exposure of volunteers and from epidemiological studies on workers exposed to sources such as radar, medical diathermy equipment, and heat sealers. They are fully supportive of the conclusions drawn from laboratory work, that adverse biological effects can be caused by temperature rises in tissue that exceed 1°C. Epidemiological studies on exposed workers and the general public have shown no major health effects associated with typical exposure environments. Although there are deficiencies in the epidemiological work, such as poor exposure assessment, the studies have yielded no convincing evidence that typical exposure levels lead to adverse reproductive outcomes or an increased cancer risk in exposed individuals.

In general, the effects of exposure of biological systems to athermal levels of amplitude-modulated EMF are small and very difficult to relate to potential health effects." (ICNIRP, 1998).

A French report (Zimlou 2001) comes to the following conclusions: *"Scientific data indicate, with relative certainty, that, during exposure to RF from a mobile phone, a variety of biological effects occur (e.g. Electroencephalogram profile, reaction time, etc.) at energy levels that do not cause any local increase in temperature. However, in the current state of knowledge of these non-thermal effects, it is not yet possible to determine whether they represent a health hazard.*

Although this assertion is backed up by little scientific argument, the hypothesis that certain medical effects are caused by the low-level RF fields associated with mobile telephones cannot be completely excluded, in the current state of knowledge. Experimental and epidemiological research into a range of health problems, including brain cancers and headaches, is currently in progress; the role of exposure to RF in these symptoms or diseases has not yet been clarified. However, in view of the exposure levels observed, the group of experts does not back the hypothesis that there is a health risk for populations living in the vicinity of base stations.

If future research were to validate this hypothesis, i.e. demonstrate the existence of health hazards, the risk, at an individual level, would probably be very low. Indeed, it is reassuring to note that it has not yet been demonstrated, in spite of the considerable amount of work done over the past several years. However, if mobile phone radio frequency fields were hazardous, the very high number of mobile telephone users could mean that, even if the individual risk were very low, the impact on public health could be considerable."

The Perception of the Problem

The concern of the general public is about those potential health effects at non-thermal levels and about the issue, whether the existent limits offer the required health protection. The public interest

in RF EMF issue is widespread in Europe. In some countries, as Switzerland, Germany and Italy, the EMF controversy is very intense.

The focus of the debate is on base stations. The mobile phone itself plays a rather minor role in the public discussion. In most communities where a network provider for mobile communication intends to establish a new station, the concerned public is opposing such project.

One reason for the amplification of the issue is the lack of appropriate and timely information. This information gap is filled with rumours and sensational stories by some parts of the media. Furthermore most of the communication provided by corporations and governmental organisations fails to meet the information needs of the public, and the present communication is in most cases too technically oriented.

Inclusion of Perceived Risk in Risk Assessment and Management

Improving EMF debate starts with a concise diagnosis and clear understanding of the communication problems. So far it might be based on empirical research. The aims are:

- making the controversy about EMF risk potentials more transparent by establishing and negotiating criteria for the evaluation of scientific data about the health and environmental impacts of EMF,
- developing and maintaining appropriate capacities for screening, monitoring and evaluating significant EMF issues as perceived by the public,
- enhancing governmental officials' understanding of the social and policy aspects of EMF issues,
- developing appropriate policies for dealing with EMF issues, i.e. policies that allow a tactful and face-saving form of communication with other stakeholders ands opponents.

Consequences of the Public Perception on Quality of Life

All EMF issues should be considered in a policy framework. And policies deal with decisions, e.g. to select a new site for a base station, to set limit values for EMF-exposure or to define prudent avoidance standards of EMF emissions. Here, a decision-making perspective based on "value-focused" thinking (Keeney 1992, Beach & Mitchell 1996) should guide all EMF risk management.

In contrast to a decision-making process that focuses on choice between alternatives, the value focused approach starts with an analysis of the values for decision-making. The values in the decision-making process should be made explicit.

The goals for EMF-communication need to be formulated explicitly in the lights of these values:

- Giving first-hand and comprehensive information about EMF risk issues,
- Setting standards for explaining the uncertainties of potential risks,
- Explaining risk reduction measures and explicitly inform on the remaining risks,
- Giving a clear picture about governmental responsibilities in relation to risk issues,

Providing decision options instead of stating an option, and relying - if possible - on joint decision-making.

