XA04N0311

Risk Assessment
A European Community Perspective

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Introduction

The world is a risky place in which to live!

The world tolerates that 750,000 deaths occur on the roads each year. Society has not yet come to terms with the added burden that urbanisation brings to developing countries. Pollution from the use of fossil fuels creates incalculable loss to the world's environment and to the health of its inhabitants. The misuse of chemicals provokes suffering and deformity. In the European Community alone, over 21 million tonnes of toxic waste have to be treated each year.

Of course, there are different types of risks: individual and societal. Individuals continue to travel by air in defiance of terrorists or faulty machinery. Whilst society urges caution in diet and nutrition, the individual is probably more worried about food additives that he is about eating too much or making a rigorous appraisal of the value of his diet!

As the Conference progresses many people will die from the causes of malnutrition, from war or societal neglect while we, individually, will be more at risk from overeating.

In other words, we perceive risks in a multitude of ways. We tolerate these risks according to our perception of what we feel is acceptable without carrying out scientific assessment of the relative severity of those risks.

If applied at a governmental level, this subjective tolerance can lead to unnecessary burdens or constraints that are disproportionate to the risk. Clearly, this is not acceptable for policy makers.

We have just seen the closure of the UNCED World Conference on the Environment in Rio de Janeiro, where the absolute need for more effective cooperation in the protection of the environment and the world inhabitants was convincingly demonstrated. The European Communities already coordinate risk assessment with its twelve Member States in a large number of areas and is increasing its international cooperation. We have recognised that it is no longer possible to carry out effective risk assessment in one country alone or to have good risk management by forgetting the next door neighbour!

The role and application of risk assessment

The Report of the WHO Health and Environment Commission's Panel on Industry records that "risk assessment" is a developing science and art with the goal of estimating the probability of occurrence of unwanted events. The Panel continues that risk assessment may provide a wide range of estimators and that uncertainty is the predominant feature of risk assessment procedures as they are described today. Risk management is a societal judgement process which

complements risk assessment. Despite its limitations in the current state of the art, for policy makers in government, risk assessment has a very substantial contribution to make in providing a more balanced and open basis for decision-making.

Risk assessment is a useful tool for setting priorities, for underpinning an effective risk management programme and for evaluating that programme, and also for achieving a better and more accurate public perception of the risk by communicating information about that risk.

Risk assessment does not imply that risk exists, but simply that it is necessary to establish, by some means or another, whether a risk exists. Risk assessment can range from a simple determination done in a few minutes to an extensive review using one of the various methodologies for risk assessment, that have been developed.

Risk assessment is an integral and important part of a three-stage process, involving:

- hazard identification;
- risk assessment;
- risk management;

which is at the centre of decision-making.

The EC, which is in its concept supranational, applies risk assessment widely throughout its programmes and initiatives. A few examples from Community action will suffice to indicate the scope for its use and the differences in the techniques of risk assessment as they are applied in practice.

— Community legislation for the Internal Market places obligations on the manufacturers and suppliers of products. For example, with the completion of the Internal Market at the end of this year, manufacturers of machinery will be obliged to make a risk assessment of their product in foreseeable uses and to eliminate risk at the design stage as far as this is possible. As part of the process of obtaining an "EC" mark for supply within the Internal Market, it will be necessary to show in the assessment process that essential safety requirements have been met.

— For chemicals, extensive rules exist in the Community for the protection of man, whether as a worker or as a member of the public, and for the environment.

  Thus, in the framework of the rules on classification, packaging and labelling based on the hazards of chemicals placed on the market and in the proposed notification scheme for new chemicals to be placed on the market, requirements are being introduced on the submission of toxicity data for the assessment process so that the risks can be more properly assessed in a scientific and quantitative way.

  The requirements of this legislation are complemented for groups of politically or technically sensitive chemicals by specific legislation englobing hazard identification, and risk assessment and management. This more specific control is valid for pharmaceuticals or food additives or pesticides where extensive scientific data, specifically designed

to reflect the particular use of the substance, are assessed by specialists as a prerequisite to its authorisation, and as will be explained later, further in-depth analyses may be required for setting Community workplace limit values.

— Protection of the public, for example, from chemicals, from other agents or from defective products, is also a subject that is addressed at Community level and which draws on the results of risk assessment. The ultimate, and often controversial, final step may be prohibition where the risks are deemed unacceptable. In other cases, the risk assessment may lead to specific restrictions or safeguards. Within its public health actions, the Community is addressing several risks of major health scourges in Europe, such as heart disease, cancer and the problems of alcohol, tobacco smoke, drugs and AIDS.

— For the environment, a subject of increasing societal concern, risk assessment is again a helpful tool in evaluating the various options for action to safeguard the quality and integrity of air, soil, water and of the flora and fauna. However, in many of these areas, the scientific knowledge and data available are often inadequate to provide a basis for more than a qualitative approach to risk assessment.

