white paper on

RISK GOVERNANCE

TOWARDS AN INTEGRATIVE APPROACH

international risk governance council

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RISK GOVERNANCE

TOWARDS AN INTEGRATIVE APPROACH

by Ortwin Renn
with Annexes by Peter Graham

MEMBERS OF THE IRGC SCIENTIFIC AND TECHNICAL COUNCIL

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FOREWORD – ABOUT IRGC AND THIS WHITE PAPER

The International Risk Governance Council (IRGC), a private, independent, not-for-profit Foundation based in Geneva, Switzerland, was founded in 2003. Our mission is to support governments, industry, NGOs and other organisations in their efforts to deal with major and global risks facing society and to foster public confidence in risk governance. We work to achieve this mission by reflecting different views and practices and providing independent, authoritative information, by improving the understanding and assessment of risk and the ambiguities involved, by exploring the future of global risk governance and by designing innovative governance strategies. We focus on issues, whether human induced or natural, which have international implications and have the potential for harm to human health and safety, the economy, the environment, and/or to the fabric of society at large. We endeavour to work and communicate in ways that account for the needs of both developed and developing countries.

The establishment of IRGC was the direct result of widespread concern within the public sector, the corporate world, academia, the media and society at large that the complexity and interdependence of an increasingly large number of risk issues was making it ever more difficult for risk managers to develop and implement adequate risk governance strategies. Consequently, IRGC is committed to promote a multidisciplinary, multi-sectoral and multi-regional approach to risk governance.

The selection and prioritisation of the risk issues we will address is the responsibility of the IRGC's Scientific and Technical Council (S&TC), whose members are both acknowledged experts in risk-related fields and the organisation's primary asset for implementing our mission. IRGC's project work is carried out by harnessing the collective knowledge and thinking of our S&TC members joined by other experts in the field in question. This White Paper is the first substantial deliverable of a project, 'Basic Concepts of Risk Characterisation and Risk Governance', that began in June 2004. All the work on this project has been defined and undertaken by a project team led by Ortwin Renn.

This White Paper represents a fundamental step towards the achievement of our mission – the development of an integrated, holistic and structured approach, a framework, by which we can investigate risk issues and the governance processes and structures pertaining to them. Following on from this investigation the framework will also aid the development of recommendations that, when implemented, will support improvements in the ways risk is identified, assessed, managed, monitored and communicated.

Within IRGC, we describe as a White Paper a document in which we present work-in-progress to both those who may benefit from it and those whose feedback may enable us to further refine the document's contents. In common with all official IRGC documents, our White Papers are only published after a formal and rigorous external peer review and this document has been subject to this process in full. As a result, we are confident of the theoretical basis for the framework but acknowledge and are aware of the need to confirm the framework's practicability, which we will do in the next phase of the project.

The testing of the framework's efficacy will involve its application in a number of areas where the risks appear not fully understood or where there is a desire or need to improve risk governance. Subjects under consideration for the testing process include energy, nanotechnology, biotechnology, stem cell research, integrated disaster risk management and infectious diseases. Upon the completion of the testing phase, we will make any necessary revisions to the framework and use it as our core mechanism for looking into risk issues.

This document, which has been informed by and draws on current approaches to risk characterisation and risk governance, is both the result of collaborative efforts by a large number of people and a signpost for how IRGC will pursue its mission. In addition to the ‘expertise collégiale’ by which we undertake all our project work and which has led to the establishment of the prototype framework outlined in the following pages, we are open and look forward to receiving and acting on knowledge and thoughts from people who may not have been a part of the process so far, particularly from recipients of the governance recommendations the framework will help us to develop and from potential end users of the framework itself.

None of IRGC’s work would be possible without the financial support we receive. In publishing this, our first White Paper, IRGC gratefully acknowledges the donations and other financial contributions we have received from the Swiss State Secretariat for Education and Research, the Swiss Federal Agency for Development and Cooperation, Electricité de France and the Swiss Reinsurance Company.

José Mariano Gago

President of IRGC

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This paper is a product of collaborative effort. A major part of this has been the research and writing of the annexes by Peter Graham. Substantial input was provided by five background papers that were commissioned to inform discussions at a project workshop held in fall 2004 in Ismaning*. In particular the paper by Jean-Pierre Contzen on organisational capacity has been largely adopted for the section on organisational capacity building. Caroline Kuenzi edited the whole manuscript carefully and added several paragraphs and, with Chris Bunting, provided text for the case examples. Howard Kunreuther provided valuable material to the section on interpretative ambiguity and interdependencies. The members of the IRGC's CHARGOV group gave helpful advice and constructive feedback in all stages of completing the manuscript. Those members are: Lutz Cleemann, Jean-Pierre Contzen, Harry Kuiper, Peter Graham, Wolfgang Kröger, Joyce Tait and Jonathan Wiener. The author is also indebted to the members of the IRGC Scientific and Technical Council for their feedback, and particularly to Manuel Heitor who acted as review coordinator. He is also grateful to the five anonymous reviewers of the manuscript who provided constructive criticism and suggestions for improvement. Additional reviews and input were also received from Eugene Rosa, Chris Bunting, Paul Stern, Granger Morgan, Marion Dreyer, Juergen Hampel, Alexander Jäger, Pia-Johanna Schweizer and the participants at the above-mentioned workshop. We are very grateful for all these contributions.

* Sponsored by the Allianz Center for Technology this workshop involved both risk practitioners and academics and was aimed at developing thinking that would lay the foundation for the present framework for risk governance. Revised versions of the workshop's background papers as well as a workshop report are available in the projects section on IRGC's website (www.irgc.org).

CONTENT OVERVIEW

TABLES AND FIGURES

1 EXECUTIVE SUMMARY

Purpose of the IRGC Risk Governance Framework

In this white paper IRGC puts forward an integrated analytic framework for risk governance which provides guidance for the development of comprehensive assessment and management strategies to cope with risks, in particular at the global level. The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders. The framework reflects IRGC's own priorities, which are the improvement of risk governance strategies for risks with international implications and which have the potential to harm human health and safety, the economy, the environment, and/or the fabric of society at large.

The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed 'risk management' or 'risk analysis', it also looks at how risk-related decision-making unfolds when a range of actors is involved, requiring co-ordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. Indeed, the problem-solving capacities of individual actors, be they government, the scientific community, business players, NGOs or civil society as a whole, are limited and often unequal to the major challenges facing society today. Risks such as those related to increasingly violent natural disasters, food safety or critical infrastructures call for co-ordinated effort amongst a variety of players beyond the frontiers of countries, sectors, hierarchical levels, disciplines and risk fields. Finally, risk governance also illuminates a risk's context by taking account of such factors as the historical and legal background, guiding principles, value systems and perceptions as well as organisational imperatives.

The process by which the IRGC framework has been built has involved a review of literature on existing approaches to risk characterisation and risk governance, important input from a technical workshop involving participants from regulatory authorities, academia and business, and further development by the author supported by external reviewers, members of the IRGC's Scientific and Technical Council and the IRGC's staff.

New components of the IRGC Risk Governance Framework

The framework offers two major innovations to the risk field: the inclusion of the societal context and a new categorisation of risk-related knowledge.

- *Inclusion of the societal context:* Besides the generic elements of risk assessment, risk management and risk communication, the framework gives equal importance to contextual aspects which, either, are directly integrated in a model risk process comprising of the above as well as additional elements or, otherwise, form the basic conditions for making any risk-related decision. Contextual aspects of the first category include the structure and interplay of the different actors dealing with risks, how these actors may differently perceive the risks and what concerns they have regarding their likely consequences. Examples of the second category include the policy-making or regulatory style as well as the socio-political impacts prevalent within the entities and institutions having a role in the risk process, their organisational imperatives and the capacity needed for effective risk governance. Linking the context with risk governance, the framework reflects the important role of risk-benefit evaluation and the need for resolving risk-risk trade-offs.

- *Categorisation of risk-related knowledge:* The framework also proposes a categorisation of risk which is based on the different states of knowledge about each particular risk, distinguishing between 'simple', 'complex', 'uncertain' and 'ambiguous' risk problems. The characterisation of a particular risk depends on the degree of difficulty of establishing the cause-effect relationship between a risk agent and its potential consequences, the reliability of this relationship and the degree of controversy with regard to both what a risk actually means for those affected and the values to be applied when judging whether or not something needs to be done about it. Examples of each risk category include, respectively, known health risks such as those related to smoking, the failure risk of interconnected technical systems such as the electricity transmission grid, atrocities such as those resulting from the changed nature and scale of international terrorism and the long-term effects and ethical acceptability of controversial technologies such as nanotechnologies. For each category, a strategy is then derived for risk assessment, risk management as well as the level and form of stakeholder participation, supported by proposals for appropriate methods and tools.

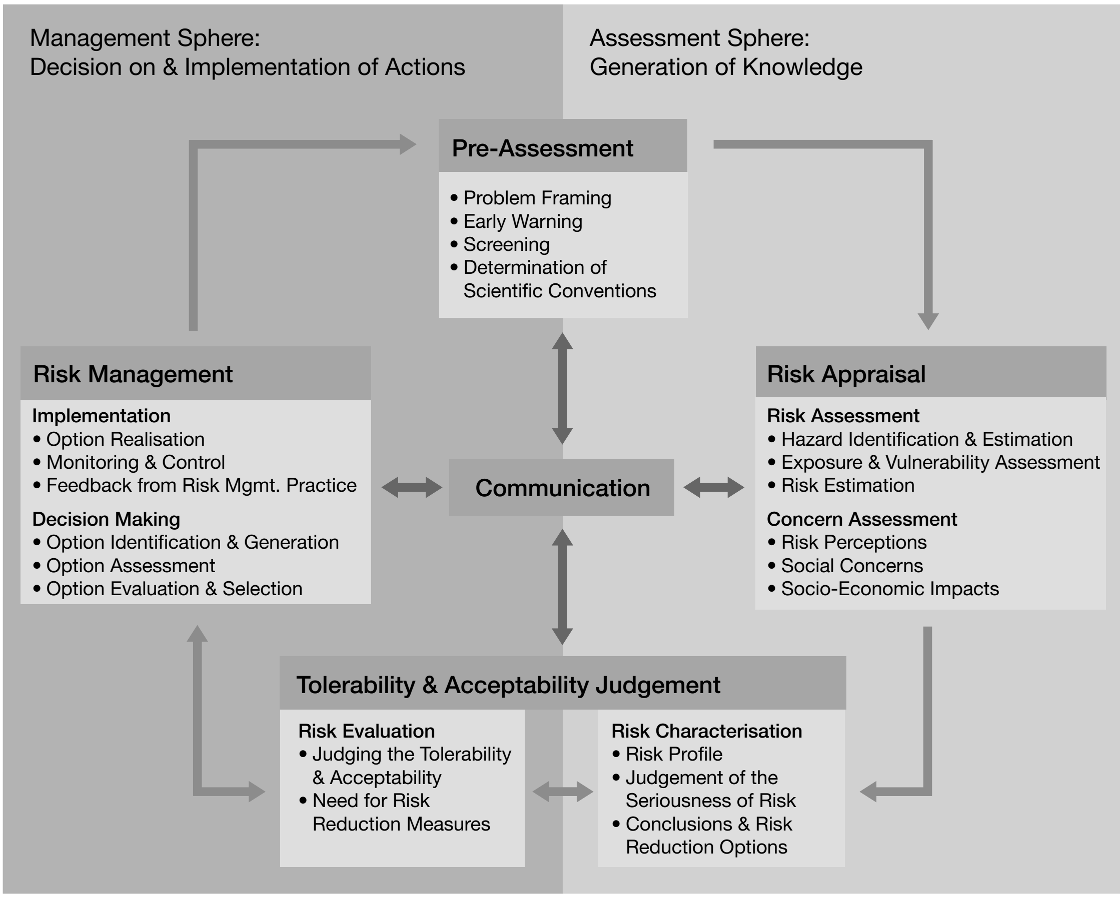
Beyond these component parts the framework includes three major value-based premises and assumptions:

- First, the framework is inspired by the conviction that both the 'factual' and the 'socio-cultural' dimension of risk need to be considered if risk governance is to produce adequate decisions and results. While the factual dimension comprises physically measurable outcomes and discusses risk in terms of a combination of potential – both positive and negative – consequences and the probability of their occurrence, the socio-cultural dimension emphasises how a particular risk is viewed when values and emotions come into play.
- The second major premise concerns the inclusiveness of the governance process, which is seen as a necessary, although not sufficient, prerequisite for tackling risks in both a sustainable and acceptable manner and, consequently, imposes an obligation to ensure the early and meaningful involvement of all stakeholders and, in particular, civil society.
- A third major premise involving values is reflected in the framework's implementation of the principles of 'good' governance: beyond the crucial commitment to participation these principles include transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law and the need for the chosen solution to be politically and legally realisable as well as ethically and publicly acceptable.

The Core of the IRGC Framework: The Risk Governance Phases

The framework's risk process, or risk handling chain is illustrated in Figure I. It breaks down into three main phases: 'pre-assessment', 'appraisal', and 'management'. A further phase, comprising the 'characterisation' and 'evaluation' of risk, is placed between the appraisal and management phases and, depending on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks, can be assigned to either of them – thus concluding the appraisal phase or marking the start of the management phase. The risk process has 'communication' as a companion to all phases of addressing and handling risk and is itself of a cyclical nature. However, the clear sequence of phases and steps offered by this process is primarily a logical and functional one and will not always correspond to reality.

Figure I: IRGC Risk Governance Framework



The purpose of the *pre-assessment* phase is to capture both the variety of issues that stakeholders and society may associate with a certain risk as well as existing indicators, routines, and conventions that may prematurely narrow down, or act as a filter for, what is going to be addressed as risk. What counts as a risk may be different for different groups of actors. The first step of pre-assessment, risk framing, therefore places particular importance on the need for all interested parties to share a common understanding of the risk issue(s) being addressed or, otherwise, to raise awareness amongst those parties of the differences in what is perceived as a risk. For a common understanding to be achieved, actors need both to agree with the underlying goal of the activity or event generating the risk and be willing to accept the risk's foreseeable implications on that very goal. A second step of the pre-assessment phase, early warning and monitoring, establishes whether signals of the risk exist that would indicate its realisation. This step also investigates the institutional means in place for monitoring the environment for such early warning signals. The third step, pre-screening, takes up and looks into the widespread practice of conducting preliminary probes into hazards or risks and, based on prioritisation schemes and existing models for dealing with risk, of assigning a risk to pre-defined assessment and management 'routes'. The fourth and final step of pre-assessment selects major assumptions, conventions and procedural rules for assessing the risk as well as the emotions associated with it.

The objective of the *risk appraisal* phase is to provide the knowledge base for the societal decision on whether or not a risk should be taken and, if so, how the risk can possibly be reduced or contained. Risk appraisal thus comprises a scientific assessment of both the risk and of questions that stakeholders may have concerning its social and economic implications.

The first component of risk appraisal, risk assessment, seeks to link a potential source of harm, a hazard, with likely consequences, specifying probabilities of occurrence for the latter. Depending on the source of a risk and the organisational culture of the community dealing with it, many different ways exist for structuring risk assessment. Despite such diversity, three core steps can be identified. These are: the identification and, if possible, estimation of the hazard, an assessment of related exposure and/or vulnerability and an estimation of the consequent risk. The latter step – risk estimation – aggregates the results of the first two steps and states, for each conceivable degree of severity of the consequence(s), a probability of occurrence. Confirming the results of risk assessments can be extremely difficult, in particular when cause-effect relationships are hard to establish, when they are instable due to variations in both causes and effects and when effects are both scarce and difficult to understand. Depending on the achievable state and quality of knowledge, risk assessment is thus confronted with three major challenges that can best be summarised using the risk categories outlined above – ‘complexity’, ‘uncertainty’ and ‘ambiguity’. For a successful outcome to the risk process and, indeed, overall risk governance, it is crucial that the implications of these challenges are made transparent at the conclusion of risk assessment and throughout all subsequent phases.

Equally important to understanding the physical attributes of the risk is detailed knowledge of stakeholders’ concerns and questions – emotions, hopes, fears, apprehensions – about the risk as well as likely social consequences, economic implications and political responses. The second component of risk appraisal, concern assessment, thus complements the results from risk assessment with insights from risk perception studies and interdisciplinary analyses of the risk’s (secondary) social and economic implications.

The most controversial phase of handling risk, *risk characterisation and evaluation,* aims at judging a risk’s acceptability and/or tolerability. A risk deemed ‘acceptable’ is usually limited in terms of negative consequences so that it is taken on without risk reduction or mitigation measures being envisaged. A risk deemed ‘tolerable’ links undertaking an activity – which is considered worthwhile for the value-added or benefit it provides – with specific measures to diminish and limit the likely adverse consequences. This judgement is informed by two distinct but closely related efforts to gather and compile the necessary knowledge which, in the case of tolerability, must additionally support an initial understanding of required risk reduction and mitigation measures. While risk characterisation compiles scientific evidence based on the results from the risk appraisal phase, risk evaluation assesses broader value-based issues that also influence the judgement. Such issues, which include questions such as the choice of technology, societal needs requiring a given risk agent to be present and the potential for substitution as well as for compensation, reach beyond the risk itself and into the realm of policy-making and societal balancing of risks and benefits.

The *risk management* phase designs and implements the actions and remedies required to tackle risks with an aim to avoid, reduce, transfer or retain them. Risk management thereby relies on a sequence of six steps which facilitates systematic decision-making. To start with, and based on a reconsideration of the knowledge gained in the risk appraisal phase and while judging the acceptability and/or tolerability of a given risk, a range of potential risk management options is identified. The options are then assessed with regard to such criteria such as effectiveness, efficiency, minimisation of external side effects, sustainability etc. These assessment results are next complemented by a value judgement on the relative weight of each of the assessment criteria, allowing an evaluation of the risk management options. This evaluation supports the next step in which one (or more) of the of risk management options is selected, normally after consideration of possible trade-offs that need to be made between a number of second-best options. The final two steps include the implementation of the selected options and the periodic monitoring and review of their performance.

Based on the dominant characteristic of each of the four risk categories ('simple', 'complexity', 'uncertainty', 'ambiguity') it is possible to identify specific safety principles and, consequently, design a targeted risk management strategy (see Table I). 'Simple' risk problems can be managed using a 'routine-based' strategy which draws on traditional decision-making instruments, best practice as well as time-tested trial-and-error. For 'complex' and 'uncertain' risk problems it is helpful to distinguish the strategies required to deal with a risk agent from those directed at the risk-absorbing system: complex risks are thus usefully addressed on the basis of 'risk-informed' and 'robustness-focussed' strategies, while uncertain risks are better managed using 'precaution-based' and 'resilience-focussed' strategies. Whereas the former strategies aim at accessing and acting on the best available scientific expertise and at reducing a system's vulnerability to known hazards and threats by improving its buffer capacity, the latter strategies pursue the goal of applying a precautionary approach in order to ensure the reversibility of critical decisions and of increasing a system's coping capacity to the point where it can withstand surprises. Finally, for 'ambiguous' risk problems the appropriate strategy consists of a 'discourse-based' strategy which seeks to create tolerance and mutual understanding of conflicting views and values with a view to eventually reconciling them.

The remaining element of the risk process is *risk communication*, which is of major importance throughout the entire risk handling chain. Not only should risk communication enable stakeholders and civil society to understand the rationale of the results and decisions from the risk appraisal and risk management phases when they are not formally part of the process, but it should also help them to make informed choices about risk, balancing factual knowledge about risk with personal interests, concerns, beliefs and resources, when they are themselves involved in risk-related decision-making. Effective risk communication consequently fosters tolerance for conflicting viewpoints and provides the basis for their resolution, and creates trust in the institutional means for assessing and managing risk and related concerns. Eventually, risk communication can have a major impact on how well society is prepared to cope with risk and react to crises and disasters. Risk communication has to perform these functions both for the experts involved in the overall risk process – requiring the exchange of information between risk assessors and managers, between scientists and policy makers, between academic disciplines and across institutional barriers – and for the 'outside world' of those affected by the process.

Wider Governance Issues: Organisational Capacity and Regulatory Styles

This white paper also addresses wider governance issues pertinent to the context of a risk and the overall risk process, thus acknowledging the many different pathways that different countries or, indeed, risk communities, may pursue for dealing with risk. The discussion of these wider issues begins with an assessment of the very notion of 'risk governance' which builds on the observation that collective decisions about risks are the outcome of a 'mosaic' of interactions between governmental or administrative actors, science communities, corporate actors and actors from civil society at large, many of the interactions taking place and relevant to only individual parts of the overall process. The interplay of these actors has various dimensions, including public participation, stakeholder involvement and the formal (horizontal and vertical) structures within which it occurs. The white paper additionally investigates organisational prerequisites for effective risk governance, which are at the crossroads of the formal responsibilities of actors and their capability and authority to successfully fulfil their roles, and makes a very short case for risk education. The organisational prerequisites are summarised under the term 'institutional and organisational capacity' and include both intellectual and material 'assets', 'skills' and as well as the framework of relations, or 'capabilities', required to make use of the former two. The discussion of wider risk governance issues concludes with a reflection on the role of political culture and a proposal for a typology of different regulatory regimes or governmental styles.

Table I: Risk Characteristics and their Implications for Risk Management

Knowledge Characterisation	Management Strategy	Appropriate Instruments	Stakeholder Participation
1 'Simple' risk problems	*Routine-based:* (tolerability/ acceptability judgement) (risk reduction)	➔ Applying 'traditional' decision-making • Risk-benefit analysis • Risk-risk trade-offs • Trial and error • Technical standards • Economic incentives • Education, labelling, information • Voluntary agreements	Instrumental discourse
2 Complexity-induced risk problems	*Risk-informed:* (risk agent and causal chain)	➔ Characterising the available evidence • Expert consensus seeking tools: o Delphi or consensus conferencing o Meta analysis o Scenario construction, etc. • Results fed into routine operation	Epistemological discourse
	Robustness-focussed: (risk absorbing system)	➔ Improving buffer capacity of risk target through: • Additional safety factors • Redundancy and diversity in designing safety devices • Improving coping capacity • Establishing high reliability organisations	
3 Uncertainty-induced risk problems	*Precaution-based:* (risk agent)	➔ Using hazard characteristics such as persistence, ubiquity etc. as proxies for risk estimates Tools include: • Containment • ALARA (as low as reasonably achievable) and ALARP (as low as reasonably possible) • BACT (best available control technology), etc.	Reflective discourse
	Resilience-focussed: (risk absorbing system)	➔ Improving capability to cope with surprises • Diversity of means to accomplish desired benefits • Avoiding high vulnerability • Allowing for flexible responses • Preparedness for adaptation	
4 Ambiguity-induced risk problems	*Discourse-based:*	➔ Application of conflict resolution methods for reaching consensus or tolerance for risk evaluation results and management option selection • Integration of stakeholder involvement in reaching closure • Emphasis on communication and social discourse	Participative discourse

Structure of the White Paper

This white paper is organised as follows: following statements on the document's purpose and objectives, target audience and scope, the framework for risk governance outlined in this abstract is described in detail. The presentation of the framework's component parts is supported by condensed discussions of risk perceptions, participation and inclusive governance as well as a short introduction to managing interdependent risk. It is rounded off with a glossary defining the terms used in the framework. The main chapters of this paper also contain three short 'case examples' dealing with train accidents, earthquakes and nuclear energy. These examples are primarily aimed at illustrating the risk categorisation proposed within the framework and at providing initial pointers for issues that the application of the framework to these risks is likely to raise. They cannot, however, and do not intend to provide a comprehensive illustration of risk governance as suggested by the framework.

The annexes to this white paper contain a summary of a number of existing approaches to risk (Annex A), an overview of risk terminology currently in use sequenced both by term (Annex B) and by organisation/publication (Annex C) and a compilation of shorthand risk 'formulas' illustrating the different use of some risk terminology within different risk communities (Annex D). It should be noted that none of the information compiled in the annexes claims to be representative – rather more it is selective and is provided with the specific purpose of demonstrating how existing approaches to, and concepts of, risk characterisation and risk governance contributed to the development of the framework for risk governance presented in this white paper.

2 PURPOSE AND OBJECTIVES OF THIS WHITE PAPER

This document aims to guide the work of the International Risk Governance Council and its various bodies in devising comprehensive and transparent approaches to 'govern' a variety of globally relevant risks. Globally relevant risks include *transboundary* risks, i.e. those that originate in one country and affect other countries (such as air pollution), *international* risks, i.e. those that originate in many countries simultaneously and lead to global impacts (such as carbon dioxide emissions for climate change) and *ubiquitous* risks, i.e. those that occur in each country in similar forms and may necessitate a co-ordinated international response (such as car accidents or airline safety). To this end the document and the framework it describes provide a common *analytic structure for investigating and supporting the treatment of risk issues* by the relevant actors in society. In doing so, the focus is not restricted to how governmental or supranational authorities deal with risk but equal importance is given to the roles of the corporate sector, science, other stakeholders as well as civil society – and their interplay. The analytic structure will, it is hoped, facilitate terminological and conceptual clarity, consistency and transparency in the daily operations of the IRGC and assure the feasibility of comparative approaches in the governance of risks across a broad range of hazardous events and activities. In particular, this document is meant to assist members of IRGC in their tasks to provide scientifically sound, economically feasible, legally and ethically justifiable and politically acceptable advice to IRGC's targeted audiences. It is also to support IRGC in its effort to combine the best available expertise in the respective field with practical guidance for both risk managers and stakeholders.

The overall objective of this document is to establish a comprehensive and consistent yet flexible prototype analytic framework and unified set of guidance for improved risk governance. This framework integrates the following components:

- Harmonised terminology with respect to key terms and concepts;
- A robust and coherent concept of framing and characterising the essential physical as well as social elements of coping with risks, including both the classic components (i.e. risk assessment, risk management and risk communication) as well as the contextual aspects such as a wider framework of risk appraisal, governance structure, risk perception, regulatory style and organisational capacity;
- A categorisation and enhancement of approaches to risk assessment and risk management including suggestions for basic safety principles and integrated appraisal and management strategies based on scientific analysis, precautionary considerations and vulnerability assessment;
- Inclusion of risk-benefit evaluation and risk-risk tradeoffs;
- A conceptual framework for integrating civil society (stakeholders from the corporate sector, NGOs, associations, science communities as well as representatives of the public) in risk governance;
- Principles of "good" risk governance;
- Requirements for improving risk governance capacity including the new perspective of integrated disaster risk management (IDRM).

This document draws on an initial compilation and critical review of work already available in this area (e.g. existing risk taxonomies and, in particular, guidance documentation on risk and risk governance) as well as on an acknowledgement of commonalities and differences between these approaches. A selection of these guidelines, manuals, standards, government reports etc. is summarised in the annex to this document. The annex also includes an overview of some key risk terminology. A glossary defining the terms and concepts used throughout this white paper may be found in Chapter 21.

3 TARGET AUDIENCE OF THIS WHITE PAPER

The primary audience of this document is IRGC itself which will use it as an analytic blueprint for its further work and will implement its recommendations within future IRGC projects. After a period of intense testing within several IRGC projects and empirical analysis of its use in different risk contexts and cultural environments, it is anticipated that a further revised version of this white paper can offer assistance and guidance to senior risk managers and decision makers as well as risk practitioners outside of the IRGC in their daily efforts to identify, assess, manage and monitor risk.

An important niche could, for instance, derive from the active transfer and dissemination of this body of knowledge to key actors in politics and society in developing countries and those in transition. Many of these countries are only now starting to formally think about issues of risk governance and IRGC's providing them with relevant information and knowledge could provide valuable insights and, possibly, help them to avoid some of the pitfalls inherent in dealing with risk. A flexible yet harmonised framework might also be of benefit to both the government and industry sectors in OECD countries, since its main thrust is to provide logically coherent and sensible guidance for conducting risk appraisals (including risk assessment as well as concern assessment), for steering risk management and for improving risk governance structures in a variety of risk areas and socio-political cultures. Therefore, this document particularly addresses all those actors who will benefit from more direct cooperation with other stakeholders and from integrated risk governance procedures. Indeed, specifying the role of these actors within an integrated framework of risk governance is one of the main goals of the IRGC, and this goal has also inspired the framework presented in this document. While it is clear that each risk field or 'case' under consideration is different in that it requires further specifications and adjustments, it is nonetheless hoped that the framework presented herein can serve as a 'default option' from which one can and should deviate if necessary.

4 SCOPE OF THE PROPOSED FRAMEWORK

This document covers a wide range of both risks and governance structures. **Risk** is understood in this document as an uncertain consequence of an event or an activity with respect to something that humans value (definition originally in: Kates et al. 1985: 21). Risks always refer to a combination of two components: the likelihood or chance of potential consequences and the severity of consequences of human activities, natural events or a combination of both. Such consequences can be positive or negative, depending on the values that people associate with them. IRGC is not covering all risk areas but confines its efforts to (predominantly negatively evaluated) risks that lead to physical consequences in terms of human life, health, and the natural and built environment. It also addresses impacts on financial assets, economic investments, social institutions, cultural heritage or psychological well-being as long as these impacts are associated with the physical consequences[1]. In addition to the strength and likelihood of these consequences, the framework emphasises the distribution of risks over time, space and populations. In particular, the timescale of appearance of adverse effects is very important and links risk governance to sustainable development (delayed effects).

In this document we distinguish risks from hazards. **Hazards** describe the potential for harm or other consequences of interest. These potentials may never even materialise if, for example, people are not exposed to the hazards or if the targets are made resilient against the hazardous effect (such as immunisation). In conceptual terms, hazards characterise the *inherent properties of the risk agent and related processes*, whereas risks describe the *potential effects that these hazards are likely to cause on specific targets such as buildings, ecosystems or human organisms and their related probabilities*.

Table 1 provides a systematic overview of the sources of risks or hazards that potentially fall within the scope of IRGC's work programme. The purpose of this overview is to lay out the variety of sources of risks rather than to claim that the categories proposed are exhaustive or mutually exclusive (review of classification in Morgan et al. 2000). Furthermore, IRGC places most attention on risk areas of global relevance (i.e. transboundary, international and ubiquitous risks) which additionally include large-scale effects (including low-probability, high-consequence outcomes), require multiple stakeholder involvement, lack a superior decision-making authority and involve the potential to cause wide-ranging concerns and outrage.

The IRGC has as one of its primary responsibilities the provision of expertise and practical advice in dealing with a novel type of risk, which the OECD has labelled **'systemic risks'** (OECD 2003). This term denotes the embeddedness of any risk to human health and the environment in a larger context of social, financial and economic consequences and increased interdependencies both across risks and between their various backgrounds. Systemic risks are at the crossroads between natural events (partially altered and amplified by human action such as the emission of greenhouse gases), economic, social and technological developments and policy-driven actions, both at the domestic and the international level. These new interrelated and interdependent risk fields also require a new form of handling risk, in which data from different risk sources are either geographically or functionally integrated into one analytical perspective. Handling systemic risks requires a holistic approach to hazard identification, risk assessment, concern assessment, tolerability/acceptability judgements and risk management. Investigating systemic risks goes beyond the usual agent-consequence analysis and focuses on interdependencies and spill-overs between risk clusters.

1 Although the IRGC focuses on physical risks and their secondary implications, the framework may also be extended to allow for the investigation of financial, social or political risks as primary risk consequences.

Table 1: Risks Taxonomy According to Hazardous Agents

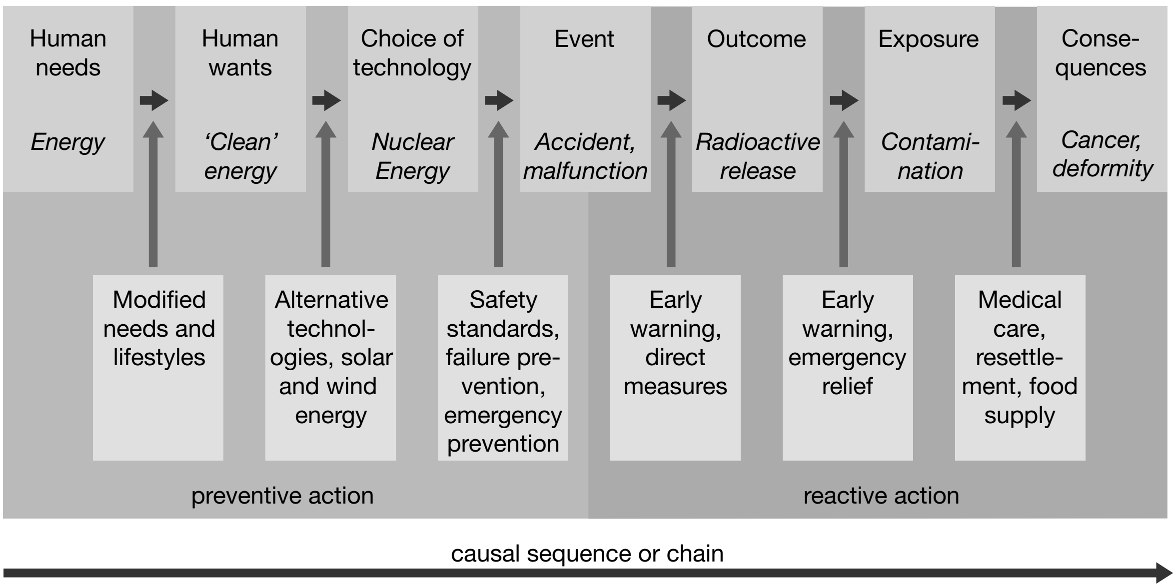
- **Physical Agents**
  - Ionising radiation
  - Non-ionising radiation
  - Noise (industrial, leisure, etc.)
  - Kinetic energy (explosion, collapse, etc.)
  - Temperature (fire, overheating, overcooling)
- **Chemical Agents**
  - Toxic substances (thresholds)
  - Genotoxic/carcinogenic substances
  - Environmental pollutants
  - Compound mixtures
- **Biological Agents**
  - Fungi and algae
  - Bacteria
  - Viruses
  - Genetically modified organisms
  - Other pathogens
- **Natural Forces**
  - Wind
  - Earthquakes
  - Volcanic activities
  - Drought
  - Flood
  - Tsunamis
  - (Wild) fire
  - Avalanche
- **Social-communicative Hazards**
  - Terrorism and sabotage
  - Human violence (criminal acts)
  - Humiliation, mobbing, stigmatising
  - Experimentation with humans (such as innovative medical applications)
  - Mass hysteria
  - Psychosomatic syndromes
- **Complex Hazards (Combinations)**
  - Food (chemical and biological)
  - Consumer products (chemical, physical, etc.)
  - Technologies (physical, chemical, etc.)
  - Large constructions such as buildings, dams, highways, bridges
  - Critical infrastructures (physical, economic, social-organisational and communicative)

5 RISK IN A BROADER CONTEXT

The focus on risk should be seen as a segment of a larger and wider perspective on how humans transform the natural into a cultural environment with the aims of improving living conditions and serving human wants and needs (Turner et al. 1990). These transformations are performed with a purpose in mind (normally a benefit to those who initiate them). When implementing these changes, intended (or tolerated) and unintended consequences may occur that meet or violate other dimensions of what humans value. Risks are not taken for their own sake; rather more they are, actively or passively, incurred because of their being an integral factor in the very activity that is geared towards achieving the particular human need or purpose. In this context, it is the major task of risk assessment to identify and explore, preferably in quantitative terms, the types, intensities and likelihood of the (normally undesired) consequences related to a risk. In addition, these consequences are associated with special concerns that individuals, social groups or different cultures may attribute to these risks. They also need to be assessed for making a prudent judgement about the tolerability or acceptability of risks. Once that judgement is made it is the task of risk management to prevent, reduce or alter these consequences by choosing appropriate actions. As obvious as this distinction between risk and concern assessment (as a tool of gaining knowledge about risks) and risk management (as a tool for handling risks) appears at first glance, the *distinction becomes blurred* in the actual risk governance process.