6.4 Genetically Modified Organisms (GMO)

The Scientific Background

Organisms genetically modified by a targeted, technology have never existed before on earth. Consequently, the risk and benefit evaluation of GMOs provides new challenges, whereas traditional plant and animal breeding are perceived as processes close to natural selection. Depending on the used methodology for genetic modification, unintended modifications in addition to the target one may occur and there may be effects on secondary metabolism in plants or by impurities in animal derived products. This whole area has been the subject of intensive research that was mainly targeted to the biological and physiological sides of risks.

The Scientific Steering Committee in its opinion of October 26/27, 2000, on the risk assessment in rapidly evolving fields used the case of genetically modified plants as an example. There still exist many uncertainties despite tremendous research efforts. The consequences of introducing this new technology for food safety evaluation have been thoroughly elaborated. The concept of Substantial Equivalence, which is to provide food safety by comparison with the respective traditional commodities, is being expanded and more clearly defined. A number of safety endpoints requiring revisiting have been identified. These include genetic transfer to other plants or other organisms, accumulation of modified traits within crop plants, potential impact on biodiversity and potential impact within the resistance area depending on the genetically introduced vectors. To cope with these uncertainties and to allow the new technology to be introduced at appropriate times, biomonitoring for post marketing surveillance and a set of further measures and restrictions has been introduced.

For the purpose of this report it is important to note, that modern methods of plant breeding not classified as genetic modification may lead to genetically modified plants with methods which are much less targeted than gene technology, and thus conceptually provides a potential for more side effects.

The Scientific Steering Committee in its opinion of October 26/27, 2000, on strategies for dealing with emerging and re-emerging scientific issues that have the potential to impact human health, directly or mediated through the environment, also used among others, the case of GMOs to emphasise scientific and management challenges.

The Perception of the Problem

It is not only lack of information and insufficient communication of what is happening in gene technology that raises public awareness. Claimed benefits of genetically modified plants include improvement of global food supply, better food quality, and economic benefits for the farmers, and less environmental impact of pesticide use. Whereas these benefits are still under debate, the individual

consumer does not see a benefit for himself – at least not for the current generations of products now on the market.

The major concern of the public however is the loss of the ethical **integrity of nature** following the wide use of this new technology or set of technologies. This concern provides a prerequisite for a non-scientific handling of the issue by the public. It causes the perception of tremendous threats possibly more specifically in those populations, which usually are susceptible to not well-defined and unspecific low risks. Further specific ethical aspects when using genetically modified animals, cloning of animals, using of human stem cells for medical research, influence also indirectly the risk perception. The controversial discussion within scientists on pros and cons and uncertainties additionally increases the negative public perception.

Inclusion of Perceived Risk in Risk Assessment and Management

The genetically modified plants are the typical example of already including quality of life aspects in the risk management –in this case - by the tool of labelling (Novel-Food Regulation) aimed to give the consumer the freedom of choice whether he takes this "risk" or not. It must be admitted, however, that in the course of time it is likely, that there is little food of plant origin, that would be totally free of products from genetically modified plants. Therefore, it would be an important measure of trust building, to tell the consumer that he or she finally will have no absolute choice due to undetected or undetectable presence of products from GMOs. Thus, either additional measures to assure that choice or a more honest communication of the limits of the existing measures are required.

Consequences of the Public Perception on Quality of Life

There are scientific issues and uncertainties regarding the safety of genetically modified organisms that in their extent depend on the methodology used, the area of application and the validity and degree of the safety investigations. It is however probable that, even with more research being done and with more restrictions, the whole public or a great part of it will accept easily this technology and feel no more threat. This means, that the mere existence of the application of the genetic modification has an impact on quality of life. A transparent and realistic value assessment of the quality of life has to be done whether and how to apply this technology in those important areas taking in account all the pro and con arguments. In areas where there is clear economic, health or social benefit for the consumer even if at the same time a risk of the technology is perceived, a full, unbiased and honest explanation of the interacting issues with the pros and cons might improve the situation.

7. MAIN CONCLUSIONS

Quality of life concept is multidimensional. It covers such aspects as human functional and psychological health, animal welfare, environmental impacts, aesthetics and community identity.

Therefore risk perception, communication, benefit estimates and value clarifications play an important role in the process of assessing and dealing with quality of life aspects.

Considering quality of life aspects requires special emphasis on communication on risks and benefits, transparency, clarity and reasonableness. Bad or poor communication can easily lead to public crisis.