— For the workplace, in contrast to rules developed in many areas of Community activity, EC legislation has put the obligation on the employer to assess risks at work and in the working environment, and to take the necessary action. In order to meet these requirements, he has to identify the hazards and decide on the measures to take which will provide the necessary protection of the health and safety of his workers.

  These measures may result in the replacement of a hazardous chemical or biological agent by one which is less hazardous; by improving process control; or by providing protective equipment to prevent exposure.

  Although a machine might have the "EC" safety mark and fulfil the appropriate standards, the employer is still obliged to address the risks relating to the actual use of the machine in his workplace. This assessment may result in the replacement of the machinery in question.

  The legislation also requires medical surveillance in certain situations for exposed persons where the risks cannot be managed without it.

— In the area of biotechnology, as for chemicals, these workplace constraints are complemented by detailed specific programmes and the Commission has been centrally involved in the European debate about the conjectural risks of biotechnology and their management.

  Scientific opinion has been critical of the focus on the supposed risks inherent in the techniques and effects of DNA recombination per se; arguing that the risks of chemicals are assessed, not of "chemistry". But public and political attention has been alerted by publicity surrounding the dramatic progress in the life sciences and technologies, and the assessment of any risks as might be affected in consequence.

  There is apprehension about the possible effects of applying such powerful tools to the familiar and value-laden processes associated with all forms of life, health and growth.

Environmental and health risk assessment of biotechnology is complex and uncertain and still in the process of development. It is not easily comparable with more well-established methodologies such as those for chemical risk assessment, and the Commission, through its various concerned departments, has initiated a number of measures to ensure that the risks can be assessed whilst maintaining a competitive environment for industry.

The European Community has progressively developed an adaptive regulatory framework for biotechnology and, in parallel, efforts in risk assessment research have built up. These efforts are planned in consultation with the Member States, some of whom also have active programmes.

Results of this research are regularly published. In this area, the Commission also participates in international fora such as the OECD expert group on safety in biotechnology, and has regular bilateral contacts with scientists in other areas of the world with comparable interests and programmes (e.g. USA).

The benefits of risk assessment and a perspective for the future

The challenges which governments have to face are many. Inevitably, choices have to be made between competing priorities. The same can be said at the level of the individual employer or enterprise. What risk assessment offers is a tool to help in making these difficult choices and a basis on which to explain to others the decisions taken.

Inevitably resources are limited. Inescapably, therefore, to be effective, international cooperation is essential.

The Community, through the expertise of its component Member States or indeed through the European Commission is forefront in cooperating at international level in assessing the hazards and risks of a multitude of offensive situations. It contributes to the management of those risks. One needs only to recall the Community's contribution to OECD, to the WHO, UNEP and ILO programmes on chemical safety, with FAO on agricultural matters, with UNIDO, and with Council of Europe to rebut any criticism of that commitment. The Community is assisting the emerging nations in Central Europe. EFTA countries are already enjoying privileged relations with the Community.

Risk assessment is not a replacement for the societal decision which leads to the management of risk. In itself it does not solve the problems and, in many cases, social, political, economic or other imperatives will result in final decisions, policies or choices, which may, in risk assessment terms, seem illogical or incoherent. But that is not to decry its contribution to the assessment process which has permitted a more open and structured debate on risk acceptance and cost benefit of common actions in the EC or in international fora.

Better identifying areas of need helps to promote a more proactive approach to prevention.

In the future, risk assessment and especially quantitative risk assessment will become increasingly important when establishing priorities and legislative provisions. It follows that legislative actions must be subject to adaptation to technical progress and the advance of scientific knowledge, and as risk assessment techniques are refined. Already a number of needs to be addressed later in the Conference can be identified.

As a first priority, there is always a need and a call for more and better data. The evaluation can only be as good as the data on which it is based. Within the Community, we are addressing this need in a number of areas such as improved toxicity data on existing chemicals, better accident and ill-health data, more uniformity in data systems so that data is compatible from different sources, and so on.

Techniques of risk assessment are frequently still of a rudimentary nature, not only because the data is lacking but because the understanding of how to go about assessment is not well understood, or because its pitfalls and limitations are not well appreciated. We need to learn from successes in one area and apply them in others, and we must avoid over-elaboration and over-emphasis where the benefit does not justify the means. This Conference will focus attention on the need for more realism about the acceptance and limitations of risk assessment; it will catalyse progress by showing the way to obtain better data and by directing experts to more refined techniques which reduce uncertainty. Perhaps more importantly, it will, by its existence, demonstrate to the world the recognition by experts, by governments, by the European Community in this European Year of Safety, Hygiene and Health Protection at Work that there is international concern that decisions are not taken on an ad hoc basis but on the basis of a proper scientific assessment of the real risks.

I would like to close with a quotation from Lord Rothschild in a recent BMA publication on risk assessment:

> "There is no point getting into a panic about the risks of life until you have compared the risks which worry you with those which don't."

Thank you.