This blurring is due to the fact that assessment starts with the respective risk agent or source and tries to both identify potential damage scenarios and their probabilities and to model its potential consequences over time and space, whereas risk management oversees a much larger terrain of potential interventions (Stern and Fineberg 1996; Jasanoff 1986: 79f; 2004). Risk management may alter human wants or needs (so that the agent is not even created or continued). It can suggest substitutes or alternatives for the same need. It can relocate or isolate activities so that exposure is prevented, or it can make risk targets less vulnerable to potential harm. Figure 1 illustrates this larger perspective for technological risks and lists the possible intervention points for risk management (taken from Hohenemser et al. 1983). Risk assessment and management are therefore not symmetrical to each other: management encompasses a much larger domain and may even occur before assessments are performed. It is often based on considerations that are not affected by or part of the assessment results. In more general terms, risk management refers to the creation and evaluation of options for initiating or changing human activities or (natural and artificial) structures with the objective being to increase the net benefit to human society and prevent harm to humans and what they value. The identification of these options and their evaluation is guided by systematic and experiential knowledge gained and prepared for this purpose by experts and stakeholders. A major proportion of that relevant knowledge comprises the results of risk assessments. However, risk managers also need to act in situations of 'non-knowledge' or insufficient knowledge about potential outcomes of human actions or activities.

Figure 1: Seven Steps of a Risk Chain: The Example of Nuclear Energy



(from Hohenemser et al. 1983)

The most complex questions emerge, however, when one looks at how society and its various actors actually handle risk. In addition to knowledge gained through risk assessments and/or option generation and evaluation through risk management, the decision-making structure of a society is itself highly complicated and often fragmented. Apart from the structure itself – the people and organisations that share responsibility for assessing and managing risk – one must also consider the need for sufficient organisational capacity to create the necessary knowledge and implement the required actions, the political and cultural norms, rules and values within a particular societal context and the subjective perceptions of individuals and groups. These factors leave their marks on the way risks are treated in different domains and socio-political cultures. To place risk within a context of – sometimes closely interwoven – decision making structures such as those prevalent in governments and related authorities, in the corporate sector and industry, in the scientific community and in other stakeholder groups is of central concern to the IRGC.

In the last decade the term **'governance'** has experienced tremendous popularity in the literature on international relations, comparative political science, policy studies, sociology of environment and technology as well as risk research[2]. On a national scale, *governance describes structures and processes for collective decision making involving governmental and non-governmental actors* (Nye and Donahue 2000). Governing choices in modern societies is seen as an interplay between governmental institutions, economic forces and civil society actors (such as NGOs). At the global level, *governance embodies a horizontally organised structure of functional self-regulation encompassing state and non-state actors bringing about collectively binding decisions without superior authority* (c.f. Rosenau 1992; Wolf 2002). In this perspective non-state actors play an increasingly relevant role and become more important, since they have decisive advantages of information and resources compared to single states.

It is useful to differentiate between *horizontal and vertical governance* (Benz and Eberlein 1999; Lyall and Tait 2004*)*. The horizontal level includes the relevant actors in decision making processes within a defined geographical or functional segment (such as all relevant actors within a community, region, nation or continent); the vertical level describes the links between these segments (such as the institutional relationships between the local, regional and state levels).

'Risk governance' involves the 'translation' of the substance and core principles of governance to the context of risk and risk-related decision-making. In IRGC's understanding, risk governance includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Encompassing the combined risk-relevant decisions and actions of both governmental and private actors, risk governance is of particular importance in, but not restricted to, situations where there is no single authority to take a binding risk management decision but where, instead, the nature of the risk requires the collaboration of, and co-ordination between, a range of different stakeholders. Risk governance however not only includes a multifaceted, multi-actor risk process but also calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and co-ordination mechanisms such as markets, incentives or self-imposed norms) and political culture, including different perceptions of risk.

When looking at risk governance structures there is no possibility of including all the variables that may influence the decision making process; there are too many. Therefore it is necessary to limit one's efforts

2 According to Rhodes (1996) there are six separate uses of the term governance: as minimal state, as corporate governance, as new public management, as good governance, as social-cybernetic systems and as self-organised networks.

to those factors and actors that, by theoretical reasoning and/or empirical analysis, are demonstrably of particular importance with respect to the outcome of risk governance. The IRGC has highlighted the following aspects of risk governance which extend beyond risk assessment and risk management:

- the structure and function of various actor groups in initiating, influencing, criticising and/or implementing risk policies and decisions;
- risk perceptions of individuals and groups;
- individual, social and cultural concerns associated with the consequences of risk;
- the regulatory and decision-making style (political culture);
- the requirements with respect to organisational and institutional capabilities for assessing, monitoring and managing risks (including emergency management).

In addition to these analytical categories, this document also addresses best practice and normative aspects of what is needed to improve governance structures and processes (EU 2001a). With respect to best practice it is interesting to note that often risk creators, in particular when directly affected by the risk they generate, engage in risk reduction and avoidance out of self-interest or on a voluntary basis (e.g. industry 'gentleman's agreements', self-restriction, industry standards). Other stakeholders' efforts in risk governance therefore have to be coordinated with what is tacitly in place already. The emphasis here is on cooperative models of public-private partnerships forming a governance system that aims at effective, efficient and fair risk management solutions[3].

6 BEFORE ASSESSMENT STARTS

Risks are *mental 'constructions'* (OECD 2003, p. 67). They are not real phenomena but originate in the human mind. Actors, however, creatively arrange and reassemble signals that they get from the 'real world' providing structure and guidance to an ongoing process of reality enactment[4]. So risks represent what people observe in reality and what they experience. The link between risk as a mental concept and reality is forged through the experience of actual harm (the consequence of risk) in the sense that human lives are lost, health impacts can be observed, the environment is damaged or buildings collapse. The invention of risk as a mental construct is contingent on the belief that human action can prevent harm in advance. Humans have the ability to design different futures, i.e. construct scenarios that serve as tools for the human mind to anticipate consequences in advance and change, within constraints of nature and culture, the course of actions accordingly.

The status of risk as a mental construct has major implications on how risk is looked at. Unlike trees or houses, one cannot scan the environment, identify the objects of interest, and count them. Risks are

3 Excluded from this document are such topics as crisis intervention, crisis communication, emergency planning and management and post-accidental relief. They will be covered in a separate document at a later stage.

4 I am indebted to Gene Rosa for giving me guidance on keeping a healthy balance between a relativist and realist version of risk. For further reading refer to Rosa (1998). It should be noted that this white paper takes no stand on the *controversial issue of constructivism versus realism of evidence and values* (this topic is extensively reviewed in Mayo and Hollander 1991, specific positions in Bradbury 1989; Douglas 1990; Shrader-Frechette 1991b; 1995; Wynne 1992; Laudan 1996; Jasanoff 2004). Whether the evidence collected represents human ideas about reality or depicts representations of reality is of no importance for the distinction between evidence and values that is suggested throughout the document. Handling risks will inevitably be directed by evidence claims (what are the causes and what are the effects?) and normative claims (what is good, acceptable and tolerable?). It is true that providing evidence is always contingent on existing normative axioms and social conventions. Likewise, normative positions are always enlightened by assumptions about reality (Ravetz 1999). The fact that evidence is never value-free and that values are never void of assumptions about evidence does not compromise the need for a functional distinction between the two. For handling risks one is forced to distinguish between what is likely to be expected when selecting option x rather than option y, on one hand, and what is more desirable or tolerable: the consequences of option x or option y, on the other hand. It is hence highly advisable to maintain the classic distinction between evidence and values and also to affirm that justifying claims for evidence versus values involves different routes of legitimisation and validation.

created and selected by human actors. What counts as a risk to someone may be an act of God to someone else or even an opportunity for a third party. Although societies have over time gained experience and collective knowledge of the potential impacts of events and activities, one cannot anticipate all potential scenarios and be worried about all the many potential consequences of a proposed activity or an expected event. By the same token, it is impossible to include all possible options for intervention. Therefore societies have been *selective* in what they have chosen to be worth considering and what to ignore (Thompson et al. 1990; Douglas 1990; Beck 1994: 9ff.). Specialised organisations have been established to monitor the environment for hints of future problems and to provide early warning of some potential future harm. This selection process is not arbitrary. It is guided by cultural values (such as the shared belief that each individual life is worth protecting), by institutional and financial resources (such as the decision of national governments to spend money or not to spend money on early warning systems against highly improbable but high-consequence events) and by systematic reasoning (such as using probability theory for distinguishing between more likely and less likely events or methods to estimate damage potential or distribution of hazards in time and space).

Based on these preliminary thoughts, a systematic review of risk-related actions needs to start with an analysis of what major societal actors such as e.g. governments, companies, the scientific community and the general public select as risks and what types of problems they label as risk problems (rather than opportunities or innovation potentials, etc.). In technical terms this is called **'framing'**. Framing in this context encompasses the selection and interpretation of phenomena as relevant risk topics (Tversky and Kahneman 1981; van der Sluijs et al. 2003; Goodwin and Wright 2004). The process of framing is already part of the governance structure since official agencies (for example food standard agencies), risk and opportunity producers (such as the food industry), those affected by risks and opportunities (such as consumer organisations) and interested bystanders (such as the media or an intellectual elite) are all involved and often in conflict with each other when framing the issue. What counts as risk may vary among these actor groups. Consumers may feel that all artificial food additives pose a risk, whereas industry may be concerned about pathogens that develop their negative potential due to the lack of consumer knowledge about food storage and preparation. Environmental groups may be concerned with the risks of industrial food versus organic food. Whether a consensus evolves about what requires consideration as a relevant risk depends on the legitimacy of the selection rule. The acceptance of selection rules rests on two conditions: first, all actors need to agree with the *underlying goal* (often legally prescribed, such as prevention of health detriments, or guarantee of an undisturbed environmental quality, for example purity laws for drinking water); secondly, they need to agree with the *implications derived from the present state of knowledge* (whether and to what degree the identified hazard impacts the desired goal). Even within this preliminary analysis, dissent can result from conflicting values as well as conflicting evidence, and, in particular, from the inadequate blending of the two. Values and evidence can be viewed as the two sides of a coin: the values govern the selection of the goal whereas the evidence governs the selection of cause-effect claims. Both need to be properly investigated when analysing risk governance but it is of particular importance to understand the values shaping the interests, perceptions and concerns of the different stakeholders as well as to identify methods for capturing how these concerns are likely to influence, or impact on, the debate about a particular risk. The actual measurements of these impacts should then be done in the most professional manner, including the characterisation of uncertainties (Keeney 1992; Pidgeon and Gregory 2004; Gregory 2004).

A second part of the pre-assessment phase concerns the institutional means of *early warning and monitoring.* Even if there is a common agreement of what should be framed as (a) risk issue(s), there may be problems in monitoring the environment for signals of risks. This is often due to a lack of institutional efforts to collect and interpret signs of risk and deficiencies in communication between those looking for early signs and those acting upon them. The recent tsunami catastrophe in Asia provides a more than telling example of the discrepancy between the possibility of early warning capabilities and the decision to install or use them. It is therefore important to look at early warning and monitoring activities when investigating risk governance.

In many risk governance processes, information about risks are pre-screened and then allocated to different assessment and management routes. In particular, industrial risk managers search for the most efficient strategy to deal with risks. This includes prioritisation policies, protocols for dealing with similar causes of risks, and optimal models combining risk reduction and insurance. Public risk regulators often use pre-screening activities to allocate risks to different agencies or to pre-defined procedures. Sometimes risks may seem to be less severe and it may be adequate to cut short risk or concern assessment. In a pending crisis situation, risk management actions may need to be taken before any assessment is even carried out. A full analysis should therefore include provisions for *risk screening* and the selection of different routes for risk assessment, concern assessment and risk management. This aspect has been called *'risk assessment policy'* in the Codex Alimentarius. It is meant to guide the assessment process in terms of assessment and management protocols, methods of investigation, statistical procedures and other scientific conventions used in assessing risks or selecting risk reduction options. A screening process may also be employed when characterising risks according to complexity, uncertainty and ambiguity as we will explain later.

Another major component of pre-assessment is the *selection of conventions and procedural rules* needed for a comprehensive scientific appraisal of the risk, i.e. for assessing the risk and the concerns related to it (see below). Any such assessment is based on prior informed yet subjective judgements or conventions articulated by the scientific community or a joint body of risk assessors and managers. Those judgements refer to (Pinkau and Renn 1998; van den Sluijs et al 2004: 54ff.):

- the social definition of what is to be regarded as adverse, for example by defining the "No Adverse Effect Level" in food (NOAEL);
- the selection rule determining which potentially negative effects should be considered in the risk governance process knowing that an infinite number of potential negative outcomes can be theoretically connected with almost any substance, activity or event;
- the aggregation rule specifying how to combine various effects within a one-dimensional scale, for example early fatalities, late fatalities, cancer, chronic diseases and so on;
- the selection of the testing and detection methods which are presently used in risk assessment, for example the use of genomics for calculating risk from transgenic plants;
- the selection of valid and reliable methods for measuring perceptions and concerns;
- the determination of models to extrapolate high dose effects to low dose situations, for example linear, quadro-linear, exponential or other functions or assumptions about thresholds or non-thresholds in dose-response relationships;
- the transfer of animal data to humans;
- assumptions about exposure or definition of target groups;
- the handling of distributional effects which may cover inter-individual, inter-group, regional, social, time-related and inter-generational aspects.

These judgements reflect the consensus among the experts or are common products of risk assessment and management (for example by licensing special testing methods). Their incorporation in guiding scientific analyses is unavoidable and this does not discredit the validity of the results. Yet it is essential that risk managers and interested parties are informed about these conventions and understand their rationale. On one hand knowledge about these conventions can lead to a more cautious apprehension of what the assessments mean and imply, on the other hand they can convey a better understanding of the constraints and conditions under which the results of the various assessments hold true.

In summary, Table 2 provides a brief overview of the four components of pre-assessment. The table also lists some indicators that may be useful as heuristic tools when investigating different risk governance processes. The choice of indicators is not exhaustive and will vary depending on risk source and risk target. Listing the indicators serves the purpose of illustrating the type of information needed to perform the task described in each step. The title 'pre-assessment' does not mean that these steps are always taken before assessments are performed. Rather they are logically located in the forefront of assessment and management. They should also not be seen as sequential steps but as elements that are closely interlinked. As a matter of fact, and depending on the situation, early warning might precede problem framing[5].

Table 2: Components of Pre-assessment in Handling Risks

Pre-assessment Components	Definition	Indicators
1 Problem framing	Different perspectives of how to conceptualise the issue	• dissent or consent on goals of selection rule • dissent or consent on relevance of evidence • choice of frame (risk, opportunity, fate)
2 Early warning	Systematic search for new hazards	• unusual events or phenomena • systematic comparison between modelled and observed phenomena • novel activities or events
3 Screening (risk assessment and concern assessment policy)	Establishing a procedure for screening hazards and risks and determining assessment and management route	• screening in place? • criteria for screening: o hazard potential o persistence o ubiquity, etc. • criteria for selecting risk assessment procedures for: o known risks o emergencies, etc. • criteria for identifying and measuring social concerns
4 Scientific conventions for risk assessment and concern assessment	Determining the assumptions and parameters of scientific modelling and evaluating methods and procedures for assessing risks and concerns	• definition of no adverse effect levels (NOAEL) • validity of methods and techniques for risk assessments • methodological rules for assessing concerns

7 RISK ASSESSMENT

The purpose of risk assessment is the generation of knowledge linking specific risk agents with uncertain but possible consequences (Lave 1987; Graham and Rhomberg 1996). The final product of risk assessment is an estimation of the risk in terms of a probability distribution of the modelled consequences (drawing on either discrete events or continuous loss functions). The different stages of risk assessment vary from

5 It should also be noted that early warning may of course also benefit from 'non-systematic' findings and incidental/accidental reporting.

risk source to risk source. Many efforts have been made to produce a harmonised set of terms and conceptual phase-model that would cover a wide range of risks and risk domains (c.f. Codex Alimentarius 2001; National Research Council 1982; 1983; Stern and Fineberg 1996; EU 2000; 2003)[6]. The most recent example is the risk guidance book by the International Programme on Chemical Safety (IPCS) and WHO (IPCS and WHO 2004). Although there are clear differences in structuring the assessment process depending on risk source and organisational culture, there is an agreement on basically three core components of risk assessment:

- an identification and, if possible, estimation of hazard;
- an assessment of exposure and/or vulnerability;
- an estimation of risk, combining the likelihood and the severity of the targeted consequences based on the identified hazardous characteristics and the exposure/vulnerability assessment.

As we have seen before it is crucial to distinguish between hazards and risks. Correspondingly, **identification** (i.e. establishing cause-effect link) and **estimation** (determining the strength of the cause-effect link) need to be performed for hazards and risks separately. The estimation of risk depends on an exposure and/or vulnerability assessment. **Exposure** refers to the contact of the hazardous agent with the target (individuals, ecosystems, buildings, etc.). **Vulnerability** describes the various degrees of the target to experience harm or damage as a result of the exposure (for example: immune system of target population, vulnerable groups, structural deficiencies in buildings, etc.). In many cases it is common practice to combine hazard and risk estimates in scenarios that allow modellers to change parameters and include different sets of context constraints.

The basis of risk assessment is the systematic use of analytical – largely probability-based – methods which have been constantly improved over the past years. Probabilistic risk assessments for large technological systems, for instance, include tools such as fault and event trees, scenario techniques, distribution models based on Geographic Information Systems (GIS), transportation modelling and empirically driven human-machine interface simulations (IAEA 1995; Stricoff 1995). With respect to human health, improved methods of modelling individual variation (Hattis 2004), dose-response relationships (Olin et al. 1995) and exposure assessments (US-EPA 1997) have been developed and successfully applied. The processing of data is often guided by inferential statistics and organised in line with decision analytic procedures. These tools have been developed to generate knowledge about cause-effect relationships, estimate the strength of these relationships, characterise remaining uncertainties and ambiguities and describe, in quantitative or qualitative form, other risk or hazard related properties that are important for risk management (IAEA 1995; IEC 1993). In short, risk assessments specify what is at stake, calculate the probabilities for (un)wanted consequences, and aggregate both components into a single dimension (Kolluru 1995: 2.3f). In general there are five methods for calculating probabilities:

- Collection of statistical data relating to the performance of a risk source in the past (actuarial extrapolation);
- Collection of statistical data relating to components of a hazardous agent or technology. This method requires a synthesis of probability judgements from component failure to system performance (probabilistic risk assessments, PRA);
- Epidemiological or experimental studies which are aimed at finding statistically significant correlations between an exposure of a hazardous agent and an adverse effect in a defined population sample (probabilistic modelling);
- Experts', or decision makers' best estimates of probabilities, in particular for events where only insufficient statistical data is available (normally employing Bayesian statistical tools);

6 An extended review of a large variety of risk taxonomies is summarised in Annex A to this document.

- Scenario techniques by which different plausible pathways from release of a harmful agent to the final loss are modelled on the basis of worst and best cases or estimated likelihood for each consequence at each knot).

All these methods are based either on the past performance of the same or a similar risk source or an experimental intervention. The possibility that the circumstances of the risk situation vary over time in an unforeseeable way and that people will thus make decisions in relation to changing hazards – sometimes they may even change in an unsystematic, unpredictable manner – leads to unresolved or remaining uncertainty (second order uncertainty). One of the main challenges of risk assessment is the systematic characterisation of these remaining uncertainties. They can partly be modelled by using inferential statistics (confidence interval) or other simulation methods (such as Monte Carlo), but often they can only be described in qualitative terms. Risk analysts consequently distinguish between *aleatory and epistemic uncertainty:* epistemic uncertainty can be reduced by more scientific research[7] while aleatory uncertainty will remain fuzzy regardless of how much research is invested in the subject (Shome et al. 1998). Remaining uncertainties pose major problems in the later stages of risk characterisation and evaluation as well as risk management since they are difficult to integrate in formal risk-benefit analyses or in setting standards.

There is no doubt that risk assessment methods have matured to become sophisticated and powerful tools in coping with the potential harm of human actions or natural events (Morgan 1990). Its worldwide application, however, in dealing and managing risks is far from reflecting this degree of power and professionalism. At the same time, there are new challenges in the risk field that need to be addressed by the risk assessment communities. These challenges refer to (c.f. Brown and Goble 1990; Hattis and Kennedey 1990; Greeno and Wilson 1995; Renn 1997):

- widening the scope of effects for using risk assessment, including chronic diseases (rather than focusing only on fatal diseases such as cancer or heart attack); risks to ecosystem stability (rather than focusing on a single species); and the secondary and tertiary risk impacts that are associated with the primary physical risks;
- addressing risk at a more aggregated and integrated level, such as studying synergistic effects of several toxins or constructing a risk profile over a geographic area that encompasses several risk causing facilities;
- studying the variations among different populations, races, and individuals and getting a more adequate picture of the ranges of sensibilities with respect to environmental pollutants, lifestyle factors, stress levels, and impacts of noise;
- integrating risk assessment in a comprehensive technology assessment or option appraisal so that the practical value of its information can be phased into the decision making process at the needed time and that its inherent limitations can be compensated through additional methods of data collection and interpretation; and
- developing more forgiving technologies that tolerate a large range of human error and provide sufficient time for initiating counteractions.

Table 3 lists the three generic components of risk assessment and provides an explanation for the terms as well as a summary list of indicators that can be used in the different risk contexts for performing the respective task. As with Table 2, the choice of indicators is not exhaustive and serves the purpose of

7 There are many tools available to model epistemic uncertainty. The Dutch guidance document on uncertainty assessment and communication lists the following tools: sensitivity analysis, error propagation methods, Monte Carlo Analysis, NUSAP (numeral, unit, spread, assessment, pedigree), expert elicitation, scenario analysis, PRIMA (pluralistic framework of integrated uncertainty management and risk analysis) and checklists for model quality assistance (van den Sluijs et al. 2004).

illustrating the type of information needed to perform the task described in each step. The three components are normally performed sequentially but, depending on circumstances, the order may be changed. Often, exposure assessments are done before hazards are estimated. If, for example, exposure can be prevented, it may not be necessary to perform any sophisticated hazard estimate.

Table 3: Generic Components of Risk Assessment

Assessment Components	Definition	Indicators
1 Hazard identification and estimation	Recognising potential for adverse effects and assessing the strength of cause-effect relationships	• properties such as flammability, etc. ○ persistence ○ irreversibility ○ ubiquity ○ delayed effects ○ potency for harm • dose-response relationships
2 Exposure/vulnerability assessment	Modelling diffusion, exposure and effects on risk targets	• exposure pathways • normalised behaviour of target • vulnerability of target
3 Risk estimation	• *Quantitative:* probability distribution of adverse effects • *Qualitative:* combination of hazard, exposure, and qualitative factors (scenario construction)	• expected risk value(s) (individual, collective) • xx% confidence interval • risk description • risk modelling as function of variations in context variables and parameters

8 GENERIC CHALLENGES FOR RISK ASSESSMENT

Risk assessment is confronted with three major challenges that can be best described using the terms 'complexity', 'uncertainty' and 'ambiguity'. These three challenges are not related to the intrinsic characteristics of hazards or risks themselves but to the *state and quality of knowledge available* about both hazards and risks. Since risks are mental constructs, the quality of their explanatory power depends on the accuracy and validity of their (real) predictions. Unlike some other scientific constructs, validating the results of risk assessments is particularly difficult because, in theory, one would need to wait indefinitely to prove that the probabilities assigned to a specific outcome were correctly assessed. If the number of predicted events is frequent and the causal chain obvious (as is the case with car accidents), validation is relatively simple and straightforward. If, however, the assessment focuses on risks where cause-effect relationships are difficult to discern, effects are rare and difficult to interpret and variations in both causes and effects are obscuring the results, the validation of the assessment results becomes a major problem. In such instances, assessment procedures are needed to characterise the existing knowledge with respect to complexity, remaining uncertainties and ambiguities (WBGU 2000, 195ff.; Klinke and Renn 2002).

- **Complexity** refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects. The nature of this difficulty may be traced back to interactive effects among these agents (synergism and antagonisms), long delay periods between cause and effect, inter-individual variation, intervening variables, and others. Risk assessors have to make judgements about the level of complexity that they are able to process and about how to treat intervening variables (such as lifestyle, other environmental factors, psychosomatic impacts, etc.). Complexity is particularly pertinent in the phase of estimation with respect to hazards as well as risks. Examples of highly complex risk include sophisticated chemical facilities, synergistic effects of potentially toxic substances, failure risk of large interconnected infrastructures and risks of critical loads to sensitive ecosystems.

- **Uncertainty** is different from complexity but often results from an incomplete or inadequate reduction of complexity in modelling cause-effect chains. Whether the world is inherently uncertain is a philosophical question that we will not pursue here. It is essential to acknowledge in the context of risk assessment that human knowledge is always incomplete and selective and thus contingent on uncertain assumptions, assertions and predictions (Functowicz and Ravetz 1992; Laudan 1996; Bruijn and ten Heuvelhof 1999). It is obvious that the modelled probability distributions within a numerical relational system can only represent an approximation of the empirical relational system with which to understand and predict uncertain events (Cooke 1991). It therefore seems prudent to include other, additional, aspects of uncertainty (Morgan and Henrion 1990; van Asselt 2000, 93-138; van den Sluijs et al. 2003). Although there is no consensus in the literature on the best means of disaggregating uncertainties, the following categories appear to be an appropriate means of distinguishing the key components of uncertainty:

  - *target variability* (based on different vulnerability of targets);
  - *systematic and random error in modelling* (based on extrapolations from animals to humans or from large doses to small doses, statistical inferential applications, etc.);
  - *indeterminacy or genuine stochastic effects* (variation of effects due to random events, in special cases congruent with statistical handling of random errors);
  - *system boundaries* (uncertainties stemming from restricted models and the need for focusing on a limited amount of variables and parameters);
  - *ignorance or non-knowledge* (uncertainties derived from lack or absence of knowledge).

  The first two components of uncertainty qualify as epistemic uncertainty and therefore can be reduced by improving the existing knowledge and by advancing the present modelling tools. The last three components are genuine uncertainty components of aleatory nature and thus can be characterised to some extent using scientific approaches but cannot be further resolved. If uncertainty, in particular the aleatory components, plays a large role then the estimation of risk becomes fuzzy. The validity of the end results is questionable and, for risk management purposes, additional information is needed such as a subjective confidence level in the risk estimates, potential alternative pathways of cause-effect relationships, ranges of reasonable estimates, loss scenarios and others. Examples for high uncertainty, particularly aleatory uncertainty, include many natural disasters such as earthquakes, possible health effects of mass pollutants below the threshold of statistical significance, acts of violence such as terrorism and sabotage and long-term effects of introducing genetically modified species into the natural environment.

- (Interpretative and normative) ambiguity is the last term in this context. Whereas uncertainty refers to a lack of clarity over the scientific or technical basis for decision making, (interpretative and normative) ambiguity is a result of divergent or contested perspectives on the justification, severity or wider 'meanings' associated with a given threat (Stirling 2003). The term *'ambiguity'* may be misleading because it has different connotations in everyday English language[8]. In relation to risk governance it is understood as 'giving rise to several meaningful and legitimate interpretations of accepted risk assessments results'. It can be divided into **interpretative ambiguity** (different interpretations of an identical assessment result: e.g. as an adverse or non-adverse effect) and **normative ambiguity** (different concepts of what can be regarded as tolerable referring e.g. to ethics, quality of life parameters, distribution of risks and benefits, etc.). A condition of ambiguity emerges where the problem lies in agreeing on the appropriate values, priorities, assumptions, or boundaries to be applied to the definition of possible outcomes. What does it mean, for example, if neuronal activities in the human brain are intensified when subjects are exposed to electromagnetic radiation? Can this be interpreted as an adverse effect or is it just a bodily response without any health implication? Many scientific disputes in the fields of risk assessment and management do not refer to differences in methodology, measurements or dose-response functions, but to the question of what all of this means for human health and environmental protection. High complexity and uncertainty favour the emergence of ambiguity, but there are also quite a few simple and highly probable risks that can cause controversy and thus ambiguity. Examples for high interpretative ambiguity include low dose radiation (ionising and non-ionising), low concentrations of genotoxic substances, food supplements and hormone treatment of cattle. Normative ambiguities can be associated, for example, with passive smoking, nuclear power, pre-natal genetic screening and genetically modified food.

9 RISK PERCEPTION

Since risk is a mental construct there is a wide variety of construction principles for conceptualising risk. Different disciplines within the natural and social sciences have formed their own concepts of risk; stakeholder groups, driven by interest and experience, have developed their specific perspective on risk; and, last but not least, representatives of civil society as well as the general public are responding to risks according to their own risk constructs and images. These images are called **'perceptions'** in the psychological and social sciences and they have been intensely researched in relation to risk – as have their underlying factors (Covello 1983; Slovic 1987; Boholm 1998; Rohrmann and Renn 2000). Risk perceptions belong to the contextual aspects that risk managers need to consider when deciding whether or not a risk should be taken as well as when designing risk reduction measures.

First of all it is highly important to know that human behaviour is primarily driven by perception and not by facts or by what is understood as facts by risk analysts and scientists. Most cognitive psychologists believe that perceptions are formed by common sense reasoning, personal experience, social communication and cultural traditions (Brehmer 1987; Drottz-Sjöberg 1991; Pidgeon et al. 1992; Pidgeon 1998). In relation to risk it has been shown that humans link certain expectations, ideas, hopes, fears and emotions with activities or events that have uncertain consequences. People do, however, not use completely irrational strategies to assess information, but, most of the time, follow relatively consistent patterns of creating images of risks and evaluating them. These patterns are related to certain evolutionary bases of coping with dangerous situations. Faced with an eminent threat, humans react with four basic strategies: *flight, fight, play dead* and, if appropriate, *experimentation* (on the basis of trial and error).

In the course of cultural evolution the basic patterns of perception were increasingly enriched with cultural patterns. These cultural patterns can be described by so-called *qualitative evaluation characteristics* (Slovic 1992). They describe properties of risks or risky situations going beyond the two

8 With respect to risk and decision making the term ambiguity has been used with various meanings. Some analysts refer to ambiguity as the conflicting goals of participants in the process (Skinner 1999), others use the term ambiguity when they refer to the inability to estimate probabilities of an event occurring (Gosh and Ray 1997: Ho et al. 2002; Stirling 2003). In the context of the present framework ambiguity denotes the variability in interpretation and normative implications with respect to accepted evidence.

classical factors of risk assessment based on which risk is usually judged, i.e. level of probability and degree of possible harm. Here, psychologists differentiate between two classes of qualitative perception patterns: on the one hand *risk-related patterns*, which are based on the properties of the source of risk; on the other hand *situation-related patterns*, based on the idiosyncrasies of the risky situation (Fischhoff et al. 1978; Slovic 1987; Slovic 1992).

One example of a risk-related pattern is the perceived 'dread' of the consequences of a possible harmful event. If, for example, a person is riding in a car and thinking about possible accidents, s/he will always be under the impression s/he would, with high probability, get away unscathed in a car accident ('fender-bender mentality'). However, if the same person is sitting in an airplane s/he will be under the impression that if something happens here there is no getting away. This feeling of apprehensiveness does not subside even when this person knows the odds and is convinced that statistically many more people die in car accidents than in airplane crashes. Situation-related patterns of perception include aspects such as voluntariness and the ability to exercise self-control. If a person is of the opinion that s/he can control the risk, then s/he will perceive it as less serious. This mode of thinking frequently takes effect where eating habits are concerned. People believe they can easily do without sweets, alcohol or other food considered unhealthy, if only they wanted to. However, mostly harmless chemical food additives are perceived as a threat to one's health. With respect to collective risks people show special concern for risks that they believe are not adequately controlled by public authorities (as in the case of GMOs).

Considered together these qualitative evaluation characteristics can be sub-divided into a limited number of consistent risk perception classes. In literature they are also called **semantic risk patterns**. The following patterns were examined particularly thoroughly (Renn 2004a):

- Risks posing an immediate threat such as nuclear energy or large dams;
- Risks dealt with as a blow of fate such as natural disasters;
- Risks presenting a challenge to one's own strength such as sports activities;
- Risk as a gamble such as lotteries, stock exchange, insurances;
- Risks as an early indication of insidious danger such as food additives, ionising radiation, viruses.

These patterns have functions similar to drawers in a filing cabinet. When faced with a new risk or when obtaining new information about a risk, most people try to file this new information into one of the existing drawers[9]. In addition to the cognitive processing of risk characteristics and risk situations, studies have shown that people tend to *stigmatise risk sources* that are associated with specific dreadful associations (Kunreuther and Heal 2003). A salient example of stigma is the reaction to products that are deemed to be carcinogenic, although there is often limited, if any, scientific evidence to support this position. The mere suspicion that a substance could cause cancer is often sufficient for generating fear and asking for strict regulatory actions. Stigmatisation leads to a cycle of public outrage and regulatory responses feeding into the process that has been described as social amplification of risk (Kasperson et al. 1988; Kasperson et al. 2003). Stimulated by media reporting, the public's perception of the risk is often amplified in ways that are difficult to explain if one were focusing on the standard elements of any technical risk assessment – probability and direct losses.

The problems associated with risk perception are compounded because of the difficulty individuals have in interpreting low probabilities when making their decisions (Kunreuther et al. 2001). In fact, there

9 The 'drawers' cannot be treated in detail here since this would exceed the scope of this document (more information in: Streffer et al. 2003, pp. 269ff).

is evidence that people may not even want data on the likelihood of an event occurring. If people do not think probabilistically, how do they make their choices? Psychological research has revealed the following patterns of drawing inferences about probabilities and risks (Tversky and Kahneman 1974; Ross 1977; Kahneman and Tversky 1979; Renn 2004a):

- The easier and faster a risk is recognised, the more conscious individuals are of it and the greater is the chance of its probability being overestimated. If, for example, an individual has known someone who died after being struck by lightning, that individual will perceive the risk of being struck by lightning as being particularly large *(availability bias)*.
- The more a risk provokes associations with known events, the more likely its probability will be overestimated. This is why, for example, the use of the term 'incinerating' in waste disposal facilities readily evokes an association with harmful chemicals, especially dioxins and furans, even if there is no way that they could be released into the environment by the facilities concerned *(anchoring effect)*.
- The more constant and similar the losses from risk sources, the more likely the impact of average losses will be underestimated. While road traffic accidents are not deemed acceptable, they are more or less passively accepted. If the average annual number of road deaths in a given country were to occur at one point in time instead of being spread out over the year, then a considerably greater level of rejection could be expected. Thus, people are not indifferent as regards the *distribution of risks over time*: they prefer even loss distribution over individual disasters (Kahneman and Tversky 1979).
- The greater the uncertainty of loss expectation, the more likely the average loss assessment will be in the region of the median of all known loss expectations. In this way, loss expectations in objectively low risks are often overestimated while objectively high risks are often underestimated *(assessment bias)*.

While important for actually evaluating and managing a risk, overestimation or underestimation of loss expectations is not, however, the most important aspect of risk perception. Instead the context-dependent nature of risk assessment is the deciding factor. This context includes the qualitative risk evaluation characteristics, the semantic images and the stigma effects. More recently, psychologists have also discovered that affect and emotions play an important role in people's decision processes (Slovic et al. 2002; Loewenstein et al. 2001). These factors are particularly relevant when individuals face a decision that involves a difficult trade-off between attributes or where there is interpretative ambiguity as to what constitutes a 'right' answer. In these cases, people often appear to resolve problems by focusing on those cues that send the strongest affective signals (Hsee and Kunreuther 2000).

The most important policy question is how to treat risk perceptions in a policy arena that includes responses of different actors and the general public (Slovic et al. 1982; Fischhoff 1985; 1995). There are two suggestions, from opposite ends of a spectrum. The first position states that the scientific concepts of risk are the only ones that can claim inter-subjective validity and applicability and, therefore, requires risk managers to obtain an assurance that (erroneous) risk perceptions are corrected via risk communication and education (Cross 1998; Coglianese 1999). The second position states that there is no overarching universally applicable quality criterion available in order to evaluate the appropriateness or validity of risk concepts. As a result, scientific concepts (often called *narratives* in this school of thought) should compete with concepts of stakeholders and public groups (Liberatore and Funtowicz 2003). If collective decisions on risk are necessary, the concept that is used to make these decisions should be negotiated among all relevant concept holders. None of these groups, including the science communities, is allowed to claim any privileged position in this negotiation.

The IRGC has strong reservations with respect to both positions. IRGC advocates an approach by which the elements of what matters to the different groups when they conceptualise risk should be regarded as equally legitimate factors for inclusion within risk governance (see also Giegerenzer and Selten 2001). This implies, for example, that if people are willing to accept higher risks when they are in control of them, then this preference cannot be de-legitimised by professional economists who favour cost-effectiveness studies that treat all risks equally. In identifying aspects of concern and worry all groups in society have the same right to raise them and to bring them to the negotiation table. However, the question of the degree to which these concerns are met or violated by risk-bearing activities or events should be primarily answered by those who have the knowledge, skills and/or the experience to measure or estimate the strength of relationships between cause (or dose) and effect. It seems wrong to give equal standing to those who intuitively estimate risks and those who assess risks on the basis of systematic observation, empirical data collection and rigorous modelling, just as it seems wrong to dismiss non-factual perceptions purely because they appear irrational to those with expert knowledge. This said, the IRGC wishes to emphasise that the proposed quality distinction between intuition and systematic knowledge does not predetermine a position in the philosophical debate on realism versus constructivism; the argument here is strictly focused on the structure and content of knowledge claims, not on claims about reality representation[10].

This position has major impacts on risk policy making and communication. Policy making needs to, inter alia, organise systematic feedback from society and, equally, to include risk perceptions as an important input to deciding on whether something should be done about a certain risk and, if so, what (Jaeger et al. 2001). How this can be accomplished is explained in the next section on risk appraisal. Risk communication is also affected, in two ways: first, it is bound to elicit, and enable the exchange of, concerns and conceptual aspects of risk among and between all relevant actors, and, secondly, risk managers are well advised to ensure that the best available knowledge is widely distributed to those who raise these concerns.

10 RISK APPRAISAL

The term *risk appraisal* has sometimes been used in the risk governance literature to include all knowledge elements necessary for risk characterisation and evaluation as well as risk management (Stirling 1998; 2003). For society to make prudent choices about risks, it is not enough to consider only the results of (scientific) risk assessment. In order to understand the concerns of the various stakeholders and public groups, information about both risk perceptions and the further implications of the direct consequences of a risk – including its social mobilisation potential (i.e. how likely is it that the activity will give rise to social opposition or protest?) – is needed and should be collected by risk management agents. In addition, other aspects of the risk causing activity that seem to be relevant for characterising and evaluating the risk and selecting risk reduction options should be pulled together and fed into the analysis. Based on such a wide range of information, risk managers can make more informed judgements and design the appropriate risk management options (Clark 2001).

Risk appraisal thus includes the scientific assessment of the risks to human health and the environment and an assessment of related concerns as well as social and economic implications. The appraisal process is and should be clearly dominated by scientific analyses – but, in contrast to the traditional risk governance model, the scientific process includes both the natural/technical as well as the social sciences, including economics. We envision risk appraisal as having two process stages: first, natural and technical scientists use their skills to produce the best estimate of the physical harm that a risk source may induce (as described in the chapter on risk assessment); secondly, social scientists and economists identify and analyse the issues that individuals or society as a whole link with a certain risk.

10 For more comprehensive arguments on this debate see footnote 4.

For this purpose the repertoire of the social sciences such as survey methods, focus groups, econometric analysis, macro-economic modelling, or structured hearings with stakeholders may be used.

Based on the results of risk assessment and the identification of individual and social concerns this second process stage also investigates and calculates *the social and economic implications of risks*. Of particular interest in this context are financial and legal implications, i.e. economic losses and liabilities, as well as social responses such as political mobilisation. These secondary implications have been addressed by the concept of *social amplification of risk* (Kasperson et al. 2001; Kasperson et al. 2003). This concept is based on the hypothesis that events pertaining to hazards interact with psychological, social, institutional, and cultural processes in ways that can heighten or attenuate individual and social perceptions of risk and shape risk behaviour. Behavioural patterns, in turn, generate secondary social or economic consequences that extend far beyond direct harm to human health or the environment, including significant indirect impacts such as liability, insurance costs, loss of confidence in institutions, or alienation from community affairs (Burns et al. 1993). Such amplified secondary effects can then trigger demands for additional institutional responses and protective actions, or, conversely (in the case of risk attenuation), place impediments in the path of needed protective actions. Secondary impacts, whether amplified or not, are of major concern to those who are obliged to take over the costs or cope with the consequences of being accountable.

Risk appraisal intends to produce the best possible scientific estimate of the physical, economic and social consequences of a risk source. It should not be confused with direct stakeholder involvement which will be covered later. Involvement by stakeholders and the population is only desirable at this stage if knowledge from these sources is needed to improve the quality of the assessments.

In a recent draft document published by the UK Treasury Department (UK Treasury Department 2004) the authors recommend a risk appraisal procedure that includes the results of risk assessment, the direct input from data on public perception and the assessment of social concerns. The document offers a tool for evaluating public concerns against six factors which are centred around the hazard(s) leading to a risk, the risk's effects and its management[11]:

- Perception of familiarity and experience with the hazard;
- Understanding the nature of the hazard and its potential impacts;
- Repercussions of the risk's effects on equity (inter-generational, intra-generational, social);
- Perception of fear and dread in relation to a risk's effect;
- Perception of personal or institutional control over the management of a risk;
- Degree of trust in risk management organisations.

A similar list of appraisal indicators was suggested by a group of Dutch researchers and the Dutch Environmental Protection Agency (van den Sluijs e.a. 2003; van den Sluijs e.a. 2004). In the late 1990s, the German Council for Global Environmental Change (WBGU) has also addressed the issue of risk appraisal and developed a set of eight criteria to characterise risks beyond the established assessment criteria (WBGU 2000). These are:

- *Extent of damage:* Adverse effects in natural units, e.g. death, injury, production loss, etc.
- *Probability of occurrence:* Estimate of relative frequency, which can be discrete or continuous.

11 Since the document has only been released in late 2004, reports about practical experiences regarding its implementation are not yet available.

- *Incertitude:* How do we take account of uncertainty in knowledge, in modelling of complex systems or in predictability in assessing a risk?
- *Ubiquity:* Geographical dispersion of damage.
- *Persistence:* How long will the damage last?
- *Reversibility:* Can the damage be reversed?
- *Delay effects:* Latency between initial event and actual damage.
- *Potential for mobilisation:* The broad social impact. Will the risk generate social conflict or outrage etc.?

After the WBGU proposal had been reviewed and discussed by many experts and risk managers, it was suggested to unfold the compact ‘mobilisation index’ and divide it into four major elements:

- *Inequity and injustice* associated with the distribution of risks and benefits over time, space and social status;
- *Psychological stress and discomfort* associated with the risk or the risk source (as measured by psychometric scales);
- *Potential for social conflict and mobilisation* (degree of political or public pressure on risk regulatory agencies);
- *Spill-over effects* that are likely to be expected when highly symbolic losses have repercussions on other fields such as financial markets or loss of credibility in management institutions.

These four sub-criteria reflect many factors that have been proven to influence risk perception as stated above[12].

When dealing with complex, uncertain and/or ambiguous risks it is essential to complement data on physical consequences with data on secondary impacts, including social responses to risk, and insights into risk perception. The suggestions listed above can provide some orientation for the criteria to be considered. Depending on the risk under investigation, additional criteria can be included or proposed criteria neglected.

11 CHARACTERISING AND EVALUATING RISKS

The most controversial part of handling risks refers to the process of delineating and justifying a judgement about the tolerability or acceptability of a given risk (HSE 2001). The term **‘tolerable’** refers to an activity that is seen as worth pursuing (for the benefit it carries) yet it requires additional efforts for risk reduction within reasonable limits. The term **‘acceptable’** refers to an activity where the remaining risks are so low that additional efforts for risk reduction are not seen as necessary. For purely natural hazards the two terms appear at first glance to be meaningless, since humans have no choice in tolerating or accepting these risks. Human activities, however, do influence the impact of natural hazards through changes in vulnerability and exposure options (such as building codes or zoning laws). Looking into the resulting risks as a function of vulnerabilities, a judgement on tolerability and acceptability with respect to the selection of protective measures becomes meaningful again. The distinction between tolerability and acceptability can thus be applied to a large array of risk sources. If tolerability and acceptability are located in a risk diagram (with probabilities on the y-axis and extent of consequences on the x-axis), the well known traffic light model emerges[13] (Figure 2). In this variant of the model the red zone signifies intolerable risk, the yellow one indicates tolerable risk in need of further

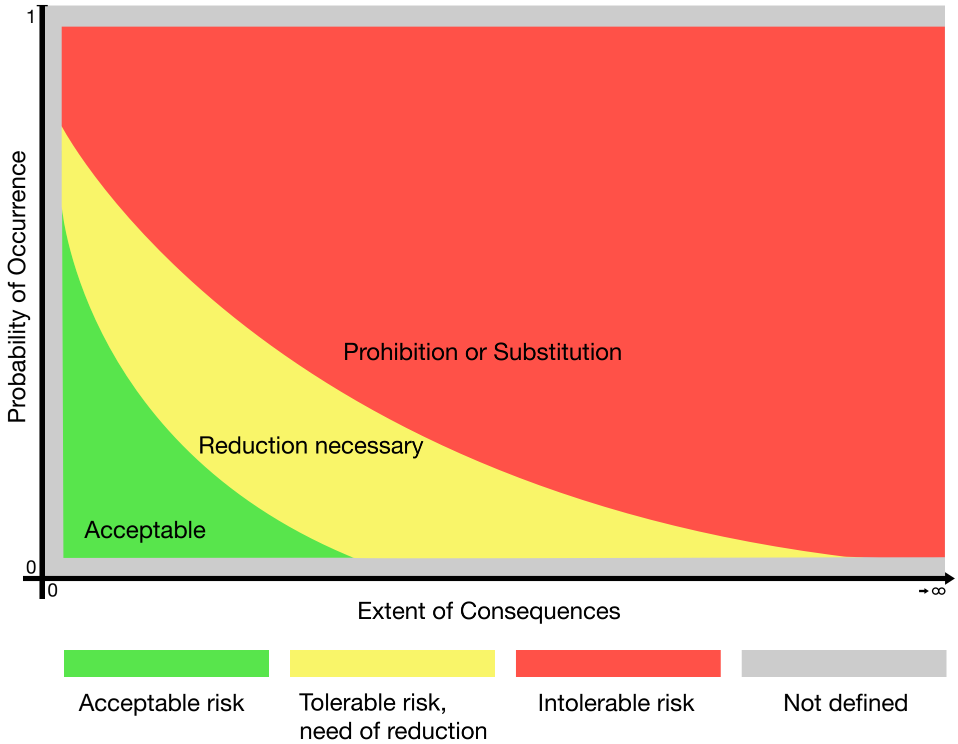
12 A similar decomposition has been proposed by the UK government (Environment Agency 1998; Pollard et al. 2000).

13 The traffic light model in this context is an illustrative means of mapping risks according to their tolerability or acceptability. The same metaphor has also been used to map the degree of controversy or normative ambiguity, for example in the area of siting mobile base stations (Kemp 1998; Kemp and Greulich 2004). The criticism that has been raised against using the traffic light model for addressing opposition to base stations is not relevant to the application of this model in the context of risk characterisation and evaluation.

management actions (in accordance with the 'as low as reasonably possible' – ALARP – principle) and the green zone shows acceptable or even negligible risk.

To draw the line between 'intolerable' and 'tolerable' as well as 'tolerable' and 'acceptable' is one of the most difficult tasks of risk governance. The UK Health and Safety Executive has developed a procedure for chemical risks based on risk-risk comparisons (Löfstedt 1997). Some Swiss cantons such as Basle County experimented with Round Tables as a means to reach consensus on drawing the two lines, whereby participants in the Round Table represented industry, administrators, county officials, environmentalists, and neighbourhood groups (RISKO 2000). Irrespective of the selected means to support this task, the judgement on acceptability or tolerability is contingent on making use of a variety of different knowledge sources. One needs to include the risk estimates derived from the risk assessment stage, and additional assessment data from the concern assessment within the appraisal stage.

Figure 2: Acceptable, Tolerable and Intolerable Risks (Traffic Light Model)



Existing taxonomies of risk differ considerably in where they position the decision-making with regard to what is acceptable and what is tolerable within the overall risk process. Some assign it to the risk assessment part, others to the risk management part and others place it at the level of policy and option assessment, reaching far beyond the narrow risk acceptance criteria. For the generic approach to risk handling that this document pursues, the question of appropriate placement should be handled in a flexible manner.

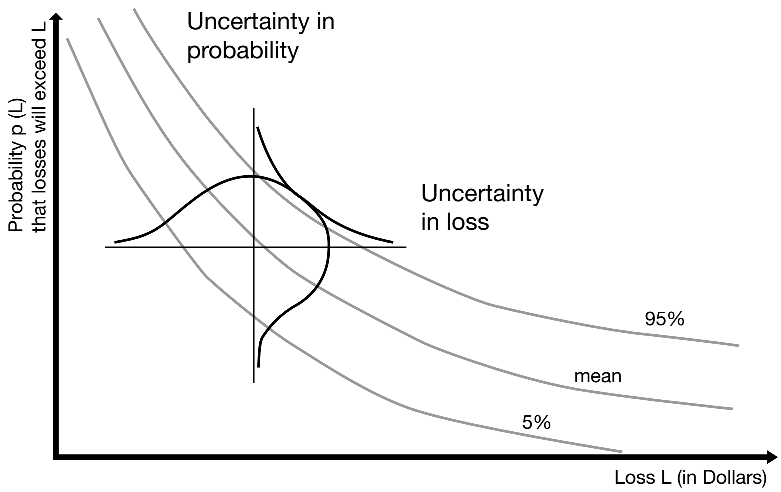
Why? As with the framing part, judgements on acceptability rely on two major inputs: *values and evidence.* What society is supposed to tolerate or accept can never be derived from looking at the evidence alone. Likewise, evidence is essential if we are to know whether a value has been violated or not (or to what degree). With respect to values and evidence we can distinguish three cases: (i) ambiguity on evidence but not on values (interpretative ambiguity) (ii) ambiguity on values but not on evidence (normative ambiguity) and (iii) ambiguities on values and evidence.

Case I: Interpretative ambiguity: In those cases where there is unanimous agreement about the underlying values and even the threshold of what is regarded as tolerable or acceptable, evidence in the form of risk estimates may be sufficient to locate the risk within the traffic light diagram. A judgement can then best be made by those who have most expertise in risk and concern assessments, in which case it makes sense to place this task within the domain of risk appraisal. The judgement will thus be based on best scientific modelling of epistemic uncertainties and the best qualitative characterisation of aleatory uncertainties. Characterisation also includes an analysis of the concerns associated with different outcomes and the likely secondary implications. It will be helpful for risk managers to receive best expert advice on potentially effective risk reduction measures and other management options that may lead to satisfactory results. It is, however, not the task of the risk appraisal team to make a selection of options, let alone decide on which option should be implemented.

Leaving the resolution of interpretative ambiguity to the risk and concern assessors places a major challenge to the science-based assessment process. It may be extremely difficult for experts to find an agreement on interpreting ambiguous results. It is not uncommon for the public to hear expert 1 say that there is 'nothing to worry about regarding a particular risk' while at the same time learning from expert 2 that 'this risk should be on your radar screen'. One way to capture these discrepancies in risk interpretations is to construct an *exceedance probability (EP) curve* (Grossi and Kunreuther 2005). An EP curve specifies the probabilities that certain level of losses will be exceeded. The losses can be measured in terms of dollars of damage, fatalities, illness or some other unit of analysis.

To illustrate with a specific example, suppose one was interested in constructing an EP curve for dollar losses to homes in Seattle from an earthquake. Using probabilistic risk assessment, one combines the set of events that could produce a given dollar loss and then determines the resulting probabilities of exceeding losses of different magnitudes. Based on these estimates, one can construct the mean EP depicted in Figure 3. By its nature, the EP curve inherently incorporates uncertainty associated with the probability of an event occurring and the magnitude of dollar losses. This uncertainty is reflected in the 5% and 95% confidence interval curves in the figure.

Figure 3: Example of Loss Exceedance Probability Curves



The EP curve also serves as an important tool for evaluating risk management options, thus assisting managers to optimise risk reduction. It puts pressure on experts to state the assumptions on which they are basing their estimates of the likelihood of certain events occurring and the resulting consequences. In fact, EP curves, such as those depicted in Figure 3, supplemented by a discussion of the nature of these assumptions, should enable the assessors to both characterise interpretative ambiguities and to provide a framework for risk managers to test the efficiency of risk reduction options.

Case 2: Normative ambiguity: If the underlying values of what could be interpreted as tolerable or acceptable are disputed, while the evidence of what is at stake is clearly given and non-controversial, the judgement needs to be based on a discourse about values and their implications. Such a discourse falls clearly in the domain of risk management. A good example may be the normative implications of risks related to smoking. Science is very familiar with these risks and there is little uncertainty and interpretative ambiguity about dose-effect relationships. Yet there is considerable debate whether smoking is tolerable or not. Being a voluntary activity some countries leave it to the decision of each consumer while others initiate major activities to reduce and even ban smoking. Another example is wearing helmets on bicycles. The statistical data on this subject is rather straightforward; there are no major uncertainties or interpretative ambiguities. Yet many countries do dot want to impinge on the freedom of each cyclist to personally decide whether or not to wear a helmet, while other countries pursue a more paternalistic policy.

Case 3: Interpretative and normative ambiguity: A third case arises where both the evidence and the values are disputed. This would imply that assessors should engage in an activity to find some common ground for characterising and qualifying the evidence and risk managers need to establish agreement about the appropriate values and their application. A good example for this third case may be the interpretative and normative implications of global climate change. An international expert group such as the Intergovernmental Panel on Climate Change (IPCC) has gone through considerable effort to articulate a common characterisation of climatic risks and their uncertainties. Given the remaining uncertainties and the complexities of the causal relationships between greenhouse gases and climate change, it is then a question of values whether governments place their priorities on prevention or on mitigation (Keeney and McDaniels 2001).

Since the third of the above cases includes both of the other two, the process of judging the tolerability and acceptability of a risk can be structured into two distinct components: risk characterisation and risk evaluation. The first step, **'risk characterisation'**, determines the evidence-based component for making the necessary judgement on the tolerability and/or acceptability of a risk; the step **'risk evaluation'** determines the value-based component for making this judgement. Risk characterisation includes tasks such as point estimates of risks, descriptions of remaining uncertainties (as undertaken for instance in climate change models or risk studies on endocrine disruptors) and potential outcome scenarios including the social and economic implications, suggestions for safety factors to include inter-target variation, assurance of compatibility with legal prescriptions, risk-risk comparisons, risk-risk trade-offs, identification of discrepancies between risk assessment and risk perceptions as well as of potential equity violations, and suggestions for reasonable standards to meet legal requirements (Stern and Fineberg 1996). The evidence collected and summarised here goes beyond the classic natural science reservoir of knowledge and includes economic and social science expertise. This is also the reason why in the process of risk characterisation an interdisciplinary team of scientists is needed to draw a complete picture of what is known and what is and may remain unknown. In the course of risk characterisation, scientists are asked to design a multi-criteria profile of the risk in question, make a judgement about the seriousness of the risk and suggest potential options to deal with the risk.

The second step, risk evaluation, broadens the picture to include pre-risk aspects such as choice of technology, social need for the specific risk agent (substitution possible?), risk-benefit balances, political priorities, potential for conflict resolution and social mobilisation potential. The main objective here is to arrive at a judgement on tolerability and acceptability based on balancing pros and cons, testing potential impacts on quality of life, discussing different development options for the economy and society and weighing the competing arguments and evidence claims in a balanced manner. It should be noted that this elaborate procedure is only necessary if tolerability and/or acceptability is disputed and if society faces major dissents and conflicts among important stakeholders. If so, the direct involvement of stakeholders and the public will be a prerequisite for successful risk governance.

The separation of evidence and values underlying the distinction between characterisation and evaluation is, of course, functional and not necessarily organisational. Since risk characterisation and evaluation are closely linked and each depends on the other, it may even be wise to perform these two steps simultaneously in a joint effort by both assessors and risk managers. As some analysts have pointed out (Löfstedt and Vogel 2001; Vogel 2003): the US regulatory system tends to favour an organisational combination of characterisation and evaluation, while European risk managers tend to maintain the organisational separation (particularly in the food area). IRGC takes no stance in this question: there are good reasons for both models, yet IRGC does insist on a functional distinction.

The distinction between the three challenges of risk assessment, i.e. complexity, uncertainty and ambiguity, can also assist assessors and managers in assigning, or dividing, the judgement task. If a given risk is characterised by high complexity, low remaining uncertainties and hardly any ambiguities (except for interpretative differences over an established scientific risk assessment result), it is wise to let the assessment team dominate the process of making tolerability/acceptability judgements. If, in contrast, the risk is characterised by major unresolved uncertainties and if the results lead to highly diverse interpretations of what they mean for society, it is advisable to let risk managers take the lead.

Table 4 summarises these two steps which, in conclusion, are closely interrelated and may be merged if the circumstances require it. The list of indicators again represents only a small selection of potential dimensions and is displayed here for illustrative purposes.

12 RISK MANAGEMENT

Risk management starts with a review of all relevant information, in particular that from the combined risk appraisal, consisting of both a risk assessment and concern assessment whereby the latter is based on risk perception studies, economic impact assessments and the scientific characterisation of social responses to the risk source. This information, together with the judgements made in the phase of risk characterisation and evaluation, form the input material on which risk management options are being assessed, evaluated and selected. At the outset, risk management is presented with three potential outcomes:

- *Intolerable situation:* this means that either the risk source (such as a technology or a chemical) needs to be abandoned or replaced or, in cases where that is not possible (for example natural hazards), vulnerabilities need to be reduced and exposure restricted.
- *Tolerable situation:* this means that the risks need to be reduced or handled in some other way within the limits of reasonable resource investments (ALARP, including best practice). This can be done by private actors (such as corporate risk managers) or public actors (such as regulatory agencies) or both (public-private partnerships).
- *Acceptable situation:* this means that the risks are so small – perhaps even regarded as negligible – that any risk reduction effort is unnecessary. However, risk sharing via insurances and/or further risk reduction on a voluntary basis present options for action which can be worthwhile pursuing even in the case of an acceptable risk.

Table 4: Tolerability/Acceptability Judgement

Assessment Components	Definition	Indicators
1 Risk characterisation	Collecting and summarising all relevant evidence necessary for making an informed choice on tolerability or acceptability of the risk in question and suggesting potential options for dealing with the risk from a scientific perspective	
	a risk profile	• risk estimates • confidence intervals • uncertainty measures • hazard characteristics • range of 'legitimate' interpretations • risk perceptions • social and economic implications
	b judging the seriousness of risk	• compatibility with legal requirements • risk-risk trade-offs • effects on equity • public acceptance
	c conclusions and risk reduction options	suggestions for: • tolerable risk levels • acceptable risk levels • options for handling risks
2 Risk evaluation	Applying societal values and norms to the judgement on tolerability and acceptability and, consequently, determining the need for risk reduction measures	• choice of technology • potential for substitution • risk-benefit comparison • political priorities • compensation potential • conflict management • potential for social mobilisation

With regard to these outcomes risk managers may either face a situation of unanimity, i.e. all relevant actors agree with how a given risk situation should be qualified, or a situation of conflict in which major actors challenge the classification undertaken by others. The degree of controversy is one of the drivers for selecting the appropriate instruments for risk prevention or risk reduction.

For a systematic analysis of the risk management process it is advisable to focus on tolerable risks and those where tolerability is disputed, for the other cases are fairly easy to deal with. In the case of intolerable risks – and often in the case of tolerable but highly disputed risks – risk managers should opt for prevention strategies as a means to replace the hazardous activity with another activity leading to identical and similar benefits. One should first make sure, however, that the replacement does not introduce more risks or more uncertainties than the agent that it replaces (Wiener 1998). In the case of acceptable risks it should be left to private actors to initiate additional risk reduction or to seek insurance for covering potential but acceptable losses (although this does not eliminate the need for all concerned to have sufficient information and resources to do so). If risks are classified as tolerable, or if there is dispute as to whether they are tolerable or acceptable, risk management needs to design and implement actions that make these risks acceptable over time. Should this not be feasible then risk management, aided by communication, needs at least to credibly convey the message that major effort is undertaken to bring these risks closer to being acceptable. This task can be described in terms of classic decision theory, i.e. in the following steps (Morgan 1990; Keeney 1992; Hammond et al. 1999):

a) *Identification and generation of risk management options:* Generic risk management options include risk avoidance, risk reduction, risk transfer and – also an option to take into account – self retention. Whereas to avoid a risk means either selecting a path which does not touch on the risk (e.g. by abandoning the development of a specific technology) or taking action in order to fully eliminate a certain risk, risk transfer deals with ways of passing the risk on to a third party. Self retention as a management option essentially means taking an informed decision to do nothing about the risk and to take full responsibility both for the decision and any consequences occurring thereafter. Risk management by means of risk reduction can be accomplished by many different means. Among them are:

   - technical standards and limits that prescribe the permissible threshold of concentrations, emissions, take-up or other measures of exposure;
   - performance standards for technological and chemical processes such as minimum temperatures in waste incinerators;
   - technical prescriptions referring to the blockage of exposure (e.g. via protective clothing) or the improvement of resilience (e.g. via immunisation or earthquake tolerant constructions);
   - governmental economic incentives including taxation, duties, subsidies and certification schemes;
   - third party incentives, i.e. private monetary or in kind incentives;
   - compensation schemes (monetary or in kind);
   - insurance and liability;
   - co-operative and informative options ranging from voluntary agreements to labelling and education programs.

   All these options can be used individually or in combination to accomplish even more effective risk reduction. Options for risk reduction can be initiated by private and public actors or both together.

b) *Assessment of risk management options with respect to predefined criteria:* Each of the options will have desired and unintended consequences which relate to the risks that they are supposed to reduce. In most instances, an assessment should be done according to the following criteria:

   - *Effectiveness:* Does the option achieve the desired effect?
   - *Efficiency:* Does the option achieve the desired effect with the least resource consumption?
   - *Minimisation of external side effects:* Does the option infringe on other valuable goods, benefits or services such as competitiveness, public health, environmental quality, social cohesion, etc.? Does it impair the efficiency and acceptance of the governance system itself?
   - *Sustainability:* Does the option contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
   - *Fairness:* Does the option burden the subjects of regulation in a fair and equitable manner?
   - *Political and legal implementability:* Is the option compatible with legal requirements and political programmes?
   - *Ethical acceptability:* Is the option morally acceptable?
   - *Public acceptance:* Will the option be accepted by those individuals who are affected by it? Are there cultural preferences or symbolic connotations that have a strong influence on how the risks are perceived?

Measuring management options against these criteria may create conflicting messages and results. Many measures that prove to be effective may turn out to be inefficient or unfair to those who will be burdened. Other measures may be sustainable but not accepted by the public or important stakeholders. These problems are aggravated when dealing with global risks. What appears to be efficient in one country may not work at all in another country. Risk managers are therefore well advised to make use of the many excellent guidance documents on how to handle risk trade-offs and how to employ decision analytic tools for dealing with conflicting evidence and values (c.f. Viscusi 1994; Wiener 1998; van der Sluijs et al. 2003; Goodwin and Wright 2004).

c) *Evaluation of risk management options:* Similar to risk evaluation, this step integrates the evidence on how the options perform with regard to the evaluation criteria with a value judgement about the relative weight each criterion should be assigned. Ideally, the evidence should come from experts and the relative weights from politically legitimate decision makers. In practical risk management, the evaluation of options is done in close cooperation between experts and decision makers. As pointed out later, this is the step in which direct stakeholder involvement and public participation is particularly important and is therefore best assured by making use of a variety methods (Rowe and Freyer 2000; OECD 2002).

d) *Selection of risk management options:* Once the different options are evaluated, a decision has to be made as to which options are selected and which rejected. This decision is obvious if one or more options turn out to be dominant (relatively better on all criteria). Otherwise, trade-offs have to be made that need legitimisation (Graham and Wiener 1995). A legitimate decision can be made on the basis of formal balancing tools (such as cost-benefit or multi-criteria-decision analysis), by the respective decision makers (given his decision is informed by a holistic view of the problem) or in conjunction with participatory procedures.

e) *Implementation of risk management options:* It is the task of risk management to oversee and control the implementation process. In many instances implementation is delegated, as when governments take decisions but leave their implementation to other public or private bodies or to the general public. However, the risk management team has at any rate the implicit mandate to supervise the implementation process or at least monitor its outcome.

f) *Monitoring of option performance:* The last step refers to the systematic observation of the effects of the options once they are implemented. The monitoring system should be designed to assess intended as well as unintended consequences. Often a formal policy assessment study is issued in order to explore the consequences of a given set of risk management measures on different dimensions of what humans value. In addition to generating feedback for the effectiveness of the options taken to reduce the risks, the monitoring phase should also provide new information on early warning signals for both new risks and old risks viewed from a new perspective. It is advisable to have the institutions performing the risk and concern assessments participate in monitoring and supervision so that their analytic skills and experience can be utilised in evaluating the performance of the selected management options.

These steps follow a logical sequence but can be arranged in different orders depending on both situation and circumstance. It might be helpful to visualise the steps not as a linear progression but as a circle forming an iterative process in which reassessment phases are intertwined with new options emerging, new crisis situations arising or new demands being placed on risk managers. Similarly, sometimes the assessment of different options causes the need for new options to be created in order to achieve the desired results. In other cases, the monitoring of existing rules impacts on the decision to add new criteria to the portfolio. Very rarely do candidate issues for risk appraisal and management thus follow the exact sequence used for the description of the process in this document. Option generation, information processing, and options selection should indeed be seen as a dynamic process with many iterative loops.

Table 5 summarises the steps of risk management in accordance with the basic model used by decision theory. The list of indicators represents the most frequently used heuristic rules for selecting input and for measuring performance.

Table 5: Generic Components of Risk Management

Management Components	Definition	Indicators
1 Option generation	Identification of potential risk handling options, in particular risk reduction, i.e. prevention, adaptation and mitigation, as well as risk avoidance, transfer and retention	• standards • performance rules • restrictions on exposure or vulnerability • economic incentives • compensation • insurance and liability • voluntary agreements • labels • information/education
2 Option assessment	Investigations of impacts of each option (economic, technical, social, political, cultural)	• effectiveness • efficiency • minimisation of side effects • sustainability • fairness • legal and political imple-mentability • ethical acceptability • public acceptance
3 Option evaluation and selection	Evaluation of options (multi-criteria analysis)	• assignment of trade-offs • incorporation of stake-holders and the public
4 Option implementation	Realisation of the most preferred option	• accountability • consistency • effectiveness
5 Monitoring and feedback	• Observation of effects of implemen-tation (link to early warning) • Ex-post evaluation	• intended impacts • non-intended impacts • policy impacts

13 RISK MANAGEMENT STRATEGIES

Based on the distinction between complexity, uncertainty, and ambiguity it is possible to design generic strategies of risk management to be applied to classes of risks, thus simplifying the risk management process as outlined above. One can distinguish four such classes:

- **Simple risk problems:** This class of risk problems requires hardly any deviation from traditional decision making. Data is provided by statistical analysis, goals are determined by law or statutory requirements and the role of risk management is to ensure that all risk reduction measures are implemented and enforced. Traditional risk-risk comparisons (or risk-risk trade-offs), risk-benefit analysis and cost-effectiveness studies are the instruments of choice for finding the most appropriate risk reduction measures. Additionally, risk managers can rely on best practice and, in cases of low impact, on trial and error. It should be noted, however, that simple risks should not be equated with small or negligible risks. The major issues here are that the potential negative consequences are obvious, the values that are applied are non-controversial and the remaining uncertainties low. Examples are car accidents, known food and health risks, regularly reoccurring natural disasters or safety devices for high buildings.

- **Complex risk problems:** For this risk class major input for risk management is provided by the scientific characterisation of the risk. Complex risk problems are often associated with major scientific dissent about complex dose-effect relationships or the alleged effectiveness of measures to decrease vulnerabilities (for complexity refers to both the risk agent and its causal connections and the risk absorbing system and its vulnerabilities). The objective for resolving complexity is to receive a complete and balanced set of risk and concern assessment results that fall within the legitimate range of plural truth claims.

  In a situation where there is no complete data the major challenge is to define the factual base for making risk management or risk regulatory decisions. So the main emphasis is on improving the reliability and validity of the results that are produced in the risk appraisal phase. Risk and concern assessors as well as managers need to make sure that all relevant knowledge claims are selected, processed and evaluated. They may not get a single answer but they might be able to get a better overview on the issues of scientific controversy. If these efforts lead to an acknowledgment of wide margins of uncertainty, the management tools of the uncertainty strategy should be applied. If input variables to decision-making can be properly defined and affirmed, risk characterisation and evaluation can be done on the basis of risk-benefit balancing and normative standard setting *(risk-based/risk-informed regulation)*. Traditional methods such as risk-risk-comparison, cost-effectiveness and cost-benefit analysis are also well-suited to facilitate the overall judgement for placing the risk in the traffic-light model (acceptable, tolerable or intolerable). These instruments, if properly used, provide effective, efficient and fair solutions with respect to finding the best trade-off between opportunities and risks. The choice of instruments includes all the classic options outlined in the section on risk management.

  It is, however, prudent to *distinguish management strategies for handling the risk agent* (such as a chemical or a technology) *from those needed for the risk absorbing system* (such as a building, an organism or an ecosystem). Addressing complex structures of risk agents requires methods for improving causal modelling and data quality control. With respect to risk absorbing systems the emphasis is on the improvement of *robustness*[14] in responding to whatever the target is going to be exposed to. Measures to improve robustness include inserting conservatisms or safety factors as an assurance against individual variation (normally a factor of 10-100 for occupational risk exposure and 100-1000 for public risk exposure), introducing redundant and diverse safety devices to improve structures against multiple stress situations, reducing the susceptibility of the target organism (example: iodine tablets for radiation protection), establishing building codes and zoning laws to protect against natural hazards as well as improving the organisational capability to initiate, enforce, monitor and revise management actions (high reliability, learning organisations).

14 The terms robustness and resilience have different meanings in different contexts. In most of the *natural hazard literature*, robustness is one of the main components of resilience. In much of the *cybernetic literature*, robustness refers to the insensitivity of numerical results to small changes, while resilience characterises the insensitivity of the entire system against surprises. Our suggestion for distinguishing the two comes close to the cybernetic use of the terms.

- **Risk problems due to high unresolved uncertainty:** If there is a high degree of remaining uncertainties, risk management needs to incorporate hazard criteria (which are comparatively easy to determine), including aspects such as reversibility, persistence, and ubiquity, and select management options empowering society to deal even with worst case scenarios (such as containment of hazardous activities, close monitoring of risk-bearing activities, securing reversibility of decisions in case risks turn out to be higher than expected). According to the IRGC, the management of risks characterised by multiple and high uncertainties should be guided by the *precautionary approach*. Since high unresolved uncertainty implies that the (true) dimensions of the risks are not (yet) known, one should pursue a cautious strategy that allows learning by restricted errors. The main management philosophy for this risk class is to allow small steps in implementation (containment approach) that enable risk managers to stop or even reverse the process as new knowledge is produced or the negative side effects become visible. The primary thrust of precaution is to avoid irreversibility (Klinke and Renn 2002)[15].

  With respect to risk absorbing systems, the main objective is to make these systems resilient so they can withstand or even tolerate surprises. In contrast to robustness, where potential threats are known in advance and the absorbing system needs to be prepared to face these threats, *resilience* is a protective strategy against unknown or highly uncertain hazards. Instruments for resilience include the strengthening of the immune system, diversification of the means for approaching identical or similar ends, reduction of the overall catastrophic potential or vulnerability even in the absence of a concrete threat, design of systems with flexible response options and the improvement of conditions for emergency management and system adaptation. Robustness and resilience are closely linked but they are not identical and require partially different types of actions and instruments.

- **Risk problems due to interpretative and normative ambiguity:** If risk information is interpreted differently by different stakeholders in society – i.e. there are different viewpoints about the relevance, meaning and implications of factual explanations and predictions for deciding about the tolerability of a risk as well as management actions – and if the values and priorities of what should be protected or reduced are subject to intense controversy, risk management needs to address the causes for these conflicting views (von Winterfeldt and Edwards 1984).

  Genetically modified organisms for agricultural purposes may serve as an example to illustrate the intricacies related to ambiguity. Surveys on the subject demonstrate that people associate high risks with the application of gene technology for social and moral reasons (Hampel and Renn 2000). Whether the benefits to the economy balance the costs to society in terms of increased health risks, was not mentioned as a major concern of the polled public. Instead, people disagreed about the social need for genetically modified food in western economies where abundance of conventional food is prevalent. They were worried about the loss of personal capacity to act when selecting and preparing food, about the long-term impacts of industrialised agriculture and the moral implications of tampering with nature (Sjöberg 1999). These concerns cannot be addressed by either scientific risk assessments or by determining the right balance between over- and under-protection. The risk issues in this debate focus on the differences between visions of the future, basic values and convictions, and the degree of confidence in the human ability to control and direct its own technological destiny. These wider concerns require the inclusion within the risk management process of those who express or represent them.

  Risk managers should thus initiate a broader societal discourse to enable participative decision making. These discursive measures are aimed at finding appropriate conflict resolution mechanisms capable of reducing the ambiguity to a manageable number of options that can be further assessed

15 The link between precaution and irreversibility was also mentioned in the aforementioned latest report on risk management by the UK Treasury Department (UK Treasury Department 2004).

and evaluated. The main effort of risk management is hence the organisation of a suitable discourse combined with the assurance that all stakeholders and public groups can question and critique the framing of the issue as well as each element of the entire risk chain.

Table 6: Risk Characteristics and their Implications for Risk Management

Knowledge Characterisation	Management Strategy	Appropriate Instruments	Stakeholder Participation
1 'Simple' risk problems	*Routine-based:* (tolerability/ acceptability judgement) (risk reduction)	➔ Applying 'traditional' decision-making • Risk-benefit analysis • Risk-risk trade-offs • Trial and error • Technical standards • Economic incentives • Education, labelling, information • Voluntary agreements	Instrumental discourse
2 Complexity-induced risk problems	*Risk-informed:* (risk agent and causal chain)	➔ Characterising the available evidence • Expert consensus seeking tools: o Delphi or consensus conferencing o Meta analysis o Scenario construction, etc. • Results fed into routine operation	Epistemological discourse
	Robustness-focussed: (risk absorbing system)	➔ Improving buffer capacity of risk target through: • Additional safety factors • Redundancy and diversity in designing safety devices • Improving coping capacity • Establishing high reliability organisations	
3 Uncertainty-induced risk problems	*Precaution-based:* (risk agent)	➔ Using hazard characteristics such as persistence, ubiquity etc. as proxies for risk estimates Tools include: • Containment • ALARA (as low as reasonably achievable) and ALARP (as low as reasonably possible) • BACT (best available control technology), etc.	Reflective discourse
	Resilience-focussed: (risk absorbing system)	➔ Improving capability to cope with surprises • Diversity of means to accomplish desired benefits • Avoiding high vulnerability • Allowing for flexible responses • Preparedness for adaptation	
4 Ambiguity-induced risk problems	*Discourse-based:*	➔ Application of conflict resolution methods for reaching consensus or tolerance for risk evaluation results and management option selection • Integration of stakeholder involvement in reaching closure • Emphasis on communication and social discourse	Participative discourse

Table 6 provides a summary of these four risk strategies and lists the instruments and tools that are most appropriate for the respective strategy. Again it should be emphasised that the list of strategies and instruments is not exhaustive and can be amended if the case requires it.

14 MANAGING INTERDEPENDENCIES

In an interdependent world, the risks faced by any individual, company, region or country depend not only on its own choices but also on those of others. Nor do these entities face one risk at a time: they need to find strategies to deal with a series of interrelated risks that are often ill-defined or outside of their control. In the context of terrorism, the risks faced by any given airline, for example, are affected by lax security at other carriers or airports. There are myriad settings that demonstrate similar interdependencies, including many problems in computer and network security, corporate governance, investment in research, and vaccination. Because interdependence does not require proximity, the antecedents to catastrophes can be quite distinct and distant from the actual disaster, as in the case of the 9/11/01 attacks when security failures at Boston's Logan Airport led to crashes at the World Trade Center (WTC), the Pentagon, and in rural Pennsylvania. The same was true in the case of the August 2003 power failures in the North-eastern US and Canada, where the initiating event occurred in Ohio, but the worst consequences were felt hundreds of miles away. Similarly a disease in one region can readily spread to other areas with which it has contact, as was the case with the rapid spread of SARS from China to its trading partners.

The more interdependencies there are within a particular setting (be this a set of organisational units, companies, a geographical area or a number of countries etc.) and the more that this setting's entities – or participants – decide not to invest in risk reduction while being able to contaminate other entities, the less incentive each potentially affected participant will have to invest in protection. At the same time, however, each participant would have been better off had all the other participants invested in risk-reducing measures. In other words, weak links may lead to suboptimal behaviour by everyone[16].

For situations in which participants are reluctant to adopt protective measures to reduce the chances of catastrophic losses due to the possibility of contamination from weak links in the system, a solution might be found in a public-private partnership. This is particularly true if the risks to be dealt with are associated with competing interpretations (ambiguities) as to what type of co-operation is required between different epistemic communities as well as risk management agencies in order to deal with various knowledge and competing value claims. Public-private partnerships also provide an interesting alternative in cases in which perceptions differ strongly and external effects are to be expected.

One way to structure such a partnership is to have government standards and regulations coupled with third party inspections and insurance to enforce these measures. Such a management-based regulatory strategy will not only encourage the addressees of the regulation, often the corporate sector, to reduce their risks from e.g. accidents and disasters. Indeed, it equally shifts the locus of decision-making from the government regulatory authority to private companies which are as a result required to do their own planning as to how they will meet a set of standards or regulations (Coglianese and Lazer 2003). This, in turn, can enable companies to choose those means and measures which are most fit for purpose within their specific environment and, eventually, may lead to a superior allocation of resources compared to more top-down forms of regulation. The combination of third party inspections in conjunction with private insurance is consequently a powerful combination of public oversight and market mechanisms that can convince many companies of the advantages of implementing the

16 A more formal game theoretic treatment of this problem has been published in Kunreuther and Heal (2003).

necessary measures to make their plants safer and encourage the remaining ones to comply with the regulation to avoid being caught and prosecuted.

Highly interdependent risks that can lead to stochastic contamination of third parties pose a specific challenge for global risk management (i.e. the management of transboundary, international and ubiquitous risks). Due to the often particularly decentralised nature of decision-making in this area, a well balanced mix of consensual (e.g. international agreements and standards, gentleman's agreements), coercive (e.g. government regulation) and incentive-based (e.g. emission certificates) strategies is necessary to deal with such risk problems. Again these strategies can be best developed in close – international and transnational – cooperation between the public and the private sector. To generate the background knowledge for such cooperation and to facilitate its realisation is one of the prime goals of IRGC.

15 STAKEHOLDER INVOLVEMENT AND PARTICIPATION

Our emphasis on governance rather than governments or administrations is meant to underline the importance that IRGC places on the inclusion of stakeholders and public groups within the risk handling process and, consequently, on the establishment of adequate public-private partnerships and participatory processes. In the context of this framework we define **stakeholders** as socially organised groups that are or will be affected by the outcome of the event or the activity from which the risk originates and/or by the risk management options taken to counter the risk. Involving stakeholders is not enough, however. Other groups, including the media, cultural elites and opinion leaders, the non-organised *affected* public and the non-organised *observing* public, all have a role to play in risk governance.

Each decision making process has two major aspects: what and whom to include on the one hand and what and how to select (closure) on the other hand (Hajer and Wagenaar 2003; Stirling 2004). *Inclusion and selection* are therefore the two essential parts of any decision or policy making activity. Classic decision analysis has been offering formal methods for generating options and evaluating these options against a set of predefined criteria. With the advent of new participatory methods, the two issues of inclusion and selection have become more complex and sophisticated than purported in these conventional methods.

The present framework advocates the notion of inclusive governance, in particular with respect to global and systemic risks. First and foremost this means that the four major actors in risk decision making, i.e. *political, business, scientific and civil society players*, should jointly engage in the process of framing the problem, generating options, evaluating options, and coming to a joint conclusion. This has also been the main recommendation of the EU White Paper on European Governance (EU 2001a). This document endorses transparency and accountability through formal consultation with multiple actors as a means for the European Union to address the various frames of governance issues and to identify culture-sensitive responses to common challenges and problems. Similarly to the actors determining the governance of a political union, it is obvious that the actors participating in risk-related decision making are guided by particular interests which derive not only from the fact that some of them are risk producers – whereas others are exposed to it – but, equally, from their individual institutional rationale and perspective. Such vested interests require specific consideration and measures so that they are made transparent and, if possible, can be reconciled. Inclusive governance, as it relates to the inclusion part of decision making, requires that (Trustnet 1999; Webler 1999; Wynne 2002):

- there has been a major attempt to involve representatives of all four actor groups (if appropriate);
- there has been a major attempt to empower all actors to participate actively and constructively in the discourse;
- there has been a major attempt to co-design the framing of the (risk) problem or the issue in a dialogue with these different groups;
- there has been a major attempt to generate a common understanding of the magnitude of the risk (based on expertise of all participants) as well as the potential risk management options and to include a plurality of options that represent the different interests and values of all parties involved;
- there has been a major effort to conduct a forum for decision-making that provides equal and fair opportunities for all parties to voice their opinion and to express their preferences; and
- there has been a clear connection between the participatory bodies of decision-making and the political implementation level.

If these conditions are met, evidence shows that actors, along with developing faith in their own competence, use the opportunity and start to place trust in each other and have confidence in the process of risk management (Kasperson et al. 1999; Viklund 2002; Beierle and Cayford 2002: 30f.). This is particularly true for the local level where the participants are familiar with each other and have more immediate access to the issue (Petts 1997). Reaching consensus and building trust on highly complex and transgressional subjects such as global change is, however, much more difficult. Being inclusive and open to social groups does not guarantee, therefore, constructive cooperation by those who are invited to participate. Some actors may reject the framing of the issue and choose to withdraw. Others may benefit from the collapse of an inclusive governance process. It is essential to monitor these processes and make sure that particular interests do not dominate the deliberations and that rules can be established and jointly approved to prevent destructive strategising.

Inclusive governance needs to address the second part of the decision making process as well, i.e. reaching closure on a set of options that are selected for further consideration, while others are rejected. *Closure* does not mean to have the final word on a development, a risk reduction plan or a regulation. Rather, it represents the product of a deliberation, i.e. the agreement that the participants reached. The problem is that the more actors, viewpoints, interests and values are included and thus represented in an arena, the more difficult it is to reach either a consensus or some other kind of joint agreement. A second set of criteria is thus needed, to evaluate the process by which closure of debates (be they final or temporary) is brought forth as well as the quality of the decision or recommendation that is generated through the closure procedure.

The first aspect, the quality of the closure process itself, can be subdivided into the following dimensions (Webler 1995; Demos 2004):

- Have all arguments been properly treated? Have all truth claims been fairly and accurately tested against commonly agreed standards of validation?
- Has all the relevant evidence, in accordance with the actual state-of-the-art knowledge, been collected and processed?
- Was systematic, experiential and practical knowledge and expertise adequately included and processed?
- Were all interests and values considered and was there a major effort to come up with fair and balanced solutions?
- Were all normative judgements made explicit and thoroughly explained? Were normative statements derived from accepted ethical principles or legally prescribed norms?

- Were all efforts undertaken to preserve plurality of lifestyles and individual freedom and to restrict the realm of collectively binding decisions to those areas in which binding rules and norms are essential and necessary to produce the wanted outcome?

Turning to the issues of outcome, additional criteria need to be addressed. They have been discussed in the political science and governance literature for a long time (Dryzek 1994; Rhodes 1997). They are usually stated as comprising effectiveness, efficiency, accountability, legitimacy, fairness, transparency, acceptance by the public and ethical acceptability. They largely coincide with those that have been postulated earlier for the assessments of risk management options.

When contemplating the requirements for inclusion, closure process and outcome quality, the IRGC is convinced that:

- more inclusive procedures enrich the generation of options and perspectives, and are therefore more responsive to the complexity, uncertainty and ambiguity of the risk phenomena which are being assessed;
- more rational closure processes provide fairer and socially and culturally more adaptive and balanced judgements;
- the combination of voluntary and regulatory actions in form of public-private partnerships can be improved through early and constructive involvement procedures; and
- the outcomes derived from these procedures are of higher quality in terms of effectiveness, efficiency, legitimacy, fairness, transparency, public acceptance and ethical acceptability than the outcomes of conventional decision-making procedures.

The potential benefits resulting from stakeholder and public involvement depend, however, on the quality of the participation process. It is not sufficient to gather all interested parties around a table and merely hope for the catharsis effect to emerge spontaneously. In particular, it is essential to treat the time and effort of the participating actors as spare resources that need to be handled with care and respect (Chess et al. 1998). The participation process should be designed so that the various actors are encouraged to contribute to the process in those areas in which they feel they are competent and can offer something to improve the quality of the final product.

In this respect the four risk classes discussed earlier, i.e. simple, complex, high uncertainty and high ambiguity risk problems, support generic suggestions for participation (Renn 2004b):

- *Simple risk problems:* For making judgements about simple risk problems a sophisticated approach to involve all potentially affected parties is not necessary. Most actors would not even seek to participate since the expected results are more or less obvious. In terms of cooperative strategies, an **'instrumental discourse'** among agency staff, directly affected groups (such as product or activity providers and immediately exposed individuals) as well as enforcement personnel is advisable. One should be aware, however, that often risks that appear simple turn out to be more complex, uncertain or ambiguous as originally assessed. It is therefore essential to revisit these risks regularly and monitor the outcomes carefully.

- *Complex risk problems:* The proper handling of complexity in risk appraisal and risk management requires transparency over the subjective judgements and the inclusion of knowledge elements that have shaped the parameters on both sides of the cost-benefit equation. Resolving complexity necessitates a discursive procedure during the appraisal phase with a direct link to the tolerability and acceptability judgement and risk management. Input for handling complexity could be provided by an **'epistemological discourse'** aimed at finding the best estimates for characterising the risks under consideration. This discourse should be inspired by different science camps and the participation of experts and knowledge carriers. They may come from academia, government, industry or civil society but their legitimacy to participate is their claim to bring new or additional knowledge to the negotiating table. The goal is to resolve cognitive conflicts. Exercises such as Delphi, Group Delphi and consensus workshops would be most advisable to serve the goals of an epistemological discourse (Webler et al. 1991; Gregory et al. 2001).

- *Risk problems due to high unresolved uncertainty:* Characterising risks, evaluating risks and designing options for risk reduction pose special challenges in situations of high uncertainty about the risk estimates. How can one judge the severity of a situation when the potential damage and its probability are unknown or highly uncertain? In this dilemma, risk managers are well advised to include the main stakeholders in the evaluation process and ask them to find a consensus on the extra margin of safety in which they would be willing to invest in exchange for avoiding potentially catastrophic consequences. This type of deliberation called **'reflective discourse'** relies on a collective reflection about balancing the possibilities for over- and under-protection. If too much protection is sought, innovations may be prevented or stalled; if we go for too little protection, society may experience unpleasant surprises. The classic question of 'how safe is safe enough' is replaced by the question of 'how much uncertainty and ignorance are the main actors willing to accept in exchange for some given benefit'. It is recommended that policy makers, representatives of major stakeholder groups, and scientists take part in this type of discourse. The reflective discourse can take different forms: round tables, open space forums, negotiated rule-making exercises, mediation or mixed advisory committees including scientists and stakeholders (Amy 1983; Perrit 1986; Rowe and Frewer 2000).

- *Risk problems due to high ambiguity:* If major ambiguities are associated with a risk problem, it is not enough to demonstrate that risk regulators are open to public concerns and address the issues that many people wish them to take care of. In these cases the process of risk evaluation needs to be open to public input and new forms of deliberation. This starts with revisiting the question of proper framing. Is the issue really a risk problem or is it in fact an issue of lifestyle and future vision? The aim is to find consensus on the dimensions of ambiguity that need to be addressed in comparing risks and benefits and balancing the pros and cons. High ambiguities require the most inclusive strategy for participation since not only directly affected groups but also those indirectly affected have something to contribute to this debate. Resolving ambiguities in risk debates requires a **'participative discourse'**, a platform where competing arguments, beliefs and values are openly discussed. The opportunity for resolving these conflicting expectations lies in the process of identifying common values, defining options that allow people to live their own vision of a 'good life' without compromising the vision of others, to find equitable and just distribution rules when it comes to common resources and to activate institutional means for reaching common welfare so all can reap the collective benefits instead of a few (coping with the classic commoners' dilemma).[17] Available sets of deliberative processes include citizen panels, citizen juries, consensus conferences, ombudspersons, citizen advisory commissions, and similar participatory instruments (Dienel 1989; Fiorino 1990; Durant and Joss 1995; Armour 1995; Applegate 1998).

Categorising risks according to the quality and nature of available information on risk may, of course, be contested among the stakeholders. Who decides whether a risk issue can be categorised as simple, complex, uncertain or ambiguous? It is possible that no consensus may be reached as to where to

17 For a more detailed analysis of participatory methods for reaching consensus refer to Barber 1984, Webler 1999 or Jaeger et al. 2001.

locate a specific risk. In those cases, a detailed (worst-case) analysis of possibilities of monitoring and surveillance may constitute the only achievable compromise (reversible removal of risk sources etc., timely detection of adverse effects, strength of surveillance systems). The best means, however, to deal with this conflict is to provide for stakeholder involvement when allocating the different risks into these four categories. This task can be located in the phase of screening as the third component of pre-assessment. Allocating risks to the four categories needs to be done before the assessment procedures start. Over the course of further analysis of risks and concerns the categorisation may change since new data and information is being collected that may necessitate a re-ordering of the risk. Yet the risk governance system that is proposed in this document builds upon the need to classify risks at the beginning and allocate them to different routes of appraisal, characterisation, evaluation and management. It seems prudent to have a screening board perform this challenging task. This board should consist of members of the risk and concern assessment team, of risk managers and key stakeholders (such as industry, NGOs and representatives of related regulatory or governmental agencies). The type of discourse required for this task is called **design discourse.** It is aimed at selecting the appropriate risk and concern assessment policy, defining priorities in handling risks, organising the appropriate involvement procedures and specifying the conditions under which the further steps of the risk handling process will be conducted.

Figure 4: The Risk Management Escalator and Stakeholder Involvement (from simple via complex and uncertain to ambiguous phenomena)

Remedy	*Statistical Risk Analysis*	*Probabilistic Risk Modelling*	*Risk Balancing Necessary* + Probabilistic Risk Modelling	*Risk Trade-off Analysis & Deliberation necessary* + Risk Balancing + Probabilistic Risk Modelling
Type of Conflict		Cognitive	• Cognitive • Evaluative	• Cognitive • Evaluative • Normative

Actors	Agency Staff	• Agency Staff
		• External Experts
			• Agency Staff
			• External Experts
			• Stakeholders
			  • Industry
			  • Directly affected groups
				• Agency Staff
				• External Experts
				• Stakeholders
				  • Industry
				  • Directly affected groups
				  • General public

Type of Discourse	Instrumental	Epistemological	Reflective	Participative
Risk Problem	Simple	Complexity induced	Uncertainty induced	Ambiguity induced

Function:	Allocation of risks to one or several of the four routes
Type of Discourse:	Design discourse
Participants:	A team of risk and concern assessors, risk managers, stakeholders and representatives of related agencies

Figure 4 provides an overview of the different requirements for participation and stakeholder involvement for the four classes of risk problems and the design discourse. As is the case with all classifications, this scheme shows an extremely simplified picture of the involvement process and it has been criticised for being too rigid in its linking of risk characteristics (complexity, uncertainty, and ambiguity) and specific forms of discourse and dialogue (van Asselt 2005). In addition to the generic distinctions shown in the below graph, it may for instance be wise to distinguish between participatory processes based on risk agent or risk absorbing issues. To conclude these caveats, the purpose of this scheme is to provide general orientation and explain a generic distinction between ideal cases rather than to offer a strict recipe for participation.

16 RISK COMMUNICATION

Given the arguments about risk perception and stakeholder involvement, the IRGC believes strongly that effective communication has to be at the core of any successful activity to assess and manage risks. The field of risk communication initially developed as a means of investigating how best expert assessments could be communicated to the public so that the tension between public perceptions and expert judgement could be bridged. In the course of time this original objective of educating the public about risks has been modified and even reversed as the professional risk community realised that most members of the public refused to become 'educated' by the experts but rather insisted that alternative positions and risk management practices should be selected by the professional community in their attempt to reduce and manage the risks of modern technology (Plough and Krimsky 1987).

In a recent review of risk communication, William Leiss identified *three phases in the evolution of risk communication practices* (Leiss 1996: 85ff). The first phase of risk communication emphasised the necessity to convey probabilistic thinking to the general public and to educate the laypersons to acknowledge and accept the risk management practices of the respective institutions. The most prominent instrument of risk communication in phase I was the application of risk comparisons. If anyone was willing to accept x fatalities as a result of voluntary activities, she or he should be obliged to accept another voluntary activity with less than x fatalities. However, this logic failed to convince audiences: people were unwilling to abstract from the context of risk-taking and the corresponding social conditions and they also rejected the reliance on expected values as the only benchmarks for evaluating risks. When this attempt at communication failed, phase II was initiated. This emphasised persuasion and focused on public relations efforts to convince people that some of their behaviour was unacceptable (such as smoking and drinking) since it exposed them to high risk levels, whereas public worries and concerns about many technological and environmental risks (such as nuclear installations, liquid gas tanks, or food additives) were regarded as overcautious due to the absence of any significant risk level. This communication process resulted in some behavioural changes at the personal level: many people started to quit some unhealthy habits. However, it did not convince a majority of these people that the current risk management practices for most of the technological facilities and environmental risks were indeed the politically appropriate response to risk. The one-way communication process of conveying a message to the public in carefully crafted, persuasive language produced little effect. Most respondents were appalled by this approach or simply did not believe the message, regardless how well it was packaged, so phase III evolved. This current phase of risk communication stresses a two-way communication process in which not only are members of the public expected to engage in a social learning process, but so are the risk managers as well. The objective of this communication effort is to build mutual trust by responding to the concerns of the public and relevant stakeholders. The ultimate goal of risk communication is to assist stakeholders in understanding the rationale of risk assessment results and risk management decisions, and to help them arrive at a balanced judgement that reflects the factual evidence about the matter at hand in relation to their own interests and values (OECD 2002). Good practices in risk communication help stakeholders to make informed choices about matters of concern to them and to create mutual trust (Hance et al.1988; Lundgreen 1994).

Risk communication is needed throughout the whole risk handling chain, from the framing of the issue to the monitoring of risk management impacts. The precise form of communication needs to reflect the nature of the risks under consideration, their context and whether they arouse, or could arouse, societal concern. Communication has to be a means to both ensure that:

- those who are central to risk framing, risk appraisal or risk management understand what is happening, how they are to be involved, and, where appropriate, what their responsibilities are, and,
- others outside the immediate risk appraisal or risk management process are informed and engaged.

The first task of risk communication, i.e. facilitating an exchange of information among risk professionals, has often been underestimated in the literature. A close communication link between risk/concern assessors and risk managers, particularly in the phases of pre-assessment and tolerability/acceptability judgement, is crucial for improving overall governance. Similarly, co-operation among natural and social scientists, close teamwork between legal and technical staff and continuous communication between policy makers and scientists are all important prerequisites for enhancing risk management performance. This is particularly important for the initial screening phase where the allocation of risks is performed.

The second task, that of communicating risk appropriately to the outside world, is also a very challenging endeavour. Many representatives of stakeholder groups and, particularly, members of the affected and non-affected public are often unfamiliar with the approaches used to assess and manage risks and/or pursue a specific agenda, trying to achieve extensive consideration of their own viewpoints. They face difficulties when asked to differentiate between the potentially dangerous properties of a substance (hazards) and the risk estimates that depend on both the properties of the substance, the exposure to humans, and the scenario of its uses (Morgan et al. 2002). Also complicating communication is the fact that some risks are acute, with severe effects that are easy to recognise, whereas others exert adverse effects only weakly but over a long period of time. Yet other risks' effects only start to show after an initial delay. Finally, it is no easy task to convey possible synergies of exposures to industrial substances with other factors that relate to lifestyle (e.g. nutrition, smoking, use of alcohol).

Effective communication, or the non-existence thereof, has a major bearing on how well people are prepared to face and cope with risk. Limited knowledge of, and involvement in, the risk management process can lead to inappropriate behaviour in emergency or risk-bearing situations (for example, when facing a pending flood or handling contaminated food or water). There is also the risk of failed communication: consumers or product users may misread or misunderstand risk warnings or labels so that they may, through ignorance, expose themselves to a larger risk than necessary. This is particularly prevalent in countries with high rates of illiteracy and unfamiliarity with risk-related terms. Providing understandable information to help people cope with risks and disasters is, however, only one function of risk communication. Most risk communication analysts list four major functions (Morgan et al. 1992; OECD 2002):

- *Education and enlightenment:* inform the audience about risks and the handling of these risks, including risk and concern assessment and management;
- *Risk training and inducement of behavioural changes:* help people cope with risks and potential disasters;

Case Example 1: Complexity – Collision and derailment of high-speed trains

During the past decade, the UK experienced a series of fatal train accidents on high-speed lines of which the worst, outside London's Paddington station on 5 October 1999, caused the death of 31 people and over 400 injuries and resulted in the complete closure of the Paddington terminus for 16 days (Ladbroke Grove accident)[18]. The accident, a head-on collision between two passenger trains after one train had passed a signal set at red, the impact of which triggered a blaze when one locomotive's diesel fuel exploded, led to a public inquiry into the safety of trains and train protections systems[19].

The accident was also subject to extensive media coverage directed in particular at emphasising claims of the detrimental effect that the recent privatisation of the UK rail system (initiated in 1993 by The Railway Act) would have on rail safety. By 1997 privatisation had led to the creation of a highly fragmented industry with train operations both separated from the ownership as well as management of the infrastructure and exposed to competition and with infrastructure maintenance often contracted out to third parties. This fragmentation, coupled with the exodus of experienced technical personnel, was now at the centre of concern. In the aftermath of the Ladbroke Grove accident, the media also insisted that this and several other fatal accidents could have been prevented had the trains been fitted with Automatic Train Protection (ATP; a technical system that prevents the driver from passing stop signals and from exceeding track speed limits) and – when fitted – had the ATP been switched on. The public reacted to all this by developing the perception that travelling by train was increasingly dangerous – in spite of long-term train accident statistics proving the contrary.

Whilst some train accidents without doubt qualify as 'simple risk' (e.g. the collision at a rural level crossing of a train with a car due to inattentiveness of the car driver), accidents involving high-speed trains in inner-city areas where 'train density' is particularly high have complexity as their dominant characteristic. Not only are these risks related to a networked critical infrastructure consisting of a multitude of interdependent elements including tracks, stations, junctions, rolling stock and timetables, they are also exacerbated by the sheer density of the interactions of the network's elements (reduction of headways between trains in order to enhance and optimise the capacity of the rail system, implying increased reliance on impeccable signalling and corresponding behavioural 'corrections' by the network's parts). Although not a major feature of the UK rail system, additional (transboundary) complexity exists for operators serving destinations in a different country, requiring interoperability between different national networks, systems, managements and operators.

The IRGC's framework for risk governance suggests that risks characterised by complexity be managed using risk-informed and robustness-focussed strategies. Managing the risk of train accidents on high-speed lines thus essentially involves two components: risk-informed actions and efforts to enhance the capacity of the system to cope with known threats. Risk-informed actions in particular involve learning from and acting on expert investigations of past accidents and near misses, with lessons learned feeding into operating procedures, maintenance practice and staff training.

Steps to enhance robustness include investment in measures to help increase capacity and improve safety, such as Automatic Train Protection. The European Rail Traffic Management System (ERTMS), a major initiative of the rail industry supported by the European Commission and EU Member States and due to 'go live' in 2008, aims to do so (in addition to promoting interoperability across Europe's high-speed rail system as stipulated in the European Council's 1996 Interoperability Directive[20]). Additional measures include further strengthening rolling stock and increasing the attention given to quality and management systems (possibly based on Safety Cases submitted to regulators) in order to enhance the robustness of maintenance of both rolling stock and track infrastructure.

As the public controversy over the Ladbroke Grove accident has shown, such measures need to be complemented with thorough and effective risk and crisis communication engaging all stakeholders, particularly if the goal of an increased market share in passenger and goods traffic for rail – a policy imperative for many governments as well as the EU[21] – is to be achieved.

18 This example focuses specifically on high-speed lines. There have also been a number of other fatal accidents on other parts of the UK rail network; see the BBC homepage (BBC 2002).

19 See Uff et al. 2001.

20 See Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system.

21 See EU 2001b.

- *Creation of confidence in institutions responsible for the assessment and management of risk:* give people the assurance that the existing risk governance structures are capable of handling risks in an effective, efficient, fair and acceptable manner (such credibility is crucial in situations in which there is a lack of personal experience and people depend on neutral and disinterested information). It should be kept in mind, however, that trust cannot be produced or generated, but only be accumulated by performance, and that it can be undermined by the lack of respect for an individual within such an institution;
- *Involvement in risk-related decisions and conflict resolution:* give stakeholders and representatives of the public the opportunity to participate in the risk appraisal and management efforts and/or be included in the resolution of conflicts about risks and appropriate risk management options.

For all four functions, risk communication needs to address the following topics:

- explain the concept of probability and stochastic effects;
- explain the difference between risk and hazard;
- deal with stigmatised risk agents or highly dreadful consequences (such as nuclear waste or cancer);
- cope with long-term effects;
- provide an understanding of synergistic effects with other lifestyle factors;
- address the problem of remaining uncertainties and ambiguities;
- cope with the diversity of stakeholders and parties in the risk appraisal and management phase;
- cope with inter-cultural differences within pluralist societies and between different nations and cultures.

Although risk communication implies a stronger role for risk professionals to provide information to the public rather than vice versa, it should be regarded as a mutual learning process in line with the requirements that Leiss postulated for phase III. Concerns, perceptions and experiential knowledge of the targeted audience(s) should thus guide risk professionals in their selection of topics and subjects: it is not the task of the communicators to decide what people need to know but to respond to the questions of what people want to know ('right to know' concept, see Baram 1984). Risk communication requires professional performance both by risk and communication experts. Scientists, communication specialists and regulators are encouraged to take a much more prominent role in risk communication, because effective risk communication can make a strong contribution to the success of a comprehensive and responsible risk management programme. IRGC will invest much of its resources and efforts in contributing to the improvement of current risk communication practices and in itself acting as an effective risk communicator.

17 WIDER GOVERNANCE ISSUES: ORGANISATIONAL CAPACITY

The above framework covering the areas of risk framing (i.e. pre-assessment), appraisal (including risk assessment as well as the assessment of risk-related concerns and the non-physical secondary implications of risk), characterisation/evaluation, management and communication concludes this document's analysis of the classic components of handling risks. Looking at organisational capacity opens a new set of wider risk governance issues which relate to the interplay between the governing actors and their capability to fulfil their role in the risk governance process.

In discussing the different components of risk appraisal and management, it was implicitly assumed that society has developed the institutional and organisational capability to perform all the tasks prescribed in each component – preferably in a matter-of-fact, objective manner. This is, of course, an ideal picture that masks the realities of the *political* context in which risk governance takes place. In particular, the framing of risk is exposed to many institutional and political forces who may wish to jump on the bandwagon of public dissent or media hype in order to push their own interests (Shubik 1991). Given the potential of risk perceptions to mobilise public outrage and, thus, to make it impossible for decision-makers not to listen, some actors in society may have an interest in orchestrating 'risk events', whereas others might have a major motivation for concealing risks or downplaying their impacts. Most political systems have responded to this manoeuvring by establishing independent risk assessment and sometimes management agencies, expecting that these are less likely to be influenced by public pressures. Although the IRGC is well aware of the political context in which risk governance takes place, it cannot provide guidance on how to govern risk debates. What it can and intends to do, however, is give advice on how to base risk governance on the best available knowledge and practice. Such advice addresses, first, the process phases of risk appraisal, management and communication as stated above and, secondly, the strengthening of institutions and agencies so that they are empowered and resourced to perform their tasks in the most effective, efficient and fair manner. As the European Commission's White Paper on European Governance pointed out, the key ingredients of 'good' governance in this sense are openness, participation, accountability, effectiveness and coherence (EU 2001a: 10). These requirements are important for all countries but, in particular, for many transitional and most developing countries. Since the IRGC's scope includes offering assistance to these countries, its work includes criteria for how to analyse and improve organisational capacity and 'good' governance practices.

For the analysis of institutional capacity it is useful to distinguish between assets, skills and capabilities (c.f. Paquet 2001). *Assets* form the social capital for risk governance in the form of knowledge bases and structural conditions for effective management. *Skills* refer to the quality of institutional and human performance in exploring, anticipating and dealing with existing and emerging risks. *Capabilities* describe the institutional framework necessary to translate assets and skills into successful policies. These three components constitute the backbone of institutional capacity for risk governance.

The assets include:

- *Rules, Norms, Regulations:* these establish rights and obligations. In the risk area, the existence of norms, standards, best practices, legal instruments etc., has always been a major and often contentious issue, hence the importance of such assets. This is true not only with regard to their prescribing of how to deal with risk but also for the absence, or the lack of observance, of rules (e.g. with regard to the end use of new technologies) which itself constitutes an increasing factor of risk.
- *Resources:* these are not limited to financial resources but comprise of an appropriate physical infrastructure for managing risk as well as the availability of adequate information, including the means for information gathering and processing.
- *Competencies and Knowledge*: this involves providing the necessary education and training and establishing and maintaining a pool of experience and expertise. Education should not only be directed at specialists but should reach out to the general public, building a culture of awareness and prevention.
- *Organisational Integration:* the capacity to access and retrieve, in a combination tailored to individual cases, each of these first three types of assets. Organisational integration is a key element, without which otherwise worthy assets will struggle to achieve much.

Case Example 2: Uncertainty – Earthquakes

In the 20th Century there was a yearly average of nearly 20 earthquakes of magnitude 7.0 or more on the Richter Scale, while the total number of tremors occurring in the world each year is estimated at several millions[22]. Whether or not one of these tremors evolves from a hazard into a risk, however, depends not only on the amount of ground-shaking but particularly on where the earthquake occurs. Comparing two extremes, a remote rocky area and a mega-city which is built on soils consisting of loosely packed water-logged materials, the difference becomes palpable: whereas in the first case there might be no harm at all, the second is likely to assume catastrophic dimensions both in terms of human life and economic damage.

Despite enormous resources invested and efforts undertaken in earthquake research, science is so far unable to reliably predict the location, magnitude and timing of earthquakes[23]. The biggest challenge related to assessing and managing earthquake risk is therefore uncertainty. As Shome et al. (1998) pointed out, this uncertainty (which they call 'aleatory') cannot be resolved by scientific knowledge, only reduced or characterised and made transparent.

A particularly shocking reminder of this insight came in the early morning of 17 January 1995, when a 7.2 magnitude earthquake hit the Japanese industrial town and seaport of Kobe[24] (Great Hanshin or South Hyogo earthquake) and resulted in over 6'000 people dead, more than 40'000 injured and 300'000 homeless. The sheer force of the earthquake and the ensuing fires turned major areas of the town into rubble and led to the collapse of the town's major critical infrastructures – leaving those who survived with severely hampered emergency services and without water, power, gas, transport and communication. Economic damage related to property exceeded USD 130 billion (approximately 2% of Japan's 1995 GDP or over 50% of Austria's GDP of that year). Of this loss only a tiny fraction, USD 3 billion, was insured. Kobe, its workforce and indeed the Japanese economy in particular suffered from a weeklong 80% incapacitation of its port which handles roughly a third of Japan's international freight transport.

While Japan is one of the most earthquake-prone countries in the world there is no doubt that it is also one of the best prepared to mitigate the effects of tremors. To some extent this reflects Japan's resource endowment which, combined with high event frequency, has led to considerable investment in efforts to increase the robustness of buildings and key infrastructures. That the Great Hanshin earthquake could cause such devastation painfully shattered Japan's confidence in the use of science and technology to effectively 'resist' earthquakes and, indeed, the paradigm of earthquake-proof infrastructure through rigid construction.

The primary focus of earthquake risk governance is necessarily on the reduction of vulnerability. IRGC's risk governance framework suggests that an appropriate strategy for risks characterised by uncertainty is to focus on reducing vulnerability through an emphasis on precaution and resilience. Since there is no way of preventing earthquakes from happening and warning times for affected areas are extremely short, the emphasis should be on resilience and, particularly, on ensuring the capacity of Japan's cities and citizens to prepare for and deal with the impact of an earthquake once it has hit, i.e. on disaster risk management. Such steps can take many different forms. On a larger scale, disaster prevention, which aims to avoid adverse effects (here considerations based on precaution come into play again), mainly comes in the form of land use and urban planning as well as building codes – the latter stipulating fire-containing measures and, in particular, design characteristics and building materials which, instead of resisting ground vibrations, absorb the vibrations and convert them into lesser motion. Many (theoretically) further-reaching prevention measures are impracticable due to natural, socio-economic and historical constraints (Japan's mountainous geography for instance imposes serious constraints on the land available for urbanisation). At the individual level, owners and occupants of homes and office premises can also take steps to avoid damage – even by screwing bookcases and other tall furniture to walls to prevent them from falling on people. Disaster mitigation, which aims to limit adverse effects, relies on flexible decision-making structures and co-ordination mechanisms between 'those in charge' and seeks to ensure responsive action based on adaptive management. A further major aspect refers to capacity building of emergency services and organisations: staff need to be well prepared for crisis, able to take decisions based on incomplete information, fast and effective in communication and skilled to perform protective measures under severe time constraints. Yet another way to reduce at least the financial implications of earthquakes damage consists in obtaining adequate insurance policies, to provide at least part of the cash with which to reconstruct if necessary.

Just ten years after the Great Hanshin earthquake, Kobe is a vibrant and prosperous city. It is almost impossible to find signs of the destruction that occurred during the earthquake, but the museum that retains the records of it and the monument to the earthquake's victims serve as reminders that the city and its inhabitants – and, indeed, global society – must always be prepared to cope with another catastrophe.

22 National Earthquake Information Center provided by the US Geological Survey. Online on Internet: http://neic.usgs.gov.

23 For a new approach to earthquake prediction which at least partly discards the prevailing wisdom of the random occurrence of earthquakes and instead postulates that a large earthquake can trigger other tremors of major scale nearby see for instance Stein 2003.

24 Data retrieved from publications from Swiss Re (Swiss Re 1995) and OECD (OECD 2004.)

Using an analogy from mathematics, the three first assets are additive while organisational integration is a multiplying factor. A non-existent organisational capability for integration would nullify the efficacy of the other factors.

Skills are related to the capacity of organisations and institutions to deal with evolving, sometimes chaotic, external conditions. Such conditions should not be considered as an eventuality that cannot be dealt with, but should, instead, be viewed as input parameters to the risk process that require adequate treatment. Skills should enable political, economic and civic actors to use effectively, and enhance the impact of, the available assets. They relate to:

- *Flexibility,* i.e. new ways to make sense of a dynamic situation – adapting to change, which in many cases means fighting against established practices and institutional inertia. An example to illustrate this point can be found in the current concern that city planning frequently still follows 19th Century practices while the increase in magnitude and frequency of extreme climatic events associated with climate change should dictate a new approach.
- *Vision,* i.e. bringing new practices into a context that would not naturally generate them – anticipating change. This implies devoting more attention to advanced methodological approaches such as foresight and scenario planning, and a preparedness to think 'outside the box'.
- *Directivity,* i.e. reframing the whole perception of the way of life – driving change that impacts on the outside world rather than limiting oneself to preventing or mitigating the effects of external forces. Several environmental policies (e.g. ban on CFCs) and security policies (e.g. ban on Weapons of Mass Destruction) adopted at the international level reflect this approach.

Using the same mathematical analogy, the three factors constituting the skills are in an additive relationship with each other. Within that relationship they can exhibit different intensities as a function of the nature of external forces.

Capabilities, finally, constitute the framework in which assets enriched by skills can be exploited for developing and implementing successful risk governance policies. Capabilities can be conceptualised as a structure with several successive layers (Wolf, in press):

- *Relations* link users and sources of knowledge as well as those carrying the authority and those bearing the risk, notably civil society. As previously stated, the participation of civil society in risk governance is essential. Relations should thus be based on inclusive decision-making in order to alleviate, at the outset, any circumstances that generate dispute and conflict and consequently aggravate risk.
- *Networks* constitute, in terms of structures, a close co-operative structure that goes beyond relations. Halfway between self-organisation and hierarchy, networks determine close links between and among groups of principally equal actors.
- *Regimes* establish the rules of the game, the framework in which the actors should act. Both relations and networks are essential for forming and sustaining regimes.

Drawing on the mathematical analogy again, the factors constituting the capabilities are additive, each having a separate but complementary function in the overall build up of capabilities.

While each of these assets, skills and capabilities would lend itself to a more detailed discussion the IRGC wishes to underline the major importance of risk education and training. In a world where 'human capital' – and in particular brainpower combined with inspiration, courage and a strong ability towards implementation – has largely become the life-blood of society's progress and prosperity, it is quite evident that one of the major keys to the successful handling of risk is in people's heads as well. Given the often systemic and global (transboundary, international and ubiquitous) nature of today's major risks, special 'competencies and knowledge' are required. Specialised in-depth expert knowledge in a restricted area or sector may no longer suffice to understand and counteract risks which spread the boundaries of academic disciplines and business sectors, have several layers of effects and are determined by a multitude of often interlinked factors. However, compartmentalised specialisation is what many educational systems still foster. This approach should, in fact, be replaced by one which emphasises risk appraisal and management in education at all levels and which considers risk under a broad and multi-disciplinary perspective. There is a particular need for this in the engineering, architecture and design disciplines where a primarily technical focus should be extended to health, safety and environmental risk. Such a new approach, fostering in fact a 'bird's eye perspective' with regard to risk, should be anchored in national science and education policies and should grow to become part of our scientific and technological culture.

All three factors – assets, skills and capabilities – are important variables when assessing and investigating risk governance structures in different countries or risk domains; they can also serve as guiding principles for identifying and researching deficiencies and providing assistance to improve capacity. It may even be possible, based on the above mathematical analogies, to construct an overall performance indicator that could help countries to evaluate their risk governance capacities and to use these elements as pathfinders for establishing new institutional frameworks to achieve improved structures for coping with risk.

18 THE ROLE OF POLITICAL CULTURE

When considering the wider environment of risk handling in modern societies, many classes of influential factors come into play. Only a few can be mentioned here. For example, the distinction between horizontal and vertical governance as introduced in the first section of this document can be helpful in describing and analysing cases of risk handling in different countries and contexts (Zürn 2000). In addition, the interplay between economic, political, scientific and civil society actors needs to be addressed when looking beyond just governmental or corporate actions.

It is the goal of the IRGC to focus particularly on risk areas which have multidimensional and transnational implications, rather than revisiting classic areas of risk regulation by individual governments or routine risk handling by private corporations. In this focus, one major aspect of risk governance concerns political culture, i.e. *regulatory regimes or governmental styles*. Each country and, in many instances, different risk domains within a country pursue different pathways for dealing with risk. The multitude of risk classification documents and meta-analyses of risk taxonomies is obvious proof of the plurality of risk handling processes and conceptual approaches. It may thus be helpful to search for some underlying principles of these approaches and classify them accordingly.

This exercise of finding common denominators in cultural and national diversity is less of a challenge than one may assume at first glance. Most analysts agree that many of the cognitive factors that govern risk perception are similar throughout the world (Rohrmann and Renn 2000). In addition, risk management styles are also becoming increasingly homogenous as the world becomes more globalised (Löfstedt and Vogel 2001). In spite of the distinct cultural differences among nations and the variations with respect to educational systems, research organisations, and structures of scientific institutions, assessment and management of risks and concerns have become universal enterprises in which nationality, cultural background or institutional setting play a minor role only. This is particularly due to the role of science in proposing and justifying regulatory standards. Research establishments as well as universities have evolved into multinational and cosmopolitan institutions that speak identical or at least similar languages and exchange ideas on world-wide communication networks[25].

Risk management depends, however, not only on scientific input. It rather rests on three components: *systematic knowledge, legally prescribed procedures and social values.* Even if the same knowledge is processed by different risk management authorities, the prescriptions for managing risk may differ in many aspects (e.g. with regard to inclusion and selection rules, interpretative frames, action plans for dealing with evidence, and others). National culture, political traditions, and social norms furthermore influence the mechanisms and institutions for integrating knowledge and expertise in the policy arenas. Policy analysts have developed a classification of governmental styles that address these aspects and mechanisms. While these styles have been labelled inconsistently in the literature, they refer to common procedures in different settings (O'Riordan and Wynne 1987). They are summarised in Table 7.

- The **'adversarial' approach** is characterised by an open forum in which different actors compete for social and political influence in the respective policy arena. The actors in such an arena use and need scientific evidence to support their position. Policy makers pay specific attention to formal proofs of evidence because their decisions can be challenged by social groups on the basis of insufficient use or negligence of scientific knowledge. Risk management and communication is essential for risk regulation in an adversarial setting because stakeholders demand to be informed and consulted. Within this socio-political context, stakeholder involvement is mandatory.

- In the **'fiduciary' approach**, the decision making process is confined to a group of patrons who are obliged to make the 'common good' the guiding principle of their action. Public scrutiny and involvement of the affected public are alien to this approach. The public can provide input to and arguments for the patrons but is not allowed to be part of the negotiation or policy formulation process. The system relies on producing faith in the competence and the fairness of the patrons involved in the decision making process. Advisors are selected according to national prestige or personal affiliations. In this political context, stakeholder involvement may even be regarded as a sign of weakness or a diffusion of personal accountability.

- The **'consensual' approach** is based on a closed circle of influential actors who negotiate behind closed doors. Social groups and scientists work together to reach a predefined goal. Controversy is not present and conflicts are reconciled on a one-to-one basis before formal negotiations take place. Risk communication in this context serves two major goals: it is supposed to reassure the public that the 'club' acts in the best interest of the public good and to convey the feeling that the relevant voices have been heard and adequately considered. Stakeholder participation is only required to the extent that the club needs further insights from the affected groups or that the composition of the club is challenged.

- The **'corporatist' approach** is similar to the consensual approach, but is far more formalised. Well-known experts are invited to join a group of carefully selected policy makers representing the major forces in society (such as the employers, the unions, the churches, the professional associations, the environmentalists). Similar to the consensual approach, risk communication is mainly addressed to the outsiders: they should gain the impression that the club is open to all 'reasonable' public demands and that it tries to find a fair compromise between public protection and innovation. Often the groups represented within the club are asked to organise their own risk management and communication programmes as a means of enhancing the credibility of the whole management process.

25 Indeed, this tendency towards a universal understanding of risk problems and a common language to describe risks and risk reduction measures is one of the most relevant reasons for establishing the IRGC.

Table 7: Characteristics of Policy Making Styles

Style	Characteristics	Risk Management
1 *Adversarial approach*	• open to professional and public scrutiny • need for scientific justification of policy selection • precise procedural rules • oriented towards producing informed decisions by plural actors	• main emphasis on mutual agreements on scientific evidence and pragmatic knowledge • integration of adversarial positions through formal rules (due process) • little emphasis on personal judgement and reflection on the side of the risk managers • stakeholder involvement essential for reaching communication objectives
2 *Fiduciary approach (patronage)*	• closed circle of „patrons“ • no public control, but public input • hardly any procedural rules • oriented towards producing faith in the system	• main emphasis on enlightenment and background knowledge through experts • strong reliance on institutional in-house “expertise“ • emphasis on demonstrating trust-worthiness • communication focused on institutional performance and “good record”
3 *Consensual approach*	• open to members of the „club“ • negotiations behind closed doors • flexible procedural rules • oriented towards producing solidarity with the club	• reputation most important attribute • strong reliance on key social actors (also non-scientific experts) • emphasis on demonstrating social consensus • communication focused on support by key actors
4 *Corporatist approach*	• open to interest groups and experts • limited public control, but high visibility • strict procedural rules outside of negotiating table • oriented towards sustaining trust to the decision making body	• main emphasis on expert judgement and demonstrating political prudence • strong reliance on impartiality of risk information and evaluation • integration by bargaining within scientifically determined limits • communication focused on fair representation of major societal interests

Although these four styles cannot be found in pure form in any country they form the backdrop of socio-political context variables against which specific risk governance structures are formed and operated. These structures, along with the individual actors’ goals and the institutional perspectives they represent, would need more specific attention and, for the time being, are difficult to classify further.

Case Example 3: Ambiguity – Nuclear energy

The use of nuclear energy for electric power has long been and remains a particularly controversial source of risk and concern. This is driven partly by perceptual factors and partly by the characteristics of the nuclear fuel cycle.

The cycle begins with, first, the extraction of natural uranium and, then, enrichment of the uranium and its concentration prior to manufacturing the fuel elements; risks of exposure to radioactive material of operating personnel are of prime concern. A nuclear reactor operates with exceedingly high energy density and inventory of radioactive substances (fission products). Multiple and diverse safety systems are provided for reactor control and decay heat removal. Their total failure is highly improbable but may lead to core damage (meltdown) and to release of parts of the core inventory, with long-lasting effects over a large geographic area. For state-of-the-art reactors, an 'extremely low frequency, potentially high consequence' risk profile is regarded as typical. Power plant operations also discharge small quantities of radioactive particles to the environment, which can accumulate in organisms and can pose a slight human cancer risk.

When the fuel in a reactor is spent, the fuel rods are consigned to a reprocessing plant, to interim storage or to a final repository. Any transport of spent fuel rods must be in proof casks, and the transport process itself is another source of risk as the probability that a cask will rupture in an accident that exceeds its design limit is not zero. In reprocessing, the risk is concentrated upon the release of radioactive substances to the environment, while in storage the isolation of the waste from the biosphere needs to be ensured for very long periods (several millennia).

Vast efforts have been made to minimise the probability of events causing harm to public health and the environment, particularly towards reducing or even preventing entirely major radioactive releases, in all stages of the cycle. Future reactors must thus be designed so that, even in the event of rare core-damaging events, off-site emergency measures are not necessary because impacts will not reach beyond the immediate neighbourhood. In final storage, several safety barriers are combined in order to exclude groundwater contamination as far as is humanly possible.

The still-ongoing controversy does not derive from the complexity of nuclear energy, nor from uncertainty: most of the processes and phenomena are largely understood and agreed. Although uncertainty about long-term behaviour of radioactive waste is clearly still an issue, time periods of many thousand years are not exclusive properties of nuclear waste; they apply to almost all inorganic material with hazardous properties. Much of the debate ín the past was directed towards further reducing uncertainty and explaining complexity rather than addressing the major problem: ambiguity. The controversy is fuelled by several ambiguities due to different perceptions of and associations with the risk. To the opponents of nuclear energy, the problem is that a meltdown and catastrophic release cannot be ruled out (catastrophic aversion), and that spent fuel remains active for such a long time period (time aversion). The proponents of nuclear power, on the other hand, are convinced that there are no other reliable options with comparably minimal greenhouse gas emissions. Each position is based on values. Value differences colour the interpretation of the data emanating from risk assessments (which is rarely disputed), as well as the way the risk is framed in the debate. Opponents accordingly judge the risks as being intolerable; to proponents, nuclear energy is an optimal means of supplying the world's electricity at minimal risk.

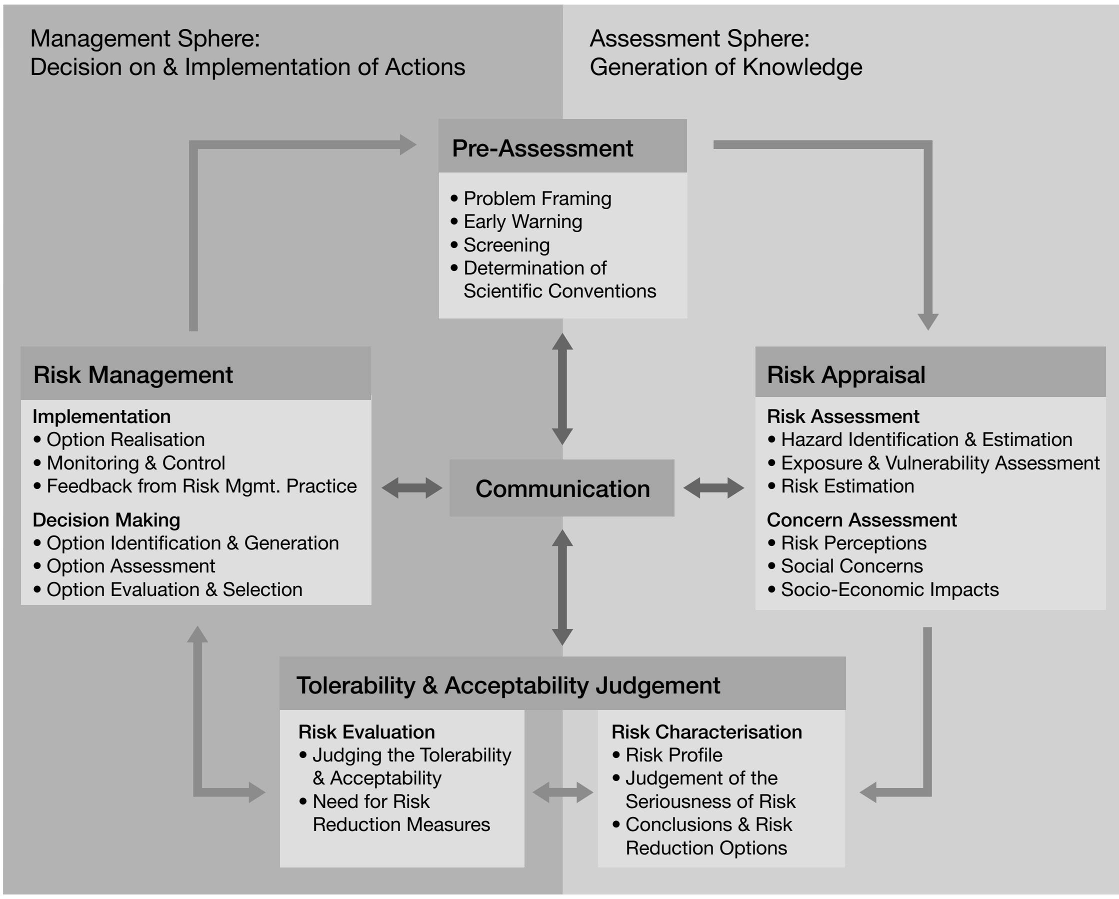
So long as there is demand for electricity and until a new technology is developed with which to meet it, the controversy over nuclear energy will continue. The controversy has led to considerable differences in the decisions of risk managers, even in Europe where Germany has decided to phase out nuclear generation, France continues to rely on it and Switzerland seeks the consent of its voters to replace an old reactor with a new one.

IRGC's risk governance framework recommends that risks with a high level of ambiguity are the subject of participative decision making involving all relevant stakeholders. The particular problem of nuclear energy is that the debate has not found a common frame or focus on which constructive negotiation and discourse could develop. Therefore, the first task for responsible risk managers is to manage the process of finding the common ground on which participative decisions can be made.

19 CONCLUSIONS

One of the main mandates of the IRGC is to assist risk/concern assessors and managers in exploring and handling risks and to promote effective and fair approaches for improving, and enhancing the visibility of, the present risk governance processes. IRGC's aim is to offer guidance and advice on how to approach the complexities, uncertainties and ambiguities of risk issues and to promote a wider understanding of their interconnectedness and transgressional nature, particularly in relation to newly emerging systemic risks. To this end the IRGC is developing an integrative framework that takes into account scientific, physical, economic, social and cultural aspects and includes effective and appropriate engagement of stakeholders – not least to ensure that both risk appraisal and risk management strategies command the widest possible acceptance and support. A prototype version of this framework is outlined in the present paper and summarised in Figure 5:

Figure 5: IRGC Risk Governance Framework



The framework has been designed, on one hand, to include enough flexibility to allow its users to do justice to the wide diversity of risk governance structures and, on the other hand, to provide sufficient clarity, consistency and unambiguous orientation across a range of different risk issues and countries.

This document, firstly, discussed a comprehensive risk handling chain, breaking down its various components into three main phases: ‘pre-assessment’, ‘appraisal’, and ‘management’. The two intermediate and closely linked stages of risk characterisation and evaluation have been placed between the appraisal and management phases and can be assigned to either of them, depending on the circumstances: if the interpretation of evidence is the guiding principle for characterising risks, then risk and concern assessors are probably the most appropriate people to handle this task; if the interpretation of underlying values and the selection of yardsticks for judging acceptability are the key problems, then risk managers should be responsible. In an ideal setting, however, this task of determining a risk’s acceptability should be performed in a joint effort by both assessors and managers. At any rate, a comprehensive, informed and value-sensitive risk management process requires a systematic compilation of results from risk assessment, risk perception studies and other context-related aspects as recommended and subsumed under the category of risk appraisal. Risk managers are thus well advised to include all the information related to the risk appraisal in evaluating the tolerability of risks and in designing and evaluating risk reduction options. The crucial task of risk communication runs parallel to all phases of handling risk: it assures transparency, public oversight and mutual understanding of the risks and their governance.

The document, secondly, addresses wider governance issues. Its starting point has been the observation that collective decisions about risks result from an interaction between science communities, governmental or administrative actors, corporate actors and actors from civil society at large. The interplay of these actors has been discussed with reference to public participation, stakeholder involvement and governance structures (horizontal and vertical). In addition, the document highlights the need for appropriate organisational capacity as a prerequisite for effective risk governance and provides a typology of regulatory styles. These variables also co-determine the institutional structure, the processing of information and values and the quality of the outcome in terms of regulations or management options.

What lessons can be drawn for the future work of IRGC from the results of the study reported in this document? First, providing a unified yet flexible concept can assist IRGC to conduct comparative analyses among and between different risk types, thus ensuring that resource distribution on risk management across risk sources and technologies follows a consistent and efficient pattern. Second, it may help IRGC to structure its projects in line with the phases and components outlined in this report. Thirdly, the framework may be a worthwhile basis for diagnosing deficiencies in existing risk governance regimes around the world and provide suggestions for how to improve them. Lastly, the document may serve a heuristic function by adding to the worldwide efforts for harmonising risk governance approaches and finding some common denominators for risk governance that provide a credible and substantive response to both the globalisation of the planet and the need for a coherent approach to the risks faced by our increasingly interconnected populations.

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21 GLOSSARY OF TERMS USED IN THIS WHITE PAPER

Acceptability: Risks are deemed to be acceptable if they are insignificant and adequately controlled. There is no pressure to reduce acceptable risks further, unless cost effective measures become available. In many ways, acceptable risks are equivalent to those everyday risks which people accept in their lives and take little action to avoid. (See also **'Intolerable Risks'** and **'Tolerability'**.)

Agent: In the context of risk a substance, energy, human activity or psychological belief that can cause harm.

ALARA: As Low As Reasonably Achievable.

ALARP: As Low As Reasonably Practicable. (Note: There is little or no difference in practice between ALARA and ALARP. 'Reasonably practicable' is defined in some countries through case law which says that a reduction in risk is 'reasonably practicable' unless the improvement achieved is grossly disproportionate to the cost of achieving that improvement.)

Ambiguity: Giving rise to several meaningful and legitimate interpretations of accepted risk assessments results. See also **'Interpretative Ambiguity'** and **'Normative Ambiguity'**. ('Ambiguity' is one of three major challenges confronting risk assessment; the others are 'complexity' and 'uncertainty'.)

Buffer Capacity: Capacity of a system to withstand a risk event (e.g. the failure of a component) through the incorporation of additional protective measures.

Complexity: Complexity refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects. ('Complexity' is one of three major challenges confronting risk assessment; the others are 'uncertainty' and 'ambiguity'.)

Coping Capacity: Building into systems, society, organisations or individuals measures to reduce the impact of a risk if it is realised. For example, measures to improve the ability of a building to resist earthquakes. (See also **'Resilience'**.)

Design discourse: A form of deliberation for defining and specifying the most appropriate route for assessment and management of a given risk.

Dose-Response Relationship: The relationship between the amount of exposure (dose) to a substance (or other hazard) and the resulting changes in health or body function. (Note: Usually applied to human beings but can be applied more widely in the environment.)

Early warning: Institutional arrangement for (systematically) looking for indicators of potentially damaging events or their precursors.

Epistemological: Concerning the nature, origin and scope of knowledge. So an 'epistemological discourse' is about the scope and the quality (validity, reliability and relevance) of the information available and is aimed at finding the best estimates for characterising the risk.

Exposure: Contact of a risk target (humans, ecosystems) with a hazard.

Flexibility: One of the skills essential to tackling modern risk situations. The ability to look for new ways to make sense of a dynamic situation, if necessary to fight against traditional practices and institutional inertia, and to find novel solutions.

Framing: The initial analysis of a risk problem looking at what the major actors, e.g. governments, companies, the scientific community and the general public, select as risks and what types of problems they label as risk problems. This defines the scope of subsequent work.

Governance: At the national level, the structure and processes for collective decision making involving governmental and non-governmental actors (Nye and Donahue 2000). At the global level, governance embodies a horizontally organised structure of functional self-regulation encompassing state and non-state actors bringing about collectively binding decision without superior authority (c.f. Rosenau 1992; Wolf 1999).

Hazard: A source of potential harm or a situation with the potential to causes loss. (Australian/New Zealand risk management standard)

Horizontal Governance: This involves all the relevant actors including government, industry, NGOs and social groups in decision-making processes with a defined geographical or functional segment, such as a community or region.

Indeterminacy: See **'Stochastic Effects'.**

Instrumental [discourse]: Used in the case of 'simple risks'. It is aimed at finding the most cost-effective measures to make the risk acceptable or at least tolerable.

Interpretative Ambiguity: Different interpretations of an identical assessment result: e.g. as an adverse or non-adverse effect.

Intolerable Risks (alternatively **'Unacceptable Risks'):** A risk that society deems to be unacceptable, no matter what benefits arise from the activity giving rise to the risk.

Justification: The case for undertaking an activity that carries an element of risk. In effect, some kind of risk/benefit analysis which demonstrates the case for the activity.

Latency: Concealed or dormant risks; latency refers to those risks where the harm emerges some considerable time after exposure (e.g. to radiation).

Normative Ambiguity: Different concepts of criteria or yardsticks that help to determine what can be regarded as tolerable referring e.g. to ethics, quality of life parameters, risk-benefit balance, distribution of risks and benefits, etc.

Organisational Capacity: The ability of organisations and individuals within organisations to fulfil their role in the risk governance process.

Participative [decision making/discourse]: Open to public input; possibly including new forms of deliberation. Examples of participative discourse include citizens' juries, consensus conferences etc.

Probabilistic Risk Assessment (PRA): Methods for calculating probability-loss functions based on statistical, experimental and/or theoretically derived data (such as event treed or fault trees). PRA is often used in the context of engineered systems.

Reflective [discourse]: Collective reflection on the course of action to take e.g. balancing possibilities of over- and under-protection in the case of large remaining uncertainties about probabilities and/or magnitude of damage(s). Examples of reflective discourse include round tables, open space forums and negotiated rule making.

Resilience: A protective strategy to build in defences to the whole system against the impact of the realisation of an unknown or highly uncertain risk. Instruments for resilience include strengthening the immune system, designing systems with flexible response options, improving emergency management etc.

Risk: An uncertain consequence of an event or an activity with respect to something that humans value (definition originally in: Kates et al. 1985: 21). Such consequences can be positive or negative, depending on the values that people associate with them.

Risk Analysis: Some organisations, e.g. Codex Alimentarius, use risk analysis as a collective term which covers risk assessment, risk management and risk communication.

Risk Appraisal: The process of bringing together all knowledge elements necessary for risk characterisation, evaluation and management. This includes not just the results of (scientific) risk assessment but also information about risk perceptions and economic and social implications of the risk consequences.

Risk Assessment: The task of identifying and exploring, preferably in quantified terms, the types, intensities and likelihood of the (normally undesired) consequences related to a risk. Risk assessment comprises hazard identification and estimation, exposure and vulnerability assessment and risk estimation.

Risk Characterisation: The process of determining the evidence based elements necessary for making judgements on the tolerability or acceptability of a risk. (See also **'Risk Evaluation'**.)

Risk Estimation: The third component of risk assessment, following hazard identification and estimation, and exposure/vulnerability assessment. This can be quantitative (e.g. a probability distribution of adverse effects) or qualitative (e.g. a scenario construction).

Risk Evaluation: The process of determining the value-based components of making a judgement on risk. This includes risk-benefit balancing or incorporation of quality of life implications and may also involve looking at such issues as the potential for social mobilisation or at pre-risk issues such as choice of technology and the social need of the particular operation giving rise to the risk (See **'Justification'**).

Risk Governance: Includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Encompassing the combined risk-relevant decisions and actions of both governmental and private actors, risk governance is of particular importance in, but not restricted to, situations where there is no single authority to take a binding risk management decision but where instead the nature of the risk requires the collaboration and co-ordination between a range of different stakeholders. Risk governance however not only includes a multifaceted, multi-actor risk process but also calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and co-ordination mechanisms such as markets, incentives or self-imposed norms) and political culture including different perceptions of risk.

Risk Management: The creation and evaluation of options for initiating or changing human activities or (natural and artificial) structures with the objective of increasing the net benefit to human society and preventing harm to humans and what they value; and the implementation of chosen options and the monitoring of their effectiveness.

Risk Mitigation: Measures to reduce the impact of a realised risk; for example, design features in a chemical plant to direct any explosive failure in a particular direction away from sensitive parts of the plant.

Risk Perception: The outcome of the processing, assimilation and evaluation of personal experiences or information about risk by individuals or groups in society.

Risk Prevention: Measures to stop a risk being realised. This often means stopping the activity giving rise to the risk. But this, because of the need for substitution, can often give rise to other risks in the substituted activity.

Risk Reduction: Measures to reduce the level of risk, for example by reducing the likelihood of the risk being realised or reducing the impact of the risk.

Risk Screening: The process of sifting and selecting information about risk in order to allocate the risk to a particular category or to a particular control regime; the process needs to be done in a manner that avoids unnecessary compartmentalisation of a risk.

Risk Trade-Offs (or Risk-Risk Trade-Offs): The phenomenon that interventions to reduce one risk can increase other risks, or shift risk to a new population.

Risk Transfer: Passing on some or all of the consequences of a risk to a third party. In some cases, this may be part of legitimate risk management e.g. to an insurance company; in other cases, for example, where those benefiting from the risk generating activity are not those who suffer from the risk (e.g. those suffering pollution down stream from a chemical plant), risk governance needs to ensure that such transfers are dealt with fully and equitably.

Robustness: This concerns primarily the insensitivity (or resistance) of parts of systems to small changes within well defined ranges of the risk consequences (contrast with 'resilience' which more concerns whole systems).

Semantic Risk Patterns: Classes of risk that reflect certain perceptive or psychological approaches to risk. For example, one such class concerns risks posing an immediate threat such as nuclear energy; another concerns activities where an individual's perception of their vulnerability is underestimated because they believe they are 'in charge', e.g. when driving a car.

Social Amplification of Risk: An overestimation or underestimation of the seriousness of a risk caused by public concern about the risk or an activity contributing to the risk.

Social Mobilisation: Social opposition or protest that feeds into collective actions (such as voting behaviour, demonstration or other forms of public protest).

Stakeholder: Socially organised groups that are or will be affected by the outcome of the event or the activity from which the risk originates and/or by the risk management options taken to counter the risk.

Stochastic Effects: Effects due to random events.

Systemic Risk: Those risks that affect the systems on which society depends – health, transport, energy, telecommunications etc. Systemic risks are at the crossroads between natural events (partially altered and amplified by human action such as the emission of greenhouse gases), economic, social and technological developments and policy-driven actions, both at the domestic and the international level.

Taxonomy: A structure for classifying risks and approaches to methods of dealing with risks.

Tolerability: An activity that is seen as worth pursuing (for the benefit it carries) yet requires additional efforts for risk reduction within reasonable limits. (See also **'Acceptability'** and **'Intolerable Risks'/ 'Unacceptable Risks'**.)

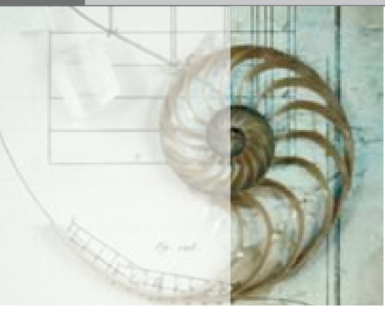
Ubiquity: In the context of risk, one for which the impact of the risk being realised is widespread, usually geographically.

Unacceptable Risks: See **'Intolerable Risks'.**

Uncertainty: A state of knowledge in which, although the factors influencing the issues are identified, the likelihood of any adverse effect or the effects themselves cannot be precisely described. (Note: this is different from ignorance about the effects or their likelihood. 'Uncertainty' is one of three major challenges confronting risk assessment; the others are 'complexity' and 'ambiguity'.)

Vertical Governance: This concerns the links between the various segments which may have an interest in an issue, e.g. between local, regional and state levels (whereas 'horizontal governance' concerns the links within those segments).

Vulnerability: The extent to which the target can experience harm or damage as a result of the exposure (for example: immune system of target population, vulnerable groups, structural deficiencies in buildings, etc.).



ANNEXES

DETAILED CONTENT ANNEXES

ABBREVIATIONS USED IN THE ANNEXES

ACGIH	American Conference of Government Industrial Hygienists
AIRMIC	The (UK) Association of Insurance and Risk Managers
ALARM	The (UK) National Forum for Risk Management in the Public Sector
ALARP	As Low As Reasonably Practicable
BATNEEC	Best Available Technology Not Entailing Excessive Cost
CEFIC	European Chemical Industry Council
COSO	(US) Committee of Sponsoring Organisations of the Treadway Commission
CPSC	(US) Consumer Product Safety Commission
FAO	Food and Agriculture Organisation
FDA	(US) Food and Drug Administration
EMPRES	Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases
EPA	(US) Environmental Protection Agency
EU	European Union
FERMA	Federation of European Risk Management Associations
HSE	(UK) Health and Safety Executive
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organisation
ICNIRP	International Commission on Non-Ionising Radiation Protection
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
ISDR	International Strategy for Disaster Reduction
ISO/IEC	International Standards Organisation/International Electrotechnical Commission
MAPP	Major Accident Prevention Policy
NRC	(US) National Research Council
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health (acronym stands for Office International des Epizooties)
OSHA	(US) Occupational Safety and Health Agency
REACH	Integrated system to manage chemical risks within the EU (acronym stands for **R**egulation, **E**valuation and **A**uthorisation of **Ch**emicals)
SRA	Society for Risk Analysis
TADs	Transboundary Animal Diseases
UN	United Nations
WBGU	German Advisory Council on Global Change (Wissenschaftlicher Beirat Globale Umweltveränderungen)
WHO	World Health Organisation
WTO	World Trade Organisation

INTRODUCTION TO THE ANNEXES

1. In looking at how the IRGC would approach the structure of risk assessment and risk management, it was important to review a cross-section of the main approaches already in use, including the terminology used. The IRGC recognises that the existing approaches are well embedded; it is not IRGC's belief that it can, or should, alter those approaches. However, as the IRGC's own crosscutting approach becomes tested and accepted, it is hoped that this will influence any further development of those approaches.

2. An appreciation of the different approaches to risk assessment and risk management is increasingly important in any case. As risk issues become more interlinked, not least because a risk in one country or industry can have impact elsewhere and two or more risk regimes (and their different approaches and terminology) then have to interact, it is more and more necessary to understand those differences and to ensure they do not inhibit effective collaboration.

3. This Annex comes in four parts. Annex A summarises some of the main approaches to risk in a wide set of environments. Essentially the summary reviews cover the following hazards or situations where risk has to be understood and managed:

   - Physical agents
   - Chemical agents
   - Biological Hazards, including human health issues
   - Complex hazards
   - Natural Forces
   - Standards
   - Government
   - Finance and Trade
   - Corporate Governance

   Although the IRGC has no current plans to investigate financial risk, it was thought appropriate to include two cases from that area, not least because the vocabulary and thinking about risk is no longer isolated, and any comparative exercise needs to include those interests. Additionally, there are potential financial implications for all the problem fields that IRGC does plan to investigate.

4. The methodology for this work has been to identify the main activities or hazards to address and to search for key documents that define the approach to risk issues. In some cases, the sources are more straightforward than in others, for example where there is a single key document that describes the unique approach in that area. But, for others, it has been necessary to build up an overview drawing on a range of information, including web site material. The summaries indicate the main sources of information.

5. The summaries in Annex A are done to a standard format to assist comparison. It is important to remember that the broad context of each of these approaches will vary:

   - Some approaches are clearly fairly generic and aimed at those who regulate risks, e.g. the Government frameworks will influence, if not instruct, regulatory agencies and will help set legal requirements for managing risk.

- Some are directed at those who manage risk. For example, the approach to major hazard risks and some of the risk management standards.
- Some are aimed at changing how the world deals with particular areas of risk and are therefore targeted at governments and opinion formers more generally. For example, the UN Report on Living with Risk and the OECD Emerging Risks Report.

6. Annex B provides an overview of how the main terms used are defined (ordered alphabetically). There is in places a lack of consistency in the use of words and phrases, and beneath that a difference in emphasis on the parts and content of the process. Risk terminology is neither consistent nor always coherent. The basic processes involved in identifying risks, assessing or analysing them (dependent on the terminology) and managing them are largely the same; but the terms used, and indeed the meaning attached to terms, varies, in some cases quite considerably, between the wide range of organisations that are involved in risk management of one sort or another. These differences are deeply embedded and cannot change easily.

7. For the reader's convenience Annex C regroups the terms provided in Annex B and orders them by organisation and/or publication respectively. It should be noted, however, that this is not intended as a comprehensive summary of risk terminology used by the organisations listed. It is the result of a limited search and undoubtedly the organisations investigated have a wider set of defined terminology than set out here. Again, this is very much an overview to demonstrate both how terminology is used and the extent to which there is convergence or divergence in the use of such terminology.

8. Annex D seeks to summarise some of the different uses of key terminology within existing risk assessment and management processes. There are important variations among some regimes as to what terms such as risk assessment and risk analysis mean – for some risk assessment is part of risk analysis and for some it is the other way round. This Annex sets out the main alternative approaches.

9. Procedural notes:

- The Summaries in Annex A are based on a range of documents and texts on websites. The titles of those documents and web sites are given in the section "Relevant Documents etc." or in footnotes and the most important of them are summarised in a references list. Direct quotes from those sources are given *in italics*. The graphs and illustrations shown in this annex have been taken from the individual source documents and remain unchanged.
- The terminology overview in Annexes B and C is necessarily selective. It draws primarily on the sources used for the summaries in Annex A and also includes some other sources such as the International Standards Organisation (ISO/IEC), the European Chemical Industry Council (CEFIC) and the Society for Risk Analysis (SRA).

ANNEX A – CURRENT APPROACHES TO RISK

A-1 Physical Agents Examples

A-1.1 Non-Ionising Radiation (ICNIRP)

Area of Risk: Risk from the wide range of non-ionising radiation to which different populations are exposed. Non-ionising radiation includes the optical radiations (ultraviolet, visible and infrared – and lasers), electric and magnetic fields, radio frequency (including microwave) radiation, and ultrasound.

Relevant Documents: ICNIRP Statement: 'General Approach to Protection against Non-Ionizing Radiation' (ICNIRP 2002)[1].

Relevant Authorities: The International Commission on Non-Ionising Radiation Protection[2] (ICNIRP) is an NGO, describing itself as *an independent group of scientific experts established to evaluate the state of knowledge about the effects of non-ionising radiation on human health […], and, where appropriate, to provide scientifically based advice on protection*[3]. It is formally recognised by the WHO, the ILO and the European Union, and thus influences the development of policies at the national, intergovernmental and supranational level.

Rationale and Context: Concerns about non-ionising radiation have increased in recent years, both as new uses and products emerge and as public perception (not always well informed) of such risks develops. Such concerns range from those for which there is a general scientific consensus (e.g. the risk of skin damage from overexposure to sunlight, or risks from equipment such as lasers or microwaves) to those where the science is far less authoritative (e.g. the possible risks from mobile phones or from living in close proximity to electrical power transmission lines).

The ICNIRP provides advice across all forms of non-ionising radiation but the responsibility for translating that advice, or advice from other sources, into practical measures to control risks lies with national or supranational authorities, which may need to take social, economic or political considerations into account, as well as scientific assessments.

Overall Approach:

ICNIRP concentrates on health risk assessments and the development of guidance.

Risk Assessments are based on critical reviews of all available evidence. Although *any single observation or study may indicate the possibility of a health risk […] risk assessment requires information from studies that meet quality criteria*[4] (which are set out in an Appendix to the General Approach Statement). The General Approach Statement sets out in some detail what evidence is addressed and how.

An important consideration is to distinguish between adverse and beneficial health effects. Additionally, some observed effects will be neither adverse nor beneficial based on current knowledge; for these the ICNIRP can make no recommendations. The ICNIRP furthermore regards medical use of radiation,

1 View this document at http://www.icnirp.de/documents/philosophy.pdf.
2 Background information on ICNIRP can be found at http://www.icnirp.de.
3 General Approach Statement, p. 540.
4 Ibid, p. 541.

where people may be exposed to much higher levels of radiation than the general population, as outside the scope of their exposure guidance.

The key elements in the ICNIRP approach are examining the nature of possible health effects, looking at how these might be related to exposure and then deciding whether guidance on limiting exposure might be developed. The General Approach Statement draws attention to the following:

- Distinguishing between adverse and beneficial health effects.
- Linking the biologically effective quantity (which measures *the efficacy by which a certain biological effect is induced*[5]) to the radiation causing the effect.
- In evaluating data, recognising the hierarchy of such data:
  - Ideally, risk assessment data should be derived from human data. But this is not always possible and, in any case, epidemiology may not provide causal evidence.
  - Animal data needs to *be carefully interpreted in order to be meaningfully extrapolated to humans*[6].

ICNIRP has a three step evaluation process. Those steps are[7]:

- *Evaluating single studies in terms of their relevance to the health effects being considered and of the quality of the methods used.* (Done by ICNIRP standing committees.)
- *For each health effect evaluated, a review of all relevant information is required.* (Done by ICNIRP standing committees.)
- *The outcomes of these steps are combined into an overall evaluation.* (Done by the full ICNIRP Commission in collaboration with the standing committees.)

The aim is to decide whether the data supports identification of an adverse health effect and, if it does, to provide:

- The biologically effective quantity;
- Exposure-effect relationship – and the threshold (below which there is no effect) if such exists;
- Populations at high risk, and any susceptibilities within populations;
- Exposure distribution.

ICNIRP bases its **guidance on limiting exposure** on scientific aspects. If it can identify a threshold below which there is no evidence of adverse effects then it can offer guidance on how to achieve that level of protection. However, if there is no threshold for safe exposure, the ICNIPR would analyse the risk and seek to quantify it, but decisions on the acceptability of the risk would fall to other authorities which would have to take into account social and economic factors.

The General Approach Statement addresses the challenges involved in producing guidance. In particular it looks at:

- Exposure characterisation and the difficulties involved in estimating the biologically effective quantity when the externally assessed level of exposure is not equal to that reaching the affected part of the body.
- The populations being protected. Should the guidelines for the general public be adjusted to take into account vulnerable groups such as the elderly or children? Should there be separate guidance for occupational exposure since the exposure of workers will be different?

5 Ibid, p. 543.
6 Ibid, p. 544.
7 Drawn from ibid, p. 544.

- The use of reduction factors, for example when relying on animal data.
- Approaches to risk management, including the use of the Precautionary Principle (where the ICNIRP endorses the European Commission's clarification on the use of the Principle).

Comment: The ICNIRP approach to risk is wholly scientifically based (although it recognises that practical decisions on risk management which may fall to others may need to take other factors into account). That approach involves rigorous evaluation of the data for evidence of harm and for the relationships between exposure and harm.

It recognises the need to use a range of data, including epidemiology and animal data as well as data about direct effects in humans, in making decisions and has established principles for handling that data. The data is evaluated by a peer process, which, by concentrating the overall evaluation for particular risks in the ICNIRP Commission, is aimed at ensuring consistency of approach and scientific rigour.

A-1.2 Aircraft Noise (ICAO)

Area of Risk: Aircraft noise in the vicinity of airports and under flight paths into airports.

Relevant Documents: 'Consolidated statement of continuing ICAO policies and practices related to environmental protection (A33-7)', adopted October 2001 (ICAO 2001)[8].

Relevant Authorities: The International Civil Aviation Organisation (ICAO) plus national and supranational authorities (e.g. EU).

Rationale and Context: Aviation gives rise to a number of environmental hazards, including increasing concerns about the contribution of air travel to global warming. A particular concern for decades has been the impact of the noise of jet engines around airports and under flight paths; this has increased as air travel has grown, and especially as night take-off and landing has become more prevalent. These concerns have been important drivers for improvements in engine design. Given the mix of aircraft using modern airports and the continuing growth of air traffic, controls on aircraft noise remain a difficult issue touching on personal welfare and health, national prosperity and international trade. It is an area in which ICAO had developed policies and practices over the years.

The expectation is that Contracting Parties (i.e. States; for ICAO is an International Governmental Organisation) to ICAO will apply agreed policies and practices; but ICAO cannot legally enforce them.

Overall Approach:

ICAO has a 'balanced approach' to aircraft noise management (Appendix C of Assembly Resolution A33-7). This *consists of identifying the noise problem at an airport and then analysing the various measures available to reduce noise through the exploration of four principal elements, namely*

- *Reduction at source (quieter aircraft),*
- *Land-use planning and management,*

8 View this document at http://www.icao.int/icao/en/env/a33-7.htm (this document contains all resolutions agreed at the 2001 Assembly).

- *Noise abatement operational procedures and*
- *Operating restrictions,*

with the goal of addressing the noise problem in the most cost-effective manner[9]. ICAO has developed policies on each of these elements, as well as on noise charges.

Risk assessment in the context of aircraft noise is therefore essentially about exposure rather than impact. Separate work has looked at the impact of noise on human welfare and health, and indeed on economic activity within areas exposed to noise. The methods for measuring aircraft noise are well developed. ICAO is concerned that the assessment is based on objective and measurable criteria and that the whole process is transparent (paragraph 2 b of Appendix C).

ICAO work on **reduction of noise at source** focuses particularly on noise certification standards for modern aircraft and helicopters (set out in Volume 1 of Annex 16 to the Convention on International Civil Aviation).

Land use planning and management *is an effective means to ensure that the activities nearby airports are compatible with aviation. Its main goal is to minimize the population affected by aircraft noise by introducing land-use zoning around airports. Compatible land-use planning and management is also a vital instrument in ensuring that the gains achieved by the reduced noise of the latest generation of aircraft are not offset by further residential development around airports.*[10] Guidance on this is also in Annex 16 (see preceding paragraph).

Noise abatement operational procedures *enable reduction of noise during aircraft operations to be achieved at comparatively low cost. There are several methods, including preferential runways and routes, as well as noise abatement procedures for take-off, approach and landing. The appropriateness of any of these measures depends on the physical lay-out of the airport and its surroundings, but in all cases the procedure must give priority to safety considerations.*[11]

Operating restrictions are essentially bans on noisy aircraft at noise-sensitive airports (primarily in developed countries). Such bans can have significant economic impact for the airlines concerned, both those in the country taking action and those based in other states, especially developing countries.

Comment: The ICAO approach is about achieving agreed and balanced means of reducing the risks and nuisance from aircraft noise by a range of measures involving both prevention, i.e. reduction of the nuisance at source, and mitigation, i.e. managing the areas affected by the nuisance.

The ICAO approach is not about risk assessment per se but about the management of an activity that carries risks for local populations. However the management of the activity also carries risks – for local, regional and even national economic activity and to the jobs and welfare of those who work in the airline and related industries; there are both national and international dimensions to this and these are undoubtedly factored into the discussions at ICAO before policies are agreed.

9 Accessible at http://www.icao.int/cgi/goto_atb.pl?icao/en/env/noise.htm;env containing an ICAO note on “A Balanced Approach to Aircraft Noise Management”.

10 Ibid.

11 Ibid.

A-2 Chemical Agents Example

A-2.1 Integrated Risk Assessment and Occupational Exposure (IPCS, European Agency for Safety and Health at Work, OSHA, HSE)

Area of Risk: Health and environmental risks from chemicals. This is a wide risk area and this summary concentrates on just two aspects, integrated risk assessment and occupational exposure to chemicals.

Relevant Authorities: International Programme for Chemical Safety (IPCS) for integrated risk assessment. Various national and regional authorities for practical limit setting and determination of control regimes; this summary looks particularly at the European Union and at OSHA (Occupational Safety and Health Agency) and the ACGIH (American Conference of Government Industrial Hygienists) in the United States of America.

Rationale and Context: *A substantial use of chemicals is essential to meet the economic and social goals of the world community*[12]. The benefits from chemicals are enormous and widespread but their manufacture, transport and use present a range of risks to the welfare of man and the environment. Historically, action to control the risks from the use of chemicals has been somewhat piecemeal. There have been a number of strands, including:

- Assessment of new chemicals coming onto the market;
- Assessment of existing chemicals in the sense of their overall impact on the environment and man and whether further controls should be applied;
- Assessment of occupational exposure of those who have to work with chemicals and determination of the necessary controls to apply (including exposure limit values); and
- Classifying and labelling chemical products coming onto the market (hazard identification).

Agenda 21, the action agenda arising from the 1992 Earth Summit in Rio de Janeiro, included a chapter on chemicals, Chapter 19, which set out a programme of work at the global level. It gave added impetus to the work of the International Programme on Chemical Safety[13], set up as a joint programme of three Cooperating Organisations - ILO, UNEP and WHO.

Integrated Risk Assessment:

Background: A group working under IPCS auspices has developed proposals for Integrated Risk Assessment (WHO/UNEP/ILO IPCS 2001)[14]. This arose from recognition that there was a need to integrate assessments of risks to human health and well-being with risks to non-human organisms, populations and ecosystems. The aim was an integrated approach that could apply to a wide variety of types of assessments including:

- Assessments that predict the effects of proposed actions;
- Assessments that estimate the ongoing effects of past actions;
- Assessments of actions at particular places;
- Assessments of risks from hazardous agents independent of location.

12 Accessible at http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21chapter19.htm.

13 For background information on IPCS see http://www.who.int/ipcs/en/. See also http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21toc.htm for a table of contents for Agenda 21 (including a link to chapter 19).

14 View these in the 'Framework for the Integration of Health and Ecological Risk Assessment' (Integrated Risk Assessment Framework) at http://www.who/int/ipcs/publications/new_issues/ira/en/.

Overall Approach:

IPCS and the integrated risk assessment framework: The integrated framework consists of three major components:

- Problem formulation – delineating the overall goals, objectives, scope and activities of the assessment.
- Analysis – data collection and modelling exercises to characterise exposure in time and space, and to define the effects on humans and ecological systems resulting from exposure.
- Risk characterisation – synthesising exposure and effect information as estimates of risk.

The integrated framework distinguishes between risk assessment and risk management. It restricts risk assessment to *the activities that provide the scientific information to be used in the decision making process. Risk management is the use of this and other kinds of information to select among possible alternatives and to implement the selected alternatives. [IPCS] maintain this distinction to focus attention on the scientific aspects of integrated risk assessment*.[15]

In this, the report recognises that other frameworks, e.g. the redefined US National Research Council (NRC) framework, the EU Risk Assessment framework for new and existing chemicals and the FAO/WHO framework developed for risk management and risk assessment of food additives, demand a greater role for risk managers and stakeholders in the risk assessment.

The EU REACH system: In the European Union, an integrated system to manage chemical risks has been agreed[16] – the **REACH** system, for **R**egulation, **E**valuation and **A**uthorisation of **Ch**emicals. REACH is set in the context of both protecting human health and the environment, and maintaining and enhancing the competitiveness of the European chemicals industry. It was developed because of increasing discontent with the existing programmes aimed at improving chemical safety, not least the slowness in evaluating existing chemicals.

This programme is aimed therefore to give impetus to the assessment and management of chemical risks: it sets deadlines and makes industry more responsible for managing risks and it also includes provisions for authorisation of chemicals of serious concern and for substitution of hazardous chemicals. In particular, by placing obligations on industry, REACH aims for accelerated risk assessments. Its work is set clearly in the context of wider international activities post-Rio.

Occupational Exposure to Chemicals[17]:

Background: A large number of workers are exposed to chemicals as part of their work either because they are involved in the manufacture of chemicals or because their work activity uses, or involves exposure to, chemicals. For that reason, many countries have developed systems for assessing that exposure and introducing suitable measures to prevent or control those occupational risks.

Overall Approach: The approach to risk assessment is broadly common across the regulatory authorities; much data is shared and there is common access to scientific data. The essential data for risk assessment includes the following:

15 Integrated Risk Assessment Framework, Section 2 ('Features of the Proposal Framework'), p. 4.
16 For more information about the system see http://europa.eu.int/comm/environment/chemicals/pdf/0188_en.pdf (European Commission White Paper on a 'Strategy for a Future Chemicals Policy', COM(2001) 88 final).
17 See http://europe.osha.eu.int/good_practice/risks/ds/oel/nomembers.stm for a very helpful summary of the use of exposure limits by different countries around the world (provided by the European Agency for Safety and Health at Work).

- Routes of exposure – in particular distinguishing respiratory, ingestion and dermal exposure – and level of exposure (using occupational hygiene data).
- Possible adverse health effects (i.e. disease). Identified through reviewing:
  - Medical or occupational hygiene data on possible diseases associated with exposure.
  - Relevant epidemiology – for some chemicals such as asbestos or benzene where there is a long history of exposure the epidemiology may be fairly strong but for many substances epidemiology may not be available.
  - Evidence from animal toxicology. This involves a range of important issues such as the right animal model for the particular human exposure under consideration; if there is a dose response relationship for animals, how is that extrapolated to humans?
- Populations at risk – are there vulnerable groups, what is the pattern of likely exposure, by all routes?
- Compounding factors, e.g. for some chemicals smoking may increase the risk of disease developing.

This data needs to be reviewed and most authorities have groups of scientific experts for this work; for example, in the EU, the Scientific Committee on Occupational Exposure Limits:

- Determines priorities for assessment;
- Evaluates the data;
- Prepares draft recommendations which are subject to 6 months consultation;
- Considers comments from consultation; and
- Prepares a final recommendation.

The assessed data with the experts' conclusions will be published in a 'Criteria Document' which is essentially a characterisation of the risk with the supporting evidence[18].

Risk management for occupational exposure to chemicals involves the selection of appropriate measures. Options include:

- Banning the use of a substance.
- Setting occupational exposure limits (i.e. a time-weighted average of exposure usually for an 8 hour period). Although the legal status of these limits may vary from one regulatory authority to the next, essentially there are two types of limits:
  - Maximum exposure limits for which there is usually an obligation to reduce exposure as far as possible. These are set for carcinogens, mutagens etc. for which it is thought there is no absolutely 'safe' level of exposure.
  - No adverse effect limits. These are levels of exposure for which there is no evidence of adverse effects and therefore no obligation to reduce exposure further.
- Setting biological exposure limits, i.e. limits for the concentration of a substance or a metabolite in blood or urine (this is done, for example, for exposure to lead).
- Prescribing forms of controlling exposure, e.g. total enclosure of the process, use of local exhaust ventilation, use of personal protection equipment etc.
- Requiring regular health surveillance.
- Requiring monitoring of exposure to ensure control measures are working.

18 The website of the European Agency for Safety and Health at Work also has a useful summary on the use of criteria documents; see http://europe.osha.eu.int/research/rtopics/rds/background.stm.

The above approaches are used by the EU[19] and by health and safety regulatory authorities at the national level, e.g. OSHA[20] in the US and the Health and Safety Executive[21] in the UK. Non-governmental bodies, e.g. the ACGIH[22] in the US, have recommended limits in some cases too, although these are clearly advisory and do not have statutory backing.

A-3 Biological Hazards Examples

A-3.1 Transboundary Animal Disease (FAO EMPRES)

Area of Risk: Animal disease emergencies such as outbreaks of epidemic diseases with the potential to cause serious socio-economic consequences for a country.

Relevant Authorities: Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases[23] (EMPRES) – Food and Agriculture Organisation (FAO). In its application, it calls on the 'Terrestrial Animal Health Code'[24] of the World Organisation for Animal Health (OIE 2004).

Rationale and Context: Transboundary animal diseases (TADs) can have significant economic, trade and/or food security consequences for many countries. Such diseases can spread easily and reach epidemic proportions; control/management, including exclusion, requires cooperation among several countries. EMPRES was established by FAO in 1994 to work to minimise the impact of such emergencies, especially in developing countries. EMPRES is a programme which deals with both plant pest and animal diseases issues.

Overall Approach: EMPRES uses risk analysis in developing plans for animal disease emergency preparedness. In particular it is concerned with imports of animals. The Terrestrial Animal Health Code regards risk analysis has having four components.

Diagram 1: The Four Components of Risk Analysis

(Source: 'Terrestrial Animal Health Code', Article 1.3.1.1. (OIE 2004))

19 See http://europa.eu.int/comm/employment_social/health_safety/occupational_en.htm for an introduction to the EU approach to occupational exposure limits and biological limit values.

20 See http://www.osha.gov/SLTC/pel/index.html for an overview of permissible exposure limits set by the US Occupational Health and Safety Administration.

21 For the UK approach to occupational exposure limits see: The Health and Safety Executive (HSE) (2003): EH40/2002 Occupational Exposure Limits Supplement 2003. London: HSE Books.

22 See http://www.acgih.org/TLV/ for an introduction on ACGIH's recommendations on 'threshold limit values' and 'biological exposure indices'.

23 See the EMPRES website at http://www.fao.org/EMPRES/.

24 View the text of the Code at http://www.oie.int/eng/normes/mcode/en_sommaire.htm on the website of OIE.

The **hazard identification** involves *identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity*[25]*.* This means looking for those agents specific to the type of animal being imported and which are present in the exporting country; whether it is already in the importing country also has to be taken into account. If no potential hazards are identified then the risk assessment needs go no further.

The Terrestrial Animal Health Code sets out principles of **risk assessment** (Article 1.3.2.3); these include statements about flexibility, about qualitative and quantitative assessments being equally valid, the encouragement of consistency and the necessity of transparency, and the documentation of uncertainties and assumptions. The steps within the risk assessment as defined in the Code are[26]:

- **Release assessment**: *describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively.*
- **Exposure assessment**: *describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).*
- **Consequence assessment:** *describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences.*
- **Risk estimation:** *integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset.*

Risk management is *the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.*[27] The Code sets out four components to risk management[28]:

- **Risk evaluation:** *comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.*
- **Option evaluation:** *the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the Member Country's appropriate level of protection.*
- **Implementation:** *the process of following through with the risk management decision and ensuring that the risk management measures are in place.*
- **Monitoring and review:** *the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.*

Risk Communication is *the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-*

25 Article 1.3.2.2, 1st paragraph of the Terrestrial Animal Health Code.
26 Drawn from Article 1.3.2.4 ibid.
27 Article 1.3.2.5.1 ibid.
28 Drawn from Article 1.3.2.6 ibid.

makers and interested parties in the importing and exporting countries[29].

Comment: The EMPRES requirements are binding in that they give countries powers to control importation on the basis of an agreed international Code. The WTO can enforce the Code in the sense of ensuring that the Code is not used as a barrier to trade but, rather, as a means of protecting animal and human health.

A-3.2 Infectious Diseases (WHO)

Area of Risk: Communicable disease that may constitute a global threat.

Relevant Documents: WHO publications on infectious and communicable diseases, particularly 'WHO SARS Risk Assessment and Preparedness Framework' (WHO/Department of Communicable Disease Surveillance and Response 2004)[30].

Relevant Authorities: The World Health Organisation (WHO).

Rationale and Context: There is increasing concern among health authorities about new (and some old) communicable diseases that might generate epidemics or even pandemics. The close proximity of man and animals, where animal disease might jump to man, and the wide availability of travel are just two of the factors that fuel this concern. WHO has a key role in monitoring the incidence and spread of such diseases, and in advising national governments about the measures they need to implement to prepare for, and, if needed, to control, an outbreak.

An important part of WHO's role is to plan for outbreaks of infectious disease. This summary concentrates on the SARS Risk Assessment and Preparedness Framework of Oct 2004, which is modelled on WHO's Influenza Pandemic Preparedness Plan. The SARS Framework addresses both the role of WHO and that of country members of WHO, distinguishing, where appropriate, between those which may be reporting SARS cases and those which are free of SARS.

Overall Approach: The SARS Risk Assessment and Preparedness Framework (hereafter referred to as the SARS Framework) deals with risk assessment of, and preparations for, the SARS threat in terms of six phases; these phases range from:

- A period where there is no evidence of outbreaks of SARS.
- The emergence of SARS (sporadic cases, confirmed human-to-human transmission, international spread, slowing down of outbreak).
- The phase when the epidemic is halted.

The SARS Framework addresses *the separate but complementary roles and responsibilities of the WHO and national health authorities when the re-emergence of SARS appears possible or actually occurs*[31]. It is aimed at decision makers, clinicians and public health professionals. The WHO recognises that the risk of SARS will vary between countries and that their risk assessments and preparedness frameworks will therefore need to vary too.

29 Drawn from Article 1.3.2.7.1 ibid.
30 View this document at http://www.who.int/csr/resources/publications/en/CDS_CSR_ARO_2004_2.pdf.
31 WHO SARS Framework, p. 5.

The SARS Framework says that the role of WHO includes:

- Global and regional surveillance and maintaining global data on SARS reporting.
- Undertaking global risk assessment and risk communication.
- Assisting national authorities in doing their risk assessments (although national authorities have the prime responsibility for those assessments).

It recommends that every government should do a SARS risk assessment in the periods between epidemics to assist the government in deciding what surveillance strategy is most appropriate for that country. WHO has defined three risk categories:

- Emergence of SARS type viruses from animals.
- Emergence of SARS from laboratories or through international travel.
- Low risk of SARS emergence or introduction.

It offers descriptors of countries that might fall into one or another of these categories[32].

The WHO separately publishes surveillance definitions for SARS[33] and the SARS Framework gives guidance on the cases that should be reported to WHO. It recognises the risk of false alarms: the phases (that is the preparedness levels) are aimed at coping better with this risk.

The SARS Framework sets out for each preparedness phase the actions that both WHO and national authorities should be undertaking. Revising risk assessments is clearly integral if there is progression from Phase 0, the inter-epidemic period, to phases 1, sporadic cases, and 2, confirmed human-to-human transmission. In particular, the Framework sets out factors that are important in assessing risk escalation.

The SARS Framework is very much about risk management and control; there is emphasis on:

- Ongoing surveillance and data collection, without which the progress of the outbreak(s) cannot be monitored and advice given.
- Risk communication – both by WHO itself and by national authorities, e.g. to speed up the reporting of cases, and to improve public hygiene.
- Advising on measures to reduce possible contamination, e.g. social distance measures, screening at airports, etc.
- Managing health care facilities that are affected by outbreaks.

Comment: The approach to risk assessment is very much to build on historical experience (i.e. the 2002/03 outbreak) supported by strong surveillance and epidemiology. There is a need to distinguish between the risks that different countries face, but countries have to be ready to re-assess their risk assessment if new evidence comes forward.

32 See Table 1 ibid, p. 8.

33 View these at http://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1/en/ (WHO guidelines for the global surveillance of SARS).

A-3.3 WHO Report on World Health

Area of Risk: Understanding risks to health with a view to determining priorities for preventing disease and injury with maximum impact.

Relevant Documents: 'World Health Report' 2002 (WHO 2002)[34].

Relevant Authorities: World Health Organisation.

Rationale and Context: The 2002 Report sets out conclusions from one of the largest research projects ever undertaken by WHO; this project concerns risks to human health around the world. The report notes that there is currently an important risk transition taking place. The successes of the past are generating a demographic transition from traditional societies where almost everyone is young to societies with rapidly increasing numbers of middle-aged and elderly people; rapid increases in international travel and trade, and the mass movement of populations mean that infectious diseases can spread very rapidly from one continent to another; more people than ever are exposed to changes often originating in other countries that pose serious long term risks to their health. These factors are of particular concern when combined in middle and low-income countries with poverty-related problems such as under-nutrition and with infectious diseases.

The report focuses on risks to health as a key to preventing disease and injury. It identifies the top 10 risks globally and regionally, which together account for a third of all deaths worldwide. But the mix of risks that are most important varies from region to region, if not country to country. The report addresses the issue of enabling governments to assess and compare the risks to health accurately, and makes key recommendations to help countries develop appropriate risk reduction policies.

Overall Approach:

Assessing Risks to Health: The Report summarises work done by WHO to estimate the burden of disease and injury[35]:

- Risk factors were assessed. These could be either:
  - exposures in the environment (e.g. unsafe water);
  - human behaviour (e.g. tobacco smoke); or
  - physiological states (e.g. hypertension).

  Protective factors (e.g. fruit and vegetable intake or exercise) as well as hazardous factors also had to be taken into account.
- Problems of comparability and the time lags between exposure and outcome have to be addressed. Ideally each risk factor should be assessed in terms of a common currency; DALY (disability adjusted life year) is in common use.
- Both proximal factors (i.e. acting directly to harm health) and distal factors (i.e. further back in the causal chain) need to be built in; and the fact that risk factors do not occur in isolation.
- Population-wide risks need to be identified as well as high-risk individuals (and it is noted that population risks may be different in different societies).
- Uncertainty is addressed and how to use the best available evidence to assess 'certain' and 'probable' risks to health.

34 For an overview of the report see http://www.who.int/whr/2002/overview/en/. The full report can be viewed at http://www.who.int/whr/2002/en/.

35 See World Health Report, Chapter 2, 'Defining and Assessing Risks to Health' (http://www.who.int/whr/2002/chapter2/en/).

- Both attributable burdens (current burden due to past exposure) and avoidable burden (proportion of future burden avoidable if current and future exposure levels are reduced) need to be addressed. This is particularly important when there is a long time lag between exposure and health outcomes, e.g. with tobacco smoke.

The risk factors considered in the report were constrained to those with potential global impact, high likelihood of causality, potential modifiability and which were neither too specific nor too broad and for which reasonably complete data was available.

Risk Perception: *Risk assessment and risk management is a political as well as a scientific process, and public perceptions of risk and risk factors involve values and beliefs as well as power and trust*[36]. This, combined with the fact that increasingly people have to take responsibility for managing risks to their health, emphasises the importance of understanding and reacting to risk perceptions, and of building trust between the public and all involved in health promotion. And in this, risk communication is essential.

The report identifies a number of influences on risk perception[37]:

- How risk is measured (e.g. in terms of economic activity or of impact on people);
- Gender (men and women tend to view risks differently);
- Differing views around the world (e.g. fatalism towards controls over risks, belief in hierarchy and experts, etc.);
- How information is framed;
- Special interest groups;
- Impact of the mass media.

It emphasises that *before interpreting risks and planning any communications or health interventions, people's basic perceptions and frames of reference for interpreting risk must be well understood*[38]. And it stresses that the general public is not homogeneous in how it reacts to risk.

Risk Reductions Strategies: The Report details some selected interventions aimed at reducing health risks; these include childhood under-nutrition, vitamin A deficiency, blood pressure and cholesterol (both separately and combined), unsafe sex and HIV/AIDS, unsafe water, sanitation and hygiene, and occupational risk factors (particularly occupational back pain). In introducing these, the report discusses some of the considerations underlying the development of such interventions. In particular, the report draws attention to[39]:

- Making judgements on strategies based on interventions targeting high risk individuals as against strategies aimed at the population as a whole or at particular groups (for example, the distinction between targeting those individuals with high blood pressure and *shifting the blood pressure for London civil servants in the direction of that of Kenyan nomads*[40]*)*.
- The role of cost-effectiveness analysis. But it is often easier to get the information needed for such analysis for interventions aimed at individuals rather than populations.

36 Ibid, introductory sentence to the Section on 'Defining and Describing Risks to Health', Chapter 3 (p. 34 in PDF version).
37 See ibid, Chapter 3, 'Perceiving Risks' (http://www.who.int/whr/2002/chapter3/en/).
38 Ibid, third paragraph in Section on 'Importance of Perception in Successful Risk Prevention', Chapter 3 (p. 43 in PDF version).
39 See ibid, Chapter 5, 'Some Strategies to Reduce Risk' (http://www.who.int/whr/2002/chapter5/en/).
40 Ibid, fourth paragraph in Sub-section on 'Individual-based versus Population Approaches to Risk Reduction', Chapter 5 (p. 105 in PDF version).

- The need to look beyond activities whose primary intent is to improve health. For example, water and sanitation programmes have considerable value for reasons other than health but they can be very effective means of improving public health.
- The importance of understanding and working on behavioural change (including understanding perceived risks).
- The role of government and legislation, including the role of financial incentives and disincentives.
- Looking at interventions jointly as well as separately.

Comment: The WHO Report is not about tackling individual risks. It is about looking at the totality of risk affecting human populations and deciding which interventions will be most effective in improving the overall state of human health. It concerns those macro decisions that face all governments and it offers methodologies for analysis of the issues and for deciding which intervention strategies to pursue.

This is a separate part of the risk equation. Much risk work looks at individual risks in isolation, seeking to understand those risks and what can be done to prevent or control them. But those risks do not exist in isolation and this report is one contribution to addressing the bigger picture extending across a range of risks.

A-4 Complex Hazards Examples

A-4.1 Nuclear Safety (IAEA, HSE)

Area of Risk: Risk from the operation of nuclear power plant and other nuclear reactors.

Relevant Documents: 'The Safety of Nuclear Installations' (IAEA 1993)[41]; 'Basic Safety Principles for Nuclear Power Plants. A report by the International Nuclear Safety Advisory Group (INSAG-12)' (IAEA 1999)[42]; 'The Tolerability of Risk from Nuclear Power Stations' (HSE 1992).

Relevant Authorities: The International Atomic Energy Agency (IAEA), the OECD Nuclear Energy Agency, national nuclear regulators (the US Nuclear Regulatory Commission, the UK Nuclear Installations Inspectorate etc.).

Rationale and Context: The responsibility for the safety of nuclear power stations rests with the operators of those stations. Governments and their appointed regulators have the responsibility of setting the standards for safety and ensuring that those standards are enforced. Licensing is an integral part of that approach.

The International Atomic Energy Agency (IAEA) is a UN body with three main areas of work:

- Safety and Security;
- Science and Technology; and
- Safeguards (i.e. in relation of non-proliferation of nuclear material) and Verification.

The IAEA adopts a range of principles, standards etc. to be used by the Agency itself in its international assistance programmes and by member states in their national programmes.

41 This document can be viewed at http://www-pub.iaea.org/MTCD/publications/PDF/Pub938e_scr.pdf.
42 View this document at http://www-pub.iaea.org/MTCD/publications/PDF/P082_scr.pdf.

Overall Approach:

General Objectives: The IAEA has defined three safety objectives for nuclear plant[43]. These are:

- ***General Nuclear Safety Objective:*** *To protect individuals, society and the environment from harm by establishing and maintaining in nuclear power plants an effective defence against radiological hazards.*
- ***Radiation Protection Objective:*** *To ensure in normal operations that radiation exposure within the plant and due to any release of radioactive material from the plant is as low as reasonably achievable, economic and social factors being taken into account, and below prescribed limits, and to ensure mitigation of the extent of radiation exposure due to accidents.*
- ***Technical Safety Objective:*** *To prevent with high confidence accidents in nuclear plants; to ensure that for all accidents taken into account in the design of the plant, even those of very low probability, radiological consequences, if any, would be minor; and to ensure that the likelihood of severe accidents with serious radiological consequences is extremely small.*

Risk Assessment: The UK Health and Safety Executive's document 'The Tolerability of Risk from Nuclear Power Stations' (HSE 1992) gives detailed general guidance on risk assessment. The risk assessment for nuclear plant should cover two main aspects – the risk from normal operations and the risk from accidents. The risk assessment will identify the main risks, the actions that are or will be taken to prevent or reduce those risks and the residual risks that remain. The risk assessment has to be submitted to the regulator who may insist on additional precautions.

There has to be a systematic approach to the risk assessment:

- Plant reliability and the risk of plant failures have to be measured or calculated in some way so far as is possible.
- Judgements will be needed on what reinforcements will be needed for the unexpected or possible uncertainties in the calculations of reliability etc.
- Judgements will also be needed on how much redundancy to build in.
- Design diversity guards against inherent design faults.
- When figures are used, they should be on the cautious side.
- The qualities of the plant and of the operational procedures need to be part of the assessment.

When quantifying risk, it is necessary to be clear as to whom or what group of people the figure applies. This requires further detailed analysis:

- Distinguish between risks to workers and to the general public.
- The public around the plant may be more vulnerable in some areas than others, e.g. due to the direction of the prevailing wind.
- Societal risks need to be considered too. Societal risks are risks to society as a whole. In a sense they represents the broader detriment caused by a major accident. They can cover the risk of output from the plant as well as the anxiety that follows major incidents.

Risks from normal operations: The risks from normal operations are primarily those from low doses of radiation. There are legally prescribed limits on exposure set down in European legislation, based on

43 Drawn from 'Safety of Nuclear Installations', p.2/3.

the work of the International Commission on Radiological Protection (ICRP); operators are, however, expected to keep the exposure of workers as low as reasonably practicable (ALARP).

The risk assessment will examine the operation of the plant against those standards and the ALARP requirement. It will need to look at the various activities undertaken by workers, e.g. inspection and repair work, the handling of waste liquid or gas etc., and the measures taken to keep workers' exposure below the limits.

Risks from accidents: The broad principles covering the risk assessment in relation to accidents are set out above. In practice, the risk assessment will need to address:

- The risk of plant failure (use of Probabilistic Safety Analysis/ Quantified Risk Assessment).
- Safety-critical computing systems.
- Natural events, e.g. the impact of an earthquake or drought.
- Human factors.
- The safety culture (starting at the top of the organisation).
- Safety in operation. The effectiveness of the control systems in preventing the system being operated outside its safety limits.
- Mitigation and emergency procedures.

Safety Management – Fundamental Principles: The IAEA report 'Basic Safety Principles for Nuclear Power Plants', INSAG-12, sets out a number of principles that are key to sound control of risks from nuclear plant. They concern management, defence in depth and technical issues.

Management responsibilities: Three fundamental principles are set out[44]:

- **Safety Culture Principle:** *An established safety culture governs the actions and interactions of all individuals and organisations engaged in activities related to nuclear power.*
- **Responsibility of the Operating Organisation Principle:** *The ultimate responsibility for the safety of a nuclear power plant rests with the operating organisations. This is in no way diluted by the separate activities and responsibilities of designers, suppliers, contractors, constructors and regulators.*
- **Regulatory Control and Independent Verification Principle:** *The government establishes the legal framework for a nuclear industry and an independent regulatory organisation which is responsible for licensing and regulatory control of nuclear power plants and for enforcing the relevant regulations. The separation between the responsibilities of the regulatory organisation and those of other parties is clear, so that the regulators retain their independence as a safety authority and are protected from undue pressure.*

Defence in Depth: A central principle is defined and two supplementary principles on accident prevention and accident mitigation[45]:

- **Defence in Depth Principle:** *To compensate for potential human and mechanical failures, a defence in depth concept is implemented, centred on several levels of protection including successive barriers preventing the release of radioactive material to the environment. The concept includes protection of the barriers by averting damage to the plant and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case these barriers are not fully effective.*

44 Drawn from 'Basic Safety Principles for Nuclear Power Plants', pp. 12-16.
45 Ibid, pp. 17-22.

- **Accident Prevention Principle:** *Principal emphasis is placed on the primary means of achieving safety, which is the prevention of accidents, particularly any which could cause severe core damage.*
- **Accident Mitigation Principle:** *In-plant and off-site mitigation measures are available and are prepared for that would substantially reduce the effects of an accidental release of radioactive material.*

General Technical Principles: A number of these have been formulated. This note will not set out the detail but the principles concerned:

- Proven Engineering Practices;
- Quality Assurance;
- Self-assessment;
- Peer Reviews;
- Human Factors;
- Safety Assessment and Verification;
- Radiation Protection;
- Operating Experience and Safety Research;
- Operating Excellence.

Licensing: A key element of the approach to nuclear safety is that the relevant inspectorate (in the UK, the Nuclear Installations Inspectorate) has to license nuclear activity. This involves the inspectorate in all aspects of nuclear operations - the design of new plant, modifications to existing plant, start-up of operations, changes to operating procedures, even changes in the staffing of nuclear plant, and any plans for decommissioning. The nuclear operators have to provide an operating safety case and, if the regulator is not satisfied, the installation may be closed down.

A-4.2 Major Hazard Industries (EU, HSE)

Area of Risk: Risk from explosions, fire, loss of containment etc. at major industrial plants that pose significant hazards to the local and possibly regional community.

Relevant Documents: EU Council Directive 96/82/EC on the Control of Major-Accident Hazards Involving Dangerous Substances[46] (Sveso II), 1996. This is applied more widely than the EU and similar approaches are used elsewhere in the world.

Relevant Authorities: Parliament, Council and Commission of the European Union; competent authorities in Member States.

Rationale and Context: Modern industrial societies need industrial plants to process chemicals into both intermediary and final products. These plants both use and store substantial quantities of chemicals, and failures in storage or in the operation of these plants can lead to explosions or releases that can cause serious damage, not just to workers at the plant but to the surrounding population and environment. And, depending on the physical nature of substances released and prevailing environmental conditions, the impact can extend considerably, e.g. downwind from a plant or along the course of a river. These effects do not respect frontiers.

46 See the Official Journal of the European Union, No. L 010 of 14 January 1997 or view this Directive at http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31996L0082&model=guichett.

The very serious dioxin release at Sveso in Italy in 1976 and other industrial accidents, such as the Flixborough Explosion in the UK in 1974, were major drivers for the first European Directive on major accident hazards (the Sveso Directive) in 1982. The Bhopal disaster in 1984 and a major release of chemicals into the Rhine from a chemical plant in 1986 led to a revision of the 1982 Directive; the Sveso II Directive was agreed in 1996. That Directive also enables the European Union to comply with the United Nations Economic Commission for Europe (UNECE) Convention on the Transboundary Effects of Industrial Accidents (2000)[47].

Overall Approach:

The Directive has essentially two aims – to prevent risks from major accident hazards[48] and to mitigate the impact of those hazards both to man and to the environment if they were to materialise. The scope goes beyond plant manufacturing of hazardous substances and also covers other operations that involve the storage of significant quantities of dangerous chemicals.

The Directive differentiates between lower-tier and higher-tier sites depending on the quantities of chemicals held. Operators of both types of sites need to notify the competent authority in their country and to have a Major Accident Prevention Policy.

Guidance from the HSE (part of the UK Competent Authority for the Directive) on the Major Accident Prevention Policy for lower tier sites includes the following[49]:

The MAPP will usually be a short and simple document setting down what is to be achieved but it should also include a summary and further references to the safety management system that will be used to put the policy into action. The detail will be contained in other documentation […] to which the MAPP can refer.

The MAPP also has to address issues relating to the safety management system. […] the key areas are:

- *organisation and personnel*
- *identification and evaluation of major hazards*
- *operational control*
- *planning for emergencies*
- *monitoring, audit and review.*

Operators of higher-tier sites need to prepare a Safety Report and to demonstrate that they have an adequate Safety Management System and Emergency Plan. HSE guidance on Safety Reports says that[50]:

The safety report must include:

- *a policy on how to prevent and mitigate major accidents;*
- *a management system for implementing that policy;*
- *an effective method for identifying any major accidents that might occur;*

47 View this Convention at http://www.unece.org/env/teia/text.htm.
48 In effect this means, for human risks, to reduce the risks to a level as low as reasonably practicable (ALARP) and for environmental risks to use the best available technology not entailing excessive cost (BATNEEC).
49 Accessible at http://www.hse.gov.uk/comah/background/comah99.htm#BACKGROUND, sub-section ‘Prepare a major accident prevention policy‘.
50 Accessible ibid, sub-section ‘Prepare a safety report’.

- *measures (such as safe plant and safe operating procedures) to prevent and mitigate major accidents;*
- *information on the safety precautions built into the plant and equipment when it was designed and constructed;*
- *details of measures (such as fire-fighting, relief systems and filters) to limit the consequences of any major accident that might occur; and*
- *information about the emergency plan for the site, which is also used by the local authority in drawing up an off-site emergency plan.*

Annex 2 to the Directive, which deals with minimum data and information to be considered in the Safety Report, includes a section on risk assessment (although that is not the term used): this says that the safety report should have a section on identification and accidental risks analysis and prevention methods. This section should cover[51]:

A. detailed description of the possible major-accident scenarios and their probability or the conditions under which they occur including a summary of the events which may play a role in triggering each of these scenarios, the causes being internal or external to the installation;
B. assessment of the extent and severity of the consequences of identified major accidents;
C. description of technical parameters and equipment used for the safety of installations.

National competent authorities give more detail on the risk assessment. These assessments will naturally be complex and will involve uncertainties; Safety Cases have to be structured so that the risk assessments are transparent and how they have been addressed is clear. HSE Guidance sets out the steps that need to be taken within the risk assessment[52]:

a. Understand the site operations, the materials involved and the process conditions;
b. Identify the hazards to people on-site and off-site and the environment;
c. Analyse the different ways the hazards can be eliminated, reduced in scale, realised and controlled;
d. For the hazards that remain, predict the likelihood of the hazards being realised taking account of the chance of success and failure of possible preventive measures;
e. Predict the corresponding consequences both when mitigation measures work and fail;
f. Analyse the associated risks and the options implicit in (d) and (e) for reducing them.
g. Decide which measures need to be implemented to make the risks to people and the environment as low as reasonably practicable (ALARP);
h. Present the results of the risk assessment to provide the evidence and arguments which demonstrate that all measures necessary have been taken to prevent and mitigate major accidents.

The Guidance then makes clear that the Safety Report needs to show how risk assessment is used to decide what measures to take to reduce the risk or mitigate the consequences. The Guidance also emphasises the need to take human factors into account.

Note that neither the Directive nor the HSE Guidance prescribes the risk assessment methodology to use; but the operator will need to justify the methodology to the regulator.

An important aspect of the Directive concerns the involvement of local planning authorities. Operators must draw up an Internal Emergency Plan; they have to send it to the local planning authority to enable

51 Annex II to Council Directive 96/82/EC, IV. A-C.

52 Accessible at http://www.hse.gov.uk/hid/land/comah2/pt2ch3.htm#Principles, Section on 'General Guidance for Assessment of Predictive Elements', No. 7.

the authority to draw up an External Emergency Plan. In addition, the Directive obliges local authorities to take the major hazard plant into account in their land use planning, for example in relation to the siting of new establishments, the development of transport routes etc. The aim in the longer term is to ensure adequate distance between major hazard plant and residential areas.

Comments: The Control of Major Hazard Industries is an ongoing challenge for modern society. Cutting edge risk assessment is used to identify risks and to predict consequences. But the key to the overall approach is to place responsibility on operators, not just to control their risks but also to be able to demonstrate to the Competent Authorities that they have done so. The whole approach, to be successful, should be seen as a collaborative effort in which both parties continue to learn.

A-4.3 Food Safety (FAO/WHO Codex Alimentarius Commission)

Area of Risk: Food-related risk to human health.

Relevant Documents: 'Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius' (Codex Alimentarius Commission 2003)[53].

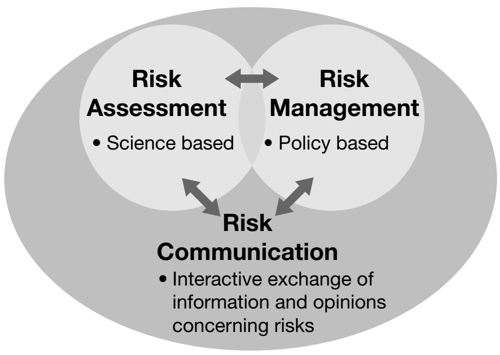
Relevant Authorities: Codex Alimentarius Commission.

Rationale and Context: The Codex Alimentarius Commission develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. *The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations*[54].

The Commission in July 2003 agreed the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. The aim is that *food safety and health aspects of Codex standards and related texts are based on risk analysis*[55].

Overall Approach:

Diagram 2: Risk Analysis Framework



(Source: WHO website at http://www.who.int/foodsafety/micro/riskanalysis/en/index.html)

53 View these at http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y4800E/y4800e0o.htm.
54 Accessible at the Codex Alimentarius website at http://www.codexalimentarius.net/web/index_en.jsp.
55 Working Principles, paragraph 2 (Section 'Scope').

The Working Principles say that risk analysis comprises three distinct components[56]:

- Risk assessment: *A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.*
- Risk management: *The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.*
- Risk communication: *The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.*

The Working Principles set out how the risk analysis should be undertaken[57]:

- *The three components should be documented fully and systematically in a transparent manner.*
- *Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.*
- *The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.*
- *There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest.*
- *Precaution is an inherent element of risk analysis. […] The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis.*

The Working Principles distinguish between risk assessment and risk assessment policy. The Working Principles state that:

Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.[58]

Risk Assessment: The Working Principles say that risk assessment should[59]:

- *Be based on all available scientific data* (quantitative if available; may also take into account qualitative information).
- *Take into account relevant production, storage and handling practices used throughout the food chain*.
- *Seek and incorporate relevant data from different parts of the world* […]. Epidemiological surveillance data, and analytical and exposure data should be sought and, if such data is not available from developing countries, then work should be put in hand.
- Consider c*onstraints, uncertainties and assumptions* relevant to the risk assessment *at each step in the risk assessment*. These should be documented.
- Be *based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy.*

56 Ibid, Annex I ('Definitions').
57 Drawn from ibid, paragraphs 4-12 (Section 'Risk Analysis – General Aspects').
58 Ibid, paragraph 14 (in Sub-section 'Risk Assessment Policy').
59 Drawn from ibid, paragraphs 20-24 (in Section 'Risk Assessment).

The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded.[60]

Risk Management: the primary objective of risk management should be the protection of consumers (notwithstanding that the Codex Alimentarius has dual purposes – protecting the health of consumers and ensuring fair trade practices)[61].

The structured approach to risk management should include[62]:

- Preliminary risk management activities. These should include *identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment*[63]*.*
- An evaluation of risk management options. This, with the risk assessment and the outcome of work on the preliminary risk management activities, should enable decisions to be taken on the management of the risk.
- Monitoring.
- A review of the decision taken.

Risk management should[64]:

- take into account relevant production, storage and handling practices used throughout the food chain;
- be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented;
- ensure transparency and consistency in the decision-making process in all cases, in order to avoid unjustified trade barriers;
- take into account the economic consequences and the feasibility of risk management options; and
- recognise the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

Risk Communication[65]**:** the Working Principles emphasise that the primary purpose of risk communication is to ensure the decision-making process takes account of all relevant information. This requires transparency and the active involvement of interested parties. The Working Principles also recognise that it is important that the Codex work on risk analysis is accessible more widely and that communication is essential to doing so.

Comment: The Working Principles have to be applied by national governments (and regional bodies such as the European Union). The World Trade Organisation can police the application of the Principles to ensure that they are not being used to protect trade (as opposed to protecting human health).

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60 Drawn from ibid, paragraph 25 (in Section 'Risk Assessment).
61 See ibid, paragraph 27 (in Section 'Risk Management').
62 Drawn from ibid, paragraphs 28 (in Section 'Risk Management').
63 Ibid, Footnote 122, attached to paragraph 28 (in Section 'Risk Management').
64 See ibid, paragraphs 28-36 (in Section 'Risk Management').
65 See ibid, paragraphs 37-41 (Section 'Risk Communication').

A-4.4 Emerging Risks in the 21st Century (OECD IFP)

Area of Risk: Systemic risks, i.e. those risks that may affect the major systems on which society depends; for example, natural disasters, industrial accidents, infectious diseases, terrorism and food safety.

Relevant Documents: 'Emerging Risks in the 21st Century – An Agenda for Action' (OECD 2003).

Relevant Authorities: Organisation for Economic Cooperation and Development (OECD), and in particular its International Futures Programme (IFP).

Rationale and Context: There is increasing concern about systemic risks in and to modern society. The OECD had identified a range of disasters that had impacted on society in recent years, e.g. severe metrological conditions, new diseases (SARS, AIDS etc.), critical breakdowns in infrastructures such as electricity blackouts in Europe and the USA, etc. The IFP studied the impact of such events on modern society with a view to identifying more effectively the challenges facing OECD countries and helping them to devise strategies to deal with these risks.

Overall Approach:

The methodology is […] an unconventional one. First, it endeavours to tackle the issue of systemic risks in a future oriented manner by examining the trends and driving forces shaping the risk landscape in the next few decades. Second […] it looks at the vulnerability of vital systems. And third, it examines a range of major risks across almost the entire risk management cycle […].[66]

The Report identifies four forces that modify systemic risks:

- Demography;
- The environment;
- Technology; and
- Socio-economic structures.

The report sees these as impacting on risk management in terms of heightened mobility and complexity, increased scale and concentration, shifting responsibilities and a changing context associated with major uncertainties. In addition, through all this, risk perception increases in importance.

Risk assessment in relation to emerging systemic risks faces a number of challenges:

- Difficulties in assessing risks scientifically (e.g. existing models are inadequate, long-term consequences often neglected, human behaviour difficult to evaluate);
- Difficulties in determining the level of risk that is appropriate (given uncertainties, perceptions etc.).

In looking at risk prevention, the report addresses a range of issues including:

- Protecting systems in advance.
- The range of frameworks for risk prevention (from centralised command-and-control to decentralised self-regulation).
- Emergency management.
- The efficiency and effectiveness of emergency services and disaster recovery.

66 Drawn from introduction and summary of the Emerging Risks Report, p 9.

The Report proposes a framework for a systemic approach to emerging systemic risks:

- A new policy approach to risk management – adopting a broader view on risk, ensuring policy consistency across risk areas, improving the coherence of risk management.
- Developing synergies between the public and private sectors – including getting the incentives right and enhancing the role of the private sector.
- Informing and involving stakeholders and the general public – developing better risk awareness and building trust.
- Strengthening international cooperation – more and better sharing of knowledge and technologies; enhancing international systems of surveillance and monitoring; frameworks for cooperation.
- Making better use of technology and research – support for new technologies that may reduce risks; working to develop tools to improve the resilience and reduce the vulnerability of systems.

Comment: This OECD study brought together experts from around the world. This report was part of the background to the OECD's support for the establishment of the International Risk Governance Council and the issues addressed by the report dovetail well with the developing work of the IRGC.

A-5 Natural Forces Examples

A-5.1 UN Report 'Living with Risk'

Area of Risk: Risks associated with natural disasters, particularly those impacting on the developing world.

Relevant Documents: 'Living with Risk – A global review of disaster reduction initiatives'. (United Nations 2004)[67].

Relevant Authorities: the United Nations Inter-Agency Secretariat of the International Strategy for Disaster Reduction (UN/ISDR). The Report builds on the work of International Decade for Natural Disaster Reduction (1990 – 1999) and of the International Strategy for Disaster Reduction (started 2000).

Rationale and Context: There has been a significant growth in the number of (what the insurance industry call) major loss events. There were 850 such events in 2000 which was 100 more than in 1999. And *the 84 great natural disasters recorded in the 1990s number three times as many as those that occurred in the 1960s*[68].

The Living with Risk Report proposes a strategic shift from disaster management practices towards an integrated disaster risk reduction approach. It stems from a growing recognition that *modern societies [cannot] afford to value their social and material assets only after they have been lost in a disaster*[69]. It also reflects a further recognition that *whilst natural phenomena causing disasters are in most cases beyond human control, vulnerability is generally a result of human activity*[70].

The work aims to promote *much greater attention to implementation of protective strategies which can contribute to saving lives and protecting property and resources before they are lost*[71].

67 View this report at http://www.unisdr.org/eng/about_isdr/bd-lwr-2004-eng.htm.
68 Living with Risk Report, p. 3.
69 Ibid, p. 7
70 Ibid, p. 7.
71 Ibid, p. 7.

Overall Approach:

Although not a methodology in terms of how risks are characterised, the ISDR work does recommend an approach to strengthen the capacity to manage risks through increasing awareness and resilience (see graphic schema at the end of this section).

Detail of approach: The approach distinguishes, in looking at risk factors, between hazards and vulnerability:

- Hazards include not just primary hazards such as cyclones or earthquakes but also secondary hazards, e.g. surges, flash floods and landslides. It emphasises that the most serious damage often comes from these secondary hazards.
- Vulnerability is a key message in the approach and a primary objective is to *minimise exposure to hazards through the development of individual, institutional and societal capacities that can withstand loss or damage*[72]. It is noted that vulnerability is shaped by a whole range of factors (e.g. socio-economic, cultural and political) which influence individuals, families, communities and countries.

The Report illustrates vulnerability with a wide range of examples from around the world.

Risk assessment (i.e. the boxes in Diagram 3 dealing with 'Vulnerability/capability analysis', 'Hazard analysis and monitoring' and 'Risk identification and impact assessment') is given special attention. *Risk assessment is a required step for the adoption of adequate and successful disaster reduction policies and measures*[73] (Principle 1 of the 1994 Yokohama Strategy and Plan of Action for a Safer World).

The Living with Risk Report notes that risk assessment includes[74]:

- *Identifying the nature, location, intensity and probability of a threat;*
- *Determining the existence and degree of vulnerabilities and exposure to those threats;*
- *Identifying the capacities and resources available to address or manage threats; and*
- *Determining acceptable levels of risk.*

The **approach to disaster risk reduction** then, on the basis of the risk identification and impact assessment, concentrates on capacity building and resilience. The Report addresses:

- Policy and Commitment;
- National institutional frameworks;
- The role of local authorities;
- Regional cooperation;
- Community action;
- Building understanding;
- Information management;
- Networking;
- Training and education etc.

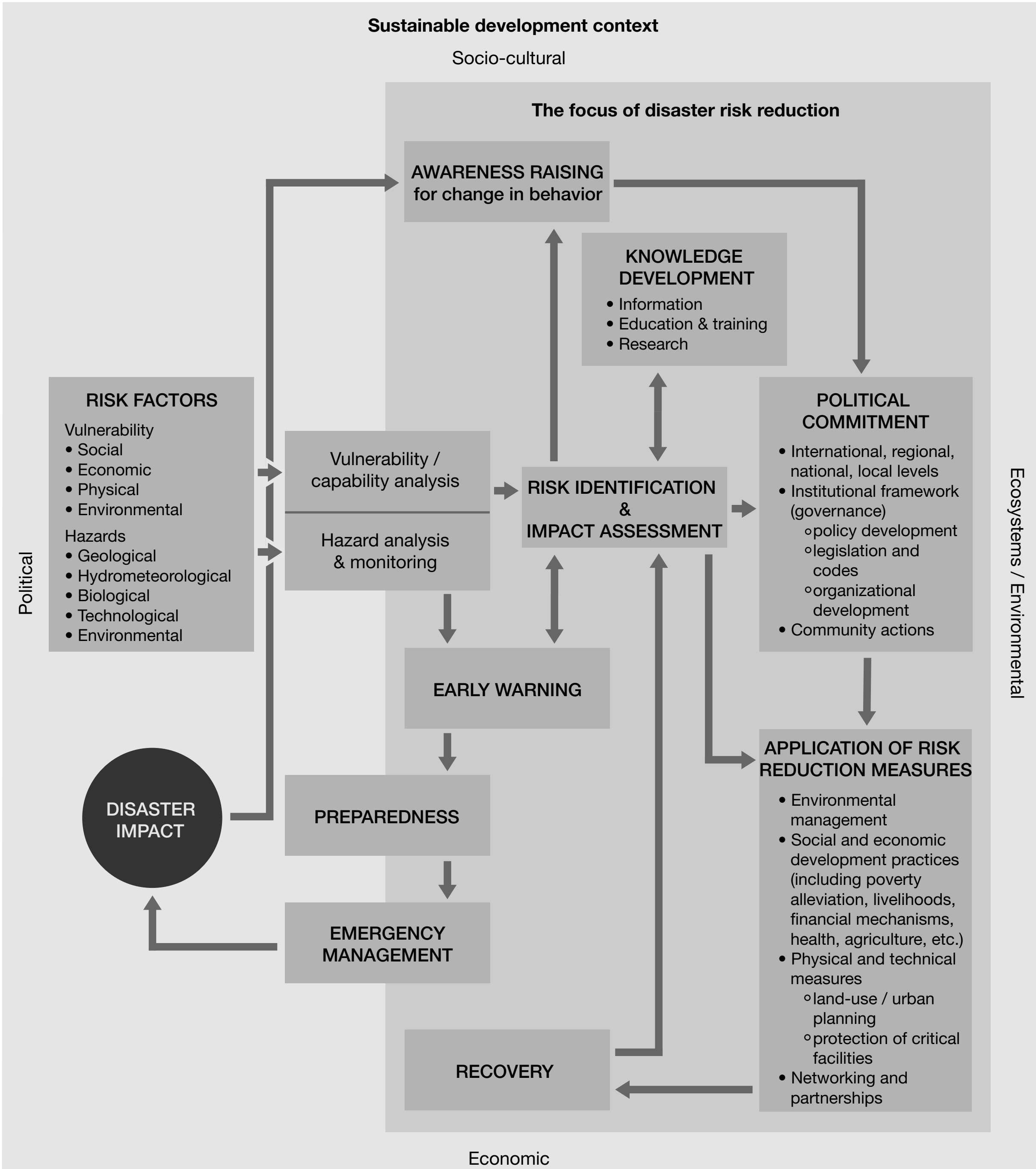
It notes *disaster risk management must be the responsibility of governments. However its success also depends on widespread decision making and the participation of many others. Policy direction and*

72 Ibid, p. 41.
73 Accessible at http://www.unisdr.org/eng/about_isdr/bd-yokohama-strat-eng.htm.
74 Ibid, p. 63.

legal foundation assure legitimacy but it is the professional and human resources available, on the ground, that are a true measure of success.[75]

Governance Considerations in Approach: This approach recognises the value of engagement across society, of improving the understanding of the risk and disasters, and of organising prevention activity at all levels of society. It is about changing how governments approach these issues and very much reflects current thinking on governance.

Diagram 3: Framework for Disaster Risk Reduction



(Source: 'Living with Risk – A global review of disaster reduction initiatives', p.15. (United Nations 2004))

75 Ibid, p. 80.

A-5.2 Strategies for Managing Global Environmental Risk (WBGU)

Area of Risk: Essentially environmental risks – but widely defined and including, for example, dependence of human society on a limited number of crop types.

Relevant Documents: 'World in Transition – Strategies for Managing Global Environmental Risks' (1998 Annual Report) (WBGU 1998)[76].

Relevant Authorities: German Advisory Council on Global Change (WBGU; established in 1992 by the Federal Ministers for Research and Technology and for Environment, Nature Conservation and Reactor Safety)[77].

Rationale and Context: This Report builds on previous Annual Reports from the German Advisory Council which each focussed on a particular aspect of global change. This Report aims to look at the overall 'domain' of global risks. It recognises that *(i)n a globally intermeshed world, in which disasters can assume global proportions more rapidly than ever before, letting events run their course and mitigating any damage that may arise is not an ethically acceptable principle*[78]. The global nature of many current environmental risks is such that even if the probability of events is low, *timely counterstrategies are essential*[79].

The Council sees a strong need to have a targeted, rational and efficient approach to dealing with real hazards; and this requires a more rational and objective international debate.

Overall Approach:

This approach offers eight criteria for evaluating risks and then proposes a set of classifications for risk, based on those criteria; those classifications in turn provide guidance on strategies for managing the risks.

The eight criteria are:

- Extent of damage: Adverse effects in natural units, e.g. death, injury, production loss etc.
- Probability of occurrence: Estimate of relative frequency, which can be discrete or continuous.
- Incertitude: How do we take account of uncertainty in knowledge, in modelling of complex systems or in predictability in assessing a risk?
- Ubiquity: Geographical dispersion of damage.
- Persistence: How long will the damage last?
- Reversibility: Can the damage be reversed?
- Delay effects: Latency between initial event and actual damage.
- Potential for mobilisation: The broad social impact. Will the risk generate social conflict or outrage etc.?

76 View the Annual Report at http://www.wbgu.de/wbgu_jg1998_engl.pdf.
77 For more information on WBGU see http://www.wbgu.de/wbgu_home_engl.html.
78 Annual Report, p. 3.
79 Ibid, p. 3.

The risk classes are then defined in terms of the probability of occurrence (P) and the extent of damage (E) and the strength of the reliability of estimates of P and E:

Tableau 1: Overview of Risk Classes

Risk Class	Characterisation	Examples
Damocles	Probability low, high reliability of estimate; extent of damage high, high reliability of estimate	nuclear energy, dams, floods
Cyclops	Probability unknown, reliability of estimate unknown; extent of damage is high and reliability of estimate is high	Earthquakes, AIDS infections, collapse of Gulf Stream
Pythia	Probability is unknown, reliability of estimate unknown; extent of damage is unknown but potentially high and reliability of estimate is unknown	BSE/nvCJD infection, self reinforcing global warming
Pandora	Probability is unknown, reliability of estimate is unknown. Effect is unknown (only assumptions) and reliability of estimation of effect is high. Long delay of consequences	Persistent organic pollutants, endocrine disrupters
Cassandra	Probability is high, reliability of estimates tends to be low. Effect tends to be high and the reliability of the estimation of effect tends to be high, too, with long delay of consequences	Gradual human induced climate change, destabilisation of terrestrial ecosystems
Medusa	Probability tends to be low, reliability of estimate tends to be low. Effect tends to be low and reliability of estimate of effect tends to be high. Mobilisation, i.e. social concern potential, is high	Electromagnetic fields

(Source: 'World in Transition – Strategies for Managing Global Environmental Risks' (WBGU 1998 Annual Report), own compilation)

The Report then develops strategies for dealing with risks in each risk class.

For Damocles, the main problem is the high disaster potential; the strategy for dealing with such risks concentrates on reducing disaster potential, strengthening resilience and effective disaster management.

For Cyclops, where probabilities are unknown but impact is high, the first priority in the strategy when managing such risks is determining the probability of occurrence, which requires research. The second priority is *preventing undesirable surprises and safeguarding society against these*[80]; this may point to compulsory insurance. The third priority is disaster management.

For the Pythia risk class, where there is high uncertainty over both probability and severity, the strategy should be focussed on precautionary measures, for example using As Low As Reasonably Achievable (ALARA) approaches. A further element in the strategy is to improve knowledge of the risks.

80 Ibid, p. 14.

For the Pandora risk class, the main problem is the uncertainty of both the probability and the extent of damage, in conjunction with high degrees of persistence and ubiquity; therefore, the strategy for dealing with Pandora risks should concentrate on developing substitutes, regulating the amount of substances used and their dispersal, and the planning of emergency management.

For the Cassandra risk class, where the probability is clear but potential damage comes with long time lags and where there is little public concern, the strategy should work to strengthen long-term responsibility through collective commitments, e.g. international conventions. It should also work to reduce the risk by encouraging the development of alternatives, e.g. products, technologies etc.

For the Medusa risk class, where there is low probability but often high social mobilisation, the strategy should be aimed at *building confidence and improving knowledge to reduce the remaining uncertainties*[81]. This requires more than just education.

The Report also addresses risk communication and emphasises that the purpose of the communication should determine the form and approach to communications. The report recognises the need to address personal, social and cognitive factors in risk communication and that *neglecting these dimensions regularly leads to the confusion of comprehension and acceptance*[82].

The Report contains a wealth of detail including many case studies that illustrate the general principles and the proposed approaches.

A-6 Standards Examples

A-6.1 Australian/New Zealand Standard on Risk Management

Area of Risk: All risks in principle. *A generic framework for establishing the context, identification, analysis, evaluation, treatment, monitoring and communication of risk*[83]*.*

Relevant Documents: Australian/New Zealand Standard on Risk Management (AS/NZS 1999)[84].

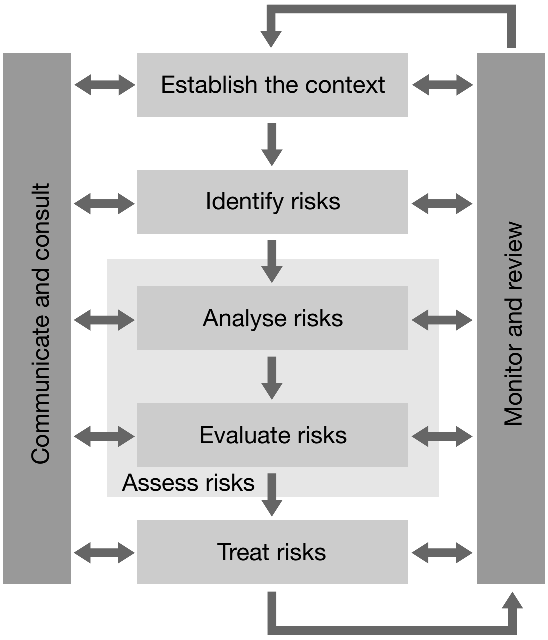
Relevant Authorities: Joint Technical Committee for Council of Standards for Australia and the Council of Standards New Zealand; March/April 1999.

Rationale and Context: The Australian and New Zealand Councils for Standards have produced this Standard for general use across society. The Handbook based on the Standard is aimed at a wide range of activities including the public sector, commercial operations, voluntary organisations and non-government organisations[85].

81 Ibid, p. 17.
82 Ibid, p. 251.
83 Australian/New Zealand Risk Management Standard, p. iii.
84 In order to buy a copy of this standard go to http://www.riskmanagement.com.au/Default.aspx?tabid=148.
85 Purchasing details at http://www.riskmanagement.com.au/Products/TheHandbook/tabid/157/Default.aspx.

Overall Approach:

Diagram 4: Risk Management Overview



(Source: Australian/New Zealand Standard on Risk Management, p. 8. (AS/NZS 1999))

Detail of Approach: The above diagram sets out the principle components of the approach. The approach provides a structured framework to organisations to manage risks as part of the overall management process. The Standard emphasises that *risk management is a multifaceted process, appropriate aspects of which are often best carried out by a multi-disciplinary team. It is an iterative process of continual improvement.*[86]

Establish the context: The Standard identifies five aspects to this[87]:

- **The strategic context:** defining *the relationship between the organisation and its environment*, including internal and external stakeholders.
- **The organisational context:** understanding *the organisation and its capabilities, as well as its goals and objectives and strategies in place to achieve them.*
- **The risk management context:** *setting the scope and boundaries for the application of the risk management process,* i.e. defining the project or activity, including extent in time and location, and establishing its goals and objectives.
- **Developing risk evaluation criteria:** Deciding *the criteria against which risk is to be evaluated*. This involves decisions on risk acceptability and risk treatment and may be based on operational, technical, financial, legal, social, humanitarian or other criteria.
- **Defining the structure:** *separating the activity or project into a set of elements […]* to *provide a logical framework for identification and analysis*.

86 Australian/New Zealand Risk Management Standard, p. 7.
87 Drawn from ibid, pp. 9-12.

Risk identification: Identifying the risks to be managed; this involves a well-structured systematic process:

- **What can happen?**
- **How and why it can happen?**
- **Tools and techniques:** for example, checklists, judgements based on experience and records, flow charts, brainstorming etc.

Risk analysis: *The objectives […] are to separate the minor acceptable risks from the major risks, and to provide data to assist in the evaluation and treatment of risks*[88]*.* Steps are[89]:

- **Determining existing controls:** *Identify existing management, technical systems and procedures to control risks and assess their strengths and weaknesses.*
- **Consequences and likelihood:** Assess these in the context of existing controls and then combine consequences and likelihood to produce a level of risk. Detailed advice on information sources and techniques to use. An annex gives a 5x5 matrix qualitative approach to handling degrees of consequence and likelihood.
- **Types of analysis:** Degree of refinement may depend on the risk information and data available. *Analysis may be qualitative, semi-quantitative or quantitative*; guidance given on each of these.
- **Sensitivity analysis:** Used *to test the effect of changes in assumptions and data.*

Risk evaluation: *Involves comparing the level of risk found during the analysis process with previously established risk criteria […]. The output of risk evaluation is a prioritised list of risks for further action […]. If risks fall into low or acceptable risk categories, they may be accepted with minimal further treatment […]. If [they do not], they should be treated using one or more of the options in the next section.*[90]

Risk treatment: *Identifying […] options, assessing those options, preparing risk treatment plans and implementing them*[91]:

- **Identifying options for risk treatment:** this sets out a series of options:
  - Avoid risk by not proceeding with activity;
  - Reduce the likelihood of occurrence;
  - Reduce consequences;
  - Transfer risk;
  - Retain the risk.
- **Assessing risk treatment options:** Selecting most appropriate options involves balancing costs against benefits. *In general, the adverse impact of risk should be made as low as reasonably practicable, irrespective of any absolute criteria*[92]. Prioritisation is necessary when costs of all risk treatments exceed budgets.
- **Preparing treatment plans:** this should *identify responsibilities, schedules, the expected outcomes of treatments, budgeting, performance measures and a review process […]*[93]*.*
- **Implementing treatment plans:** Ideally by those best able to control the risk.

88 Ibid, p. 12.
89 Drawn from ibid, pp. 13-15.
90 Drawn from ibid, p. 15/16.
91 Ibid, p. 16.
92 Ibid, p. 18.
93 Ibid, p. 19.

Monitoring and review: Monitoring the risks, the effectiveness of the risk treatment plan etc. Ongoing review to ensure the management plan remains relevant.

Communication and consultation[94]**:** *Important […] at each step of the risk management process*. Importance of *developing communication plans for both internal and external stakeholders at an early stage*. Emphasis on two way dialogue with efforts focussed on consultation. Need for awareness of perception of risks.

Comment: A very general and generic approach. Valuable as an overall structure but does not address in any detail issues such as uncertainty, different characteristics of risk such as ubiquity or persistence. Nor does it cover societal aspects of risk in any detail – although it refers to perceptions of risk and the fact that these need to be detailed and understood.

Our understanding is that although it is clearly framed in the context of Australian and New Zealand society and economies, i.e. developed countries, the methodology has gained wide acceptance in the Pacific Basin and is used in many of the countries in that region.

A-6.2 FERMA Risk Management Standard

Area of Risk: Broad scope but essentially aimed at business sector risks. Note that this Standard is aimed at enabling organisations to add value to their activities. It is not just about stopping or minimising the impact of negative events: it encourages organisations to establish their tolerance of, or appetite for, risk.

Relevant Documents: FERMA adopted Standard 'A Risk Management Standard' (FERMA 2002)[95].

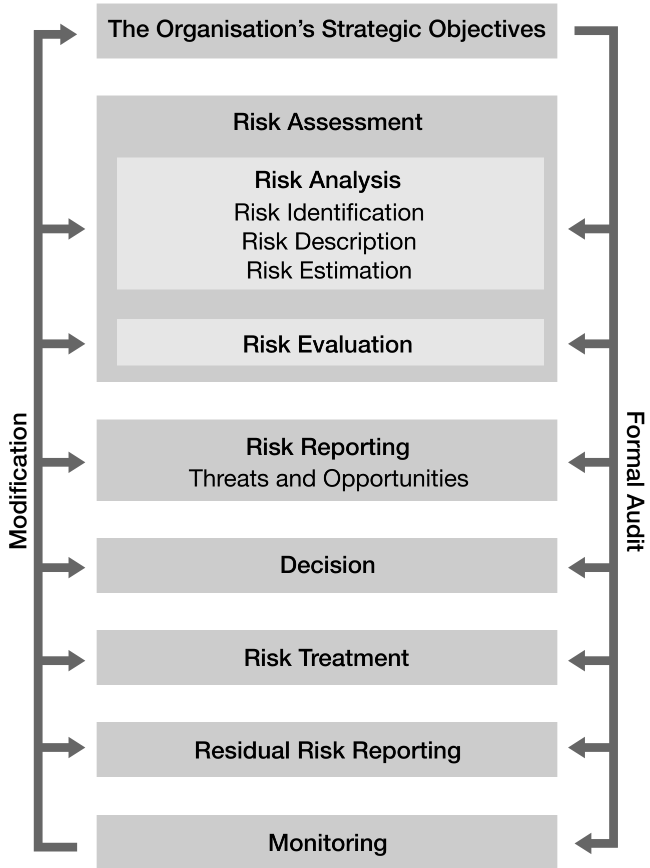
Relevant Authorities: The Federation of European Risk Management Associations (FERMA) adopted in 2003 the Risk Management Standard published in the UK in 2002. That Standard is the work of three UK risk management bodies[96] – the private and public sector risk management associations, AIRMIC[97] and ALARM[98], and the Institute of Risk Management[99].

Overall Approach:

The below diagram sets out the overall approach adopted in the Standard.

94 Drawn from ibid, p. 20.
95 This Standard can be viewed in electronic format and retrieved from FERMA's website at: http://www.ferma-asso.org/Risk%20Managers%20section/Entreprise%20Risk%20Management%20Corporate%20Governance/RM%20standard%20UK.15.11.04.pdf.
96 See http://www.ferma-asso.org/4-14.html.
97 The Association of Insurance and Risk Managers (AIRMIC) (http://www.airmic.com/).
98 The National Forum for Risk Management in the Public Sector (ALARM) (http://www.alarm-uk.com/).
99 See http://www.theirm.org/.

Diagram 5: The Risk Management Process



(Source: 'A Risk Management Standard', p. 5. (FERMA 2002))

Detail of Approach: The Standard uses the ISO/IEC Guide 73 (ISO 2002) definition of risk assessment as the overall process of risk analysis and risk evaluation.

Risk analysis comprises[100]:

- Risk identification – this *sets out to identify an organisation's exposure to uncertainty.* This needs to cover the organisation itself, its market and the environment in which it operates.
- Risk description – *display(ing) the identified risks in a structured format*.
- Risk estimation monitoring – covering both opportunities and threats in a structured manner. This can involve quantitative, semi-quantitative and qualitative approaches.
- Risk analysis methods and techniques – the Standard offers a range of techniques, covering both 'upside' and 'downside' risks.
- Risk profile: This assigns *a significance to each risk and provides a tool for prioritising risk assessment effort*.

Risk evaluation involves comparing *the estimated risks against the risk criteria that the organisation has established. Risk criteria may include associated costs and benefits, legal requirements, socio-economic and environmental factors […].*[101]

100 Drawn from FERMA Risk Management Standard, pp. 6-9.
101 Ibid, p. 10.

Risk treatment *is the process of selecting and implementing measures to modify the risk*[102]. Risk control and mitigation are clearly important but the Standard also expects risk treatment to include consideration of risk avoidance, risk transfer, etc.

Risk reporting and communication deals with both internal and external reporting. External reporting is very much in terms of maintaining stakeholder and shareholder confidence that risks are being managed.

Comment: The Standard is very much aimed at internal controls and management approaches. It clearly reinforces corporate governance but not wider governance considerations.

A-7 Government Examples

A-7.1 USA – Red Book; Presidential/Congressional Commission Report; NRC Report 'Understanding Risk'

Area of Risk: The Red Book (1983) dealt with the risk of cancer and other health effects associated with exposure to toxic substances. The Presidential/Congressional Commission which reported in 1997 concentrated on human health hazards from chronic exposure to environmental agents and on ecological risk assessment. The 1996 NRC Report 'Understanding Risk' took a much broader canvas of risk and addressed risk characterisation, including social, behavioural, economic and ethical aspects of risk as well as scientific and technical issues.

Relevant Documents: 'Risk Assessment in the Federal Government: Managing the Process' (so-called 'Red Book') (National Research Council 1983)[103]. 'Framework for Environmental Health Risk Management' (final report) (Presidential/Congressional Commission 1997)[104]. 'Understanding Risk: Informing Decisions in a Democratic Society' (National Research Council 1996)[105].

Relevant Authorities: For the Red Book, the Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, the US National Research Council. The US Presidential/Congressional Commission on Risk Assessment and Risk Management was appointed by the White House and the Congress of United States. It was mandated in the 1990 Clean Air Act, appointed 1993/4 and reported in 1997. For Understanding Risk, the Committee on Risk Characterisation, the Commission on Behavioural and Social Sciences and Education, the US National Research Council.

The Red Book and the Presidential/Congressional Commission's work concern the actions of a number of Federal Agencies – the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Safety and Health Agency (OSHA) and the Consumer Product Safety Commission (CPSC). The Understanding Risk work was supported by the EPA, the US Nuclear Regulatory Commission, the Departments of Defence, Health and Human Services, Agriculture, and Energy as well as some non-governmental organisations (e.g. the Chemical Manufacturers Association).

102 Ibid, p. 10.
103 The Red Book can be bought at http://www.nap.edu/openbook.php?record_id=366&page=17.
104 See http://www.riskworld.com/riskcommission/Default.html for details about the Commission and online access to the report.
105 The Understanding Risk Report is available at http://www.nap.edu/openbook.php?record_id=5138&page=1.

The Red Book:

Overall Approach: This report is primarily concerned with improving the scientific validity of risk assessment. It emphasises the need to separate risk assessment and risk management.

The Report uses the term **risk assessment** to mean *the characterization of the potential adverse health effects of human exposures to environmental hazards*[106]*.* It says that it comprises four major steps[107]:

- *Hazard identification*
- *Dose-response assessment*
- *Exposure assessment*
- *Risk characterization*

Risk management is seen as *the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision*[108]*.*

The Report recognises the inherent limitations in making conclusive risk assessment conclusions. Uncertainty (of probability, health effects, etc.), limited analytical resources and the sheer complexity of the assessment mean that the process of reaching conclusions is difficult; this can be compounded by external pressures (e.g. public opinion, economic interests, congressional action). The Report's conclusions for institutional reform were focussed on *reorganization to ensure that risk assessments are protected from inappropriate policy influences* and on the *development and use of uniform guidelines for carrying out risk assessments*[109]*.* It recommended[110]:

- *Regulatory agencies to take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives.*
- *Uniform inference guidelines [should] be developed for the use of federal regulatory agencies in the risk assessment process.*

The Report makes clear that the purpose of inference guidelines is to specify *a predetermined choice among the options that arise in inferring human risk from data that are not fully adequate or not drawn directly from human experience*[111]*.* This would mean a move away from an approach in *which inference options are selected on a substance-by-substance basis*[112].

Governance Considerations in Approach: This report dates from 1983 and is concerned essentially with the use of science to reach decisions on risk from toxic substances. It does not bring in issues such as stakeholder engagement in these debates (although the later US Presidential/Congressional Commission on Risk Assessment and Risk Management does deal with this in some detail).

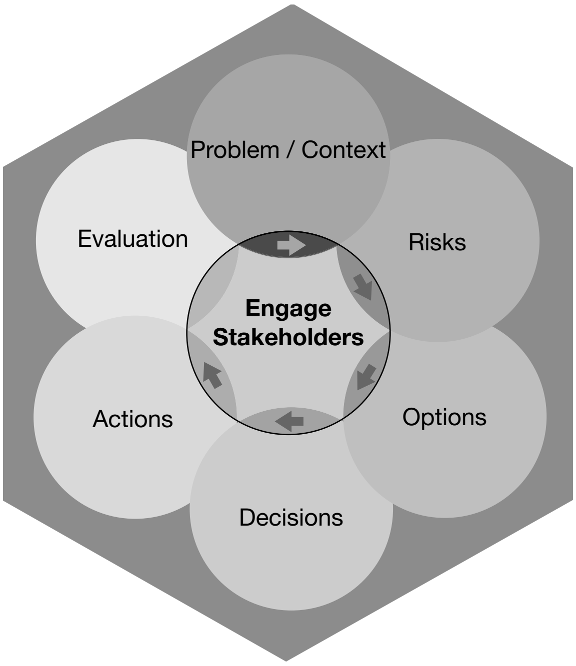
106 Red Book, p. 18.
107 Ibid, p. 19/20.
108 Ibid, p. 3.
109 Ibid, p. 14.
110 Drawn from ibid, p. 7.
111 Ibid, p. 4.
112 Ibid, p. 51.

US Presidential/Congressional Commission on Risk Assessment and Risk Management:

Overall Approach: The Commission was charged with examining the use of risk assessment and risk management in regulatory programmes aimed at preventing cancer and other human health effects caused by exposure to hazardous substances. It aimed to tackle issues inherent in multiple exposures and to get away from the then predominant regulatory approach of dealing with one chemical at a time. It therefore concentrates on how to undertake risk assessment and risk management in practice; in particular, it aimed to develop creative, integrated strategies that address multiple environmental media and multiple sources of risk.

The diagram below encapsulates the Framework it proposed.

Diagram 6: Framework for Risk Management



(Source: 'Framework for Environmental Health Risk Management', Volume 1, p. 3. (Presidential/Congressional Commission 1997))

The report claims that the Framework is general enough to work in a wide variety of situations – the level of effort and resources invested being scaled to the importance of the problem, potential severity and economic impact of the risk, the level of controversy surrounding it, and resource constraints.

The **Problem context** involves[113]:

- *Identifying and characterising [the] […] problem, or […] potential problem […]*
- *Putting the problem in its public health or ecological context*
- *Determining risk management goals*
- *Identifying risk managers […]*
- *Implementing a process for engaging stakeholders*

113 Drawn from 'Framework for Environmental Health Risk Management', p. 7.

Analysing the risks involves both risk assessment and risk characterisation. The risk management goals should influence the focus and extent of the risk assessment. The risk assessment should be *performed by considering intrinsic hazards, the extent of exposure and information about the relationship between exposures and responses*[114]. Given that there is seldom enough information, *risk assessors have to use a combination of scientific information and best judgement*[115].

A risk characterisation, which is the outcome of the risk assessment, should typically address the following:

- Nature and likelihood of the health risk and individuals or groups at risk;
- Severity of anticipated adverse effects or impacts;
- Whether effects are reversible;
- Strength of the scientific evidence;
- Uncertainty about nature or magnitude of risk;
- Other sources of same type of risk;
- Distribution of risk in relation to other risks;
- Other impacts, e.g. social or cultural.

Examining options: *This stage involves identifying potential risk management options (both regulatory and non-regulatory) and evaluating their effectiveness, feasibility, costs, benefits, unintended consequences, and cultural or social impacts.* […]. *Stakeholders can play an important role in all facets of identifying and analysing options.*[116]

Making a decision: This addresses:

- Who decides?
- What is the best decision?
  - This needs to take account of the best available scientific, economic and other information and of the multi-source/multi-chemical/multi-risk context.
  - Priority should be given to preventing risks, not just controlling them.
  - Risk management options should be feasible with benefits closely related to costs.
  - Need for sensitivity to socio/political/cultural considerations.
- What happens if there is not enough information to make a decision?

Taking action: The Framework advocates a wide range of stakeholders playing roles in order to improve the chances of success. These may include public bodies, community groups, business, unions, citizens etc. Such stakeholders can assist in developing action plans, in communicating with affected parties and in monitoring.

Evaluating results: This should cover evaluation both of the risk management actions and of the process leading to implementation.

Governance Considerations in Approach: Consultation and engagement with stakeholders is a key element of the approach, especially in the framing of the problem/context – note the arrows in the diagram and especially the bold arrow for Problem/Context. The approach is also about overall effectiveness, i.e. taking all risks and sources of risks into account.

114 Ibid, p. 24.
115 Ibid, p. 24.
116 Drawn from ibid, p. 29.

'Understanding Risk: Informing Decisions in a Democratic Society':

Overall Approach: The work of the Committee is targeted on risk characterisation. This stage of the risk assessment process is seen as critical; but it often suffers from over-simplification or a skewing of the results which in turn means that it might not address key concerns and could reduce trust in the risk analysis. The Report looks at how risk characterisation might be improved so that it fosters informed decision making and helps settle controversies over risk; it looks at both technical aspects and how to incorporate relevant social, economic, behavioural and ethical aspects.

The Report rejects the idea of risk characterisation being just *a summary or translation of the results of a technical analysis for the use of a decision maker*[117]. As well as the risks of misleading scientific and technical information, such an approach does not enable the risk characterisation to cover *the overall process of comprehending and dealing with risk*[118]. The Report envisages instead *a process in which the characterization of risk emerges from a combination of analysis and deliberation*[119]*.* To this end it sets out seven principles[120]:

1. *Risk characterization should be a* ***decision-driven activity****, directed towards informing choices and solving problems.* (So the risk characterisation should be for those involved in risk decisions and not just the decision taker(s).)
2. *Coping with a risk situation requires a* ***broad understanding*** *of the relevant losses, harms, or consequences to the interested and affected parties.* (This means that risk characterisations should, where appropriate, address socio-economic, ecological and ethical outcomes. If needed they should address particular populations rather than just the whole population. Perspectives of interested and affected parties should be brought in.)
3. *Risk characterization is the outcome of an* ***analytical-deliberative process****.* (This principle goes on to describe features of that process, e.g. appropriate systematic analysis, responding to the needs of affected parties, treatment of uncertainties, deliberations that focus on the problem and on improving understanding and participation.)
4. *Those responsible for a risk characterization should begin by developing a provisional* ***diagnosis of the decision situation*** *so that they can better match the analytic-deliberative process leading to the characterization to the needs of the decision [...].* (The Report notes that the level of effort that should go into the process is situation dependent, as is the breadth of participation. But it also notes that using the wrong process can undermine the decision-making process.)
5. *The analytical-deliberative process leading to a risk characterization should include early and explicit attention to* ***problem formulation****; representation of […] interested and affected parties at this stage is imperative.*
6. *The analytical-deliberative process should be mutual and recursive.* (In other words, it should be iterative between analysis and deliberation).
7. *Each organization responsible for making risk decisions should work to build organizational capability to conform to the principles of sound risk characterization.* (The application of this principle may involve staff training, the recruitment or engagement of specific expertise, and possible organisational change. Evaluation of current activities can inform future work on risk characterisation.)

117 Understanding Risk Report, p. 1.
118 Ibid, p. 1.
119 Ibid, p. 1/2.
120 Drawn from ibid, pp. 2-9.

Comment: These three reports, although clearly very influential, are only a small part of the material about approaches to risk in the US. There is much more material available on risk analysis, risk assessment and risk characterisation in the documents and on the web sites of US regulatory bodies such as the EPA and OSHA. The EPA has a Risk Characterization Handbook[121], produced in 2000, which draws on the reports covered in this summary as well as much other material.

A-7.2 UK – Report 'Risk: Improving Government's Capability to Handle Risk and Uncertainty'

Area of Risk: Covers all aspects of the management of risk by government. This includes government's role in handling material risks such as BSE and how government manages risks to the delivery of its programmes.

Relevant Documents: 'Risk: Improving government's capability to handle risk and uncertainty' (UK Cabinet Office 2002)[122].

Relevant Authorities: UK Prime Minister's Strategy Unit; November 2002.

Rationale and Context: The BSE Inquiry in 2000 raised questions about how government should identify and manage risk. The National Audit Office had also published reports in 2000 and 2001 which highlighted the need for improvements in government's handling of risk more widely. The Cabinet Office Report was the UK government's response. It was undertaken at a time when broader public service reform was under consideration and it was influenced by, and influenced, that work.

Overall Approach:

Diagram 7: The Risk Management Process

(Source: 'Risk: Improving government's capability to handle risk and uncertainty', p. 44. (UK Cabinet Office 2002))

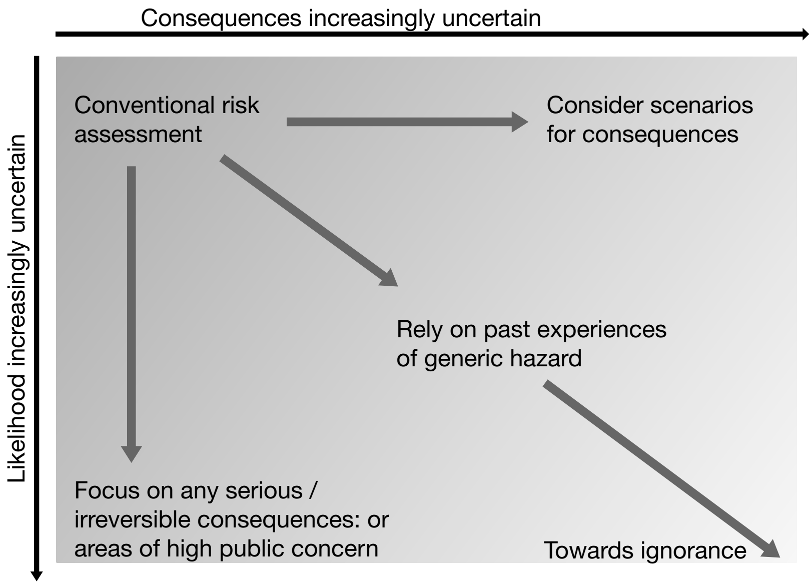
121 View the handbook at http://epa.gov/osa/spc/htm/rchandbk.pdf.
122 View this report at http://www.number-10.gov.uk/SU/RISK/REPORT/downloads/su-risk.pdf.

Detail of Approach: Set very much in the context of what government itself can do. The overall approach proposes attention to five broad areas[123]:

- **What could happen (identification).** This will involve *rigorous assessment of trends, possibilities, dangers, their likelihood and impact*.
- **What matters (assessment).** *Judgements […] on the desirability or otherwise of different outcomes taking account for example of the importance of the reliability of a service, the advantages to be gained from an innovation […]*.
- **What can be done (action).** *Having established what matters, government then needs to plan ways to avoid, mitigate, anticipate and otherwise cope with the potential risk, and to plan for uncertainty*.
- **What has happened (review).** *Having taken initial action, government needs to assess whether it has had the intended effect, whether the assessment of risks needs to change and what further action is needed*.
- **Communication and learning:** This supports all the above and involves communication *both with those potentially affected by the risks and with those who can help manage the risks*.

The above covers the range of risks facing government. It has to take account of uncertainty:

Diagram 8: Risk Assessment and Uncertainty

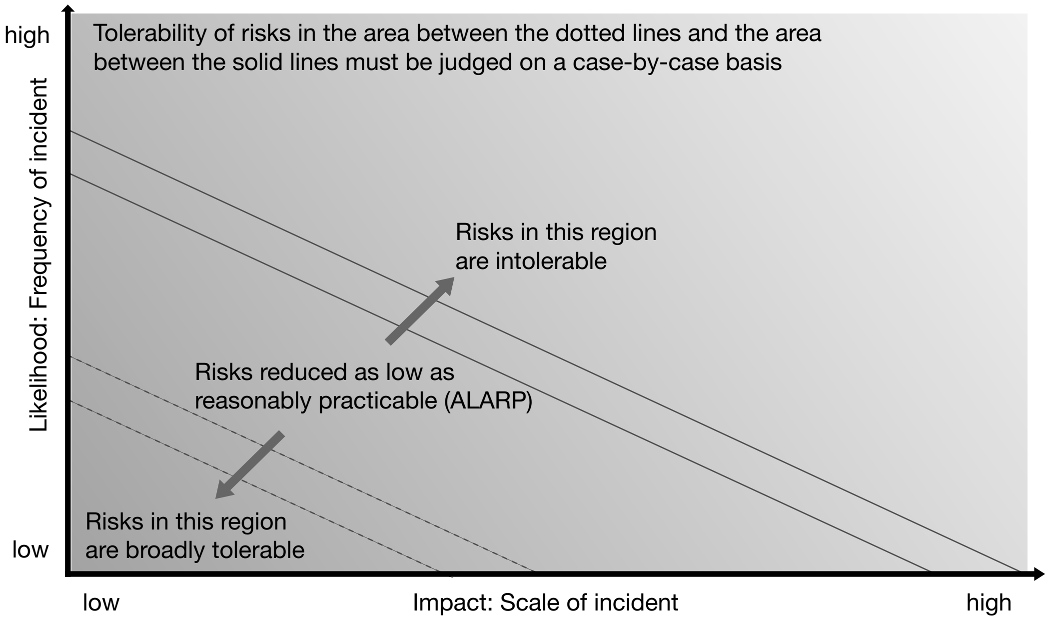


(Source: 'Risk: Improving government's capability to handle risk and uncertainty', p. 47. (UK Cabinet Office 2002))

123 Drawn from UK Cabinet Office Report on Risk, p. 6.

Government equally has to consider the appetite for risk:

Diagram 9: Responding to Risk – Tolerability and ALARP



(Source: 'Risk: Improving government's capability to handle risk and uncertainty', p. 50. (UK Cabinet Office 2002))

The document recognises that government has a number of roles, including a regulatory role. Regulation may in some circumstances be part of the way the risk is managed. Government's other roles are 'stewardship' and 'management'; these have an equally important part in the overall approach.

The Report concluded with six recommendations[124]:

1. *Handling risk should be firmly embedded in government's policy making, planning and delivery.*
2. *Government's capacity to handle strategic risks should be enhanced.*
3. *Risk planning should be supported by good practice, guidance and skills development.*
4. *Departments and agencies should make earning and maintaining public trust a priority when dealing with risks to the public.*
5. *Ministers and senior officials should take a clear lead in improving risk handling.*
6. *The quality of government risk management should be improved through a two-year programme of change, linked to the Spending Review timetable and clearly set in the context of public sector reform.*

A programme was set up to ensure that the Cabinet Office Report was followed through. A final report to the Prime Minister on that programme in December 2004[125] concluded that there had been significant progress: in particular, many systematic efforts had been made to address key areas of risk and this started having an impact on service delivery (e.g. in dealing with fraud or smuggling). The report also said, however, that more needed to be done.

124 Drawn from ibid, pp. 105-109.

125 The report can be viewed at http://www.hm-treasury.gov.uk/media/D70/A0/risk_programme.pdf.

Governance Considerations in Approach: A range of considerations are brought out in the report, including:

- Government to publish its principles for handling risks to the public.
- Government to follow five principles in managing risks to the public:
  - Openness and transparency;
  - Engagement;
  - Proportionality and precaution;
  - Evidence;
  - Responsibility.

Comment: This report and action plan is not about how better to assess and deal with individual risks. It is more about government better recognising that managing risk is a key part of its business and setting an agenda to improve risk handling, including better equipping departments to identify and manage risks and to ensure more integrated approaches across government.

A-8 Finance and Trade Examples

A-8.1 World Trade (WTO)

Area of Risk: All risks whose possible management or control has an impact on international trade.

Relevant Documents: This summary concentrates on WTO work on the application of Sanitary and Phytosanitary measures as set out in the 'Agreement on the Application of Sanitary and Phytosanitary Measures'[126] (WTO 1995).

Relevant Authorities: The World Trade Organisation[127].

Rationale and Context: Negotiations in the World Trade rounds are aimed at liberalising world trade, i.e. removing barriers to trade of all sorts. The World Trade Organisation is responsible for administering the agreements on world trade; disputes can be arbitrated in the World Trade Court. Some of the disputes over whether constraints on trade are legitimate centre on the interpretation of risk. The Agreement on Sanitary and Phytosanitary Measures, part of the Uruguay Round of Trade Agreements, *concerns the application of sanitary and phytosanitary measures — in other words food safety and animal and plant health regulations*[128]. The Agreement is intended to work alongside the work of the Codex Alimentarius Commission, the World Organisation for Animal Health, and the international and regional organisations operating within the framework of the International Plant Protection Convention.

The Agreement recognises that governments have the right to take sanitary and phytosanitary measures but that they should be applied only to the extent necessary to protect human, animal or plant life or health and should not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail […]. Members may maintain or introduce measures which result in higher standards [to those set in international standards etc.] if there is scientific justification or as a consequence of consistent risk decisions based on an appropriate risk assessment. The Agreement spells out procedures and criteria for the

126 View this Agreement at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.
127 For more information on WTO see http://www.wto.org/index.htm.
128 Accessible at the WTO website at http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#bAgreement (rubric summarising the Uruguay Agreements).

assessment of risk and the determination of appropriate levels of sanitary or phytosanitary protection.[129]

Overall Approach: The essential requirements in the Agreement on risk assessment and risk management are[130]:

1. *[Ensuring that] sanitary or phytosanitary measures are based on an [appropriate] assessment […] of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.*
2. Risk assessments should *take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and, quarantine or other treatment.*
3. *In assessing the risk […] and determining the measure to be applied […], Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.*
4. *Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects. […]*
7. *In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. […].*

Further sections deal with avoiding arbitrary or unjustifiable measures if they result in discrimination or a disguised restriction on trade, with ensuring that measures are no more trade restrictive than they need to be, and the need to supply explanations when requested.

More detailed guidance on the WTO says[131]:

Members must establish SPS measures on the basis of an evaluation of the actual risks involved. The parameters used in such risk analyses commonly include substantial safety margins as a precautionary measure. […]. The SPS Agreement encourages the use of a systematic approach to risk assessment. […]. Risk assessments may be qualitative or quantitative. Quantitative risk assessment in particular can be a costly process requiring expertise, and an adequate sanitary infrastructure, and this may not always be within the reach of countries with budget constraints and scarce resources. This implies that there are significant advantages in adopting established international standards.

It also deals with precautionary measures[132]:

The SPS Agreement allows Members to take precautionary measures in cases of emergency and when sufficient scientific evidence does not yet exist to support definitive measures. For example, following the BSE scare in 1996, and in the absence of sufficient scientific evidence, several emergency bans were immediately introduced. However, these emergency measures should only be provisional. Within a reasonable period of time, governments must seek the additional information needed to carry out a more objective assessment of the risks involved, and review their measures accordingly.

129 Drawn from ibid.
130 Drawn from Article 5 of the Agreement.
131 Accessible at http://www.wto.org/english/thewto_e/whatis_e/eol/e/wto03/wto3_28.htm#note1 (Section 'The Process').
132 Ibid (Section 'Exceptions').

Comment: The Agreement on Sanitary and Phytosanitary Measures is just one agreement in the Uruguay Round and its application has to be seen in the context of the Uruguay Round as a whole. But the Agreement illustrates well the general principles that the WTO applies in dealing with the tension between safety measures and trade based on risk assessment. The WTO's role in relation to safety measures extends far wider than sanitary and phytosanitary measures. For example a few years ago the WTO was involved in adjudicating on whether bans on various white asbestos products were legitimate under its rules; that debate centred on risk assessment.

A-8.2 Banking Supervision (Basel Committee on Banking Supervision)

Area of Risk: International supervision of banking regulation across countries.

Relevant Documents: Basel Accord, plus amendments and related documents (Basel Committee on Banking Supervision 1988-2004)[133].

Relevant Authorities: The Basel Committee on Banking Supervision was set up by the G 10 countries and Luxembourg to:

- *define the roles of regulators in cross-jurisdictional situations;*
- *ensure that international banks or bank holding companies do not escape comprehensive supervision by a "home" regulatory authority;*
- *promote uniform capital requirements so banks from different countries may compete with one another on a "level playing field"* [134].

Rationale and Context: The Basel Committee was established following a debacle in 1974 when a German bank was put into liquidation and a number of payments to that bank in Deutschmarks for exchange into US Dollars were lost because of time zone differences and the fact that the Bank ceased to trade before the US Dollar payments were scheduled to be paid. The Basel Committee has no legislative authority but the participating countries are in practice bound by the agreements.

The 1988 Basel Accord, amended in 1996 in the light of experience, sets out minimal capital requirements for banks; these became law in G-10 countries in 1992. The focus of that Accord was the credit risk associated with deposit taking and lending. A second accord, Basel II, dealing with operational risk, was finalised in 2004 and is to come into effect in December 2006.

This summary does not seek to look at the complex models and approaches used in the banking sector to deal with these risks. It restricts itself to the overall models underpinning this work and our aim is primarily to enable a comparison with the handling of other (non-financial) risks that concern the IRGC.

Overall Approach:

Credit risk[135]**:** Credit risk arises *from uncertainty in a counterparty's ability to meet its obligations*. The counterparties can range from individuals to governments and the obligations from car loans to derivative transactions. There are essentially three components to the risk:

133 These can be viewed at http://www.bis.org/publ/bcbs.htm.

134 Accessible at http://www.riskglossary.com/articles/basle_committee.htm#1988%20Basle%20Accord, a webpage called 'Risk Glossary' which summarises the approach of the Basel Committee.

135 Drawn from ibid, rubric on credit risk (http://www.riskglossary.com/articles/credit_risk.htm).

- Default probability: in other words, how probable is it that the counterparty will default on its obligation?
- Credit exposure: if there is a default, how large will the exposure (i.e. initial loss) be?
- Recovery rate: what proportion of the loss might be recovered, e.g. through bankruptcy or other proceedings?

In this, it is important to assess the **credit quality** of a counterparty: this is their ability to meet their obligations and it covers both their default probability and the anticipated recovery rate.

In assessing the credit quality of a counterparty, credit analysts will review information about the counterparty, e.g. balance sheets and other financial information, as well as the nature of the obligation (e.g. is it secured?). On the basis of this, a **credit rating** may be assigned. There are various systems of credit rating; Standard and Poor's, which is widely used, is set out at the end of this summary.

Managing or mitigating credit risk is an essential part of banking. One widely used tool is **credit risk limits** that are used by the banks to specify how much exposure they will accept from a particular counterparty. These may include industry or country credit risk limits as well as limits for individual counterparties. Credit risk limits can be 'hedged' with more complex financial tools such as credit derivatives. (Indeed, the financial sector uses 'hedging' as an almost generic means of managing risk.)

Operational risk[136]**:** These are those stemming from other than credit and market risks. They include employee errors, system failures, loss of physical assets, e.g. through fire or flood, and criminal fraud. The challenge for the Basel Committee was to find a way to manage these risks that was comparable with their initiatives on credit risk.

It was recognised that there were essentially two subgroups of risk:

- Low outcome but frequent risks.
- Substantial outcome but infrequent.

It was also established that most such risks were best managed locally, i.e. within the department in which they arose.

In terms of assessing the risks, both qualitative and quantitative methods could be used:

- Qualitative methods could include loss event reports, management oversight, employee feedback, internal audit.
- Quantitative methods have been developed to allow banks to assign charges for operational risks, and Basel II allows large banks to develop their own models.
- Models for infrequent but potentially catastrophic risks could be built on those used by the insurance industry while risks happening more often can be analysed statistically.

The Basel Committee has promoted **risk indicators** to help banks in identifying the general level of operational risk. Risk indicators could include *backroom staff overtime, staffing levels, daily transaction volumes, employee turnover rates and systems downtime*. These then need to be related, if possible, to loss events.

136 Drawn from ibid, rubric on operational risk (http://www.riskglossary.com/link/operational_risk.htm).

Managing the operational risks could involve:

- Avoiding some risks.
- Accepting others but mitigating their consequences.
- Simply accepting some risks as part of doing business.

Specific measures might involve:

- employee selection and training;
- close management oversight;
- segregation of duties;
- purchase of insurance;
- exiting certain businesses; and
- the capitalisation of risks.

Tableau 2: Standard and Poor's Credit Ratings

AAA	Best credit quality—Extremely reliable with regard to financial obligations.
AA	Very good credit quality—Very reliable.
A	More susceptible to economic conditions—still good credit quality.
BBB	Lowest rating in investment grade.
BB	Caution is necessary—Best sub-investment credit quality.
B	Vulnerable to changes in economic conditions—Currently showing the ability to meet its financial obligations.
CCC	Currently vulnerable to nonpayment—Dependent on favorable economic conditions.
CC	Highly vulnerable to a payment default.
C	Close to or already bankrupt—payment on the obligation currently continued.
D	Payment default on some financial obligation has actually occurred.

This is the system of credit ratings Standard & Poor's applies to bonds. Ratings can be modified with + or – signs, so a AA– is a higher rating than is an A+ rating. With such modifications, BBB– is the lowest investment grade rating. Other credit rating systems are similar. Source: Standard & Poor's.

(Source: 'Risk Glossary' website at http://www.riskglossary.com/link/credit_risk.htm)

A-9 Corporate Governance and Enterprise Risk Management Example

A-9.1 UK Combined Code on Corporate Governance and COSO Framework

Area of Risk: Risk to business of all types, be they environmental, health and safety, financial, to corporate reputation etc.

Relevant Documents: 'The Combined Code on Corporate Governance' (Financial Services Agency 2003)[137]. 'Enterprise Risk Management – Integrated Framework' (COSO 2004)[138].

Relevant Authorities: The UK Financial Services Agency; Committee of Sponsoring Organisations of the Treadway Commission.

Rationale and Context: Corporate governance concerns how business manages itself. It aims to improve confidence in corporate structures for the benefit of stakeholders, for example, investors, employees, consumers etc. Recent prominent business failures in a range of countries, along with widespread public and media concern about aspects of corporate management (for example, large severance pay to those who appear to have presided over significant business failure, misleading corporate data) have led to a strengthening of corporate governance provisions in many countries. The UK Combined Code is just one example. The COSO Framework is not strictly about just corporate governance – it concerns enterprise risk management; but its application will strengthen corporate governance.

The Combined Code addresses five main aspects of corporate management:

- The role and performance of directors;
- Remuneration of both executive and non-executive directors;
- Accountability and audit;
- Relations with shareholders; and
- Role of institutional investors.

Actions in all these areas are aimed at reducing risk in one way or another. However Principle C2 of the Code deals specifically with internal control; it says:

The Board should maintain a sound system of internal control to safeguard shareholders' investment and the company's assets[139].

The Combined Code contains specific guidance on internal control and risk management (The Turnbull Guidance) aimed at supporting companies in implementing that Principle. The summary below deals with the Turnbull Guidance.

The COSO Framework was developed during the recent period of significant business failures and scandals. COSO already had an Integrated Framework for Internal Control and the new Framework is