Professional risk communication tools are essential in all cases and must in particular facilitate the individual decisions. Unfortunately they are still not well developed and implemented.

Aspects of quality of life, beyond the traditional risk assessment and management, have already been included in the process in a non-systematic way via the precautionary principle and by considering public concerns. This has been demonstrated in issues like BSE, GMO, pesticides and EMF.

In the past of public health policy, quantitative indicators such as life expectancy played a dominant role in risk assessment. On the contrary quality of life has always been the main issue in animal welfare. In many cases public crises have probably arise because of not considering enough the qualitative aspects in risk assessment and risk management. The cases studies presented above are examples of lack of appropriate and proactive strategies.

Therefore, it is very important to complement the classical risk assessment by including quality of life parameters. It needs to be considered whether the quality of life criteria should constitute an additional dimension to the assessment *sensu stricto* or if it should be conducted in a separate, regular and interactive process. Probably the second option is more appropriate since the whole process will require a more intensive interaction between risk assessors, other stakeholders and risk managers. However quality of life should be a concern from the beginning and should be integrated as an additional step to the current risk assessment. The current risk assessment leads to thresholds not to be exceeded or to actions to forbid. It is the basis of the current regulations. The quality of life assessments are useful to help the groups and individuals to make their own choices. They do not necessarily lead to regulations but they can be the basis for actions to promote actions.

An important issue is to deal with is the question of the values and acceptability that can vary between people and groups, depending on their cultural attitudes and preferences. A framework needs to be developed to allow costs and benefits to be compared in an understandable and transparent way. Despite a substantial amount of work done during the past years (for example by developing the Hazard Analysis Critical Control Point, HACCP methods) progress in this area is essential. In its absence it is likely that public crises will occur again.

It is essential when reviewing a risk assessment document to distinguish between the different kinds of data sets, facts and figures, models and theoretical assumptions, values and believes. Further research is needed to characterise the different types of data in terms of importance and strength of evidence.

9. RECOMMENDATIONS

Quality of life should be considered as a part of the scientific assessment and should be implemented as soon as possible. For that purpose new members with appropriate expertise are needed in the different scientific committees and procedures establishing the dialogue between the scientific committees and the stakeholders should be designed. That interface between scientific advisors and other stakeholders could be included as an initiative to help in the issue of "governance" in the EU. It could be included in a process that will begin by defining the risk profile and then by implementing the different steps of the assessment (Figure 2).

The quality of life assessment should cover the impact of the risk factors as well as the perceived impact. It should also include the perceived impacts of managerial decisions. Several steps could be defined when introducing those considerations by taking in account first some of the easier to measure parameters.

Specific research should be developed which should aim at defining the parameters to be included in the quality of life assessment and the process allowing to reach recommendations.

10. IMPLEMENTATION

For implementation two different actions could be taken:

- *The first one would be to ask a group of experts from the social sciences to work on any risk assessment report and to evaluate it in the light of their own disciplines. As a following step, it is recommended that the Commission invites a group of experts from the involved disciplines to prepare a targeted guidance providing the details of introduction of the identified quality of life criteria and tools in the risk assessments of the scientific committees.*
- The second one could be, as suggested previously, to build a framework making risk assessors, risk managers and stakeholders working together on those questions. It will be the opportunity for the risk managers to describe the different criteria used for taking their decisions (societal, economic, ethic, political,…) and to the risk assessors to analyse the possibility to introduce objective measures which could help the decisions on those areas.

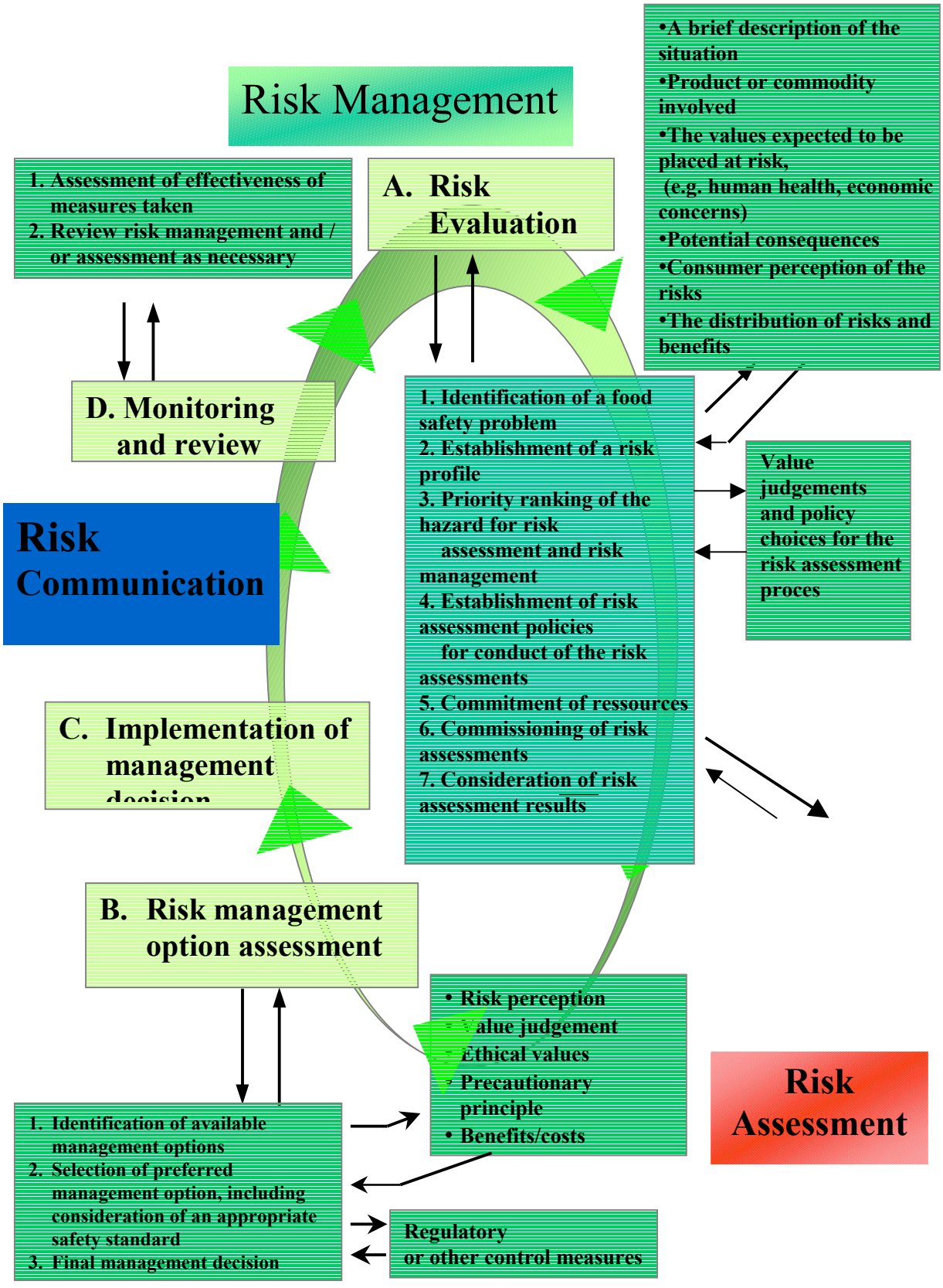

Figure 2: General schedule of the risk analysis

10. RESEARCH

A substantial amount of research has been implemented in areas related to the quality of life during the past years. A List of projects funded by DG Research is attached to the report of the working group. Considering the nature of research needed, its transdisciplinary character, the intensive interactions required between the disciplines and the users of the research results, it is proposed to establish a NETWORK on QUALITY OF LIFE AND HEALTH

A draft list of research topics has been proposed by the members of the group, which is attached (Annex 2).

11. ACKNOWLEDGEMENTS

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Annex 2

Draft list of Research topics

Research to minimise uncertainties on risk related questions needs to be continued to improve risk assessment and thus provide an improved basis for facts-based risk perception.

Specific research topics on quality of life:

- ethics of risk assessment (moral, philosophy),
-risk perception research (applied social psychology),
- comparative risk assessment,
-societal values (empirical sociology),
-multiattribute evaluation (decision science),
-evaluating scientific evidence under uncertainty,
- elaboration of a quality of life terminology by harmonising needs and approaches,
- development of improved tools for uncertainty communication,
- tools to analyse variability in the parameters discussed, their causes and how to improve them,
- development of deterministic and stochastic systems for balanced cost and benefit inclusion in the risk analysis,
- cost saving by introduction of Quality of life concept for health care, potential economic constraints in other sectors,
- consequences of the new paradigm for “responsible care” of industry,
- development of education programmes for scientists and journalists in risk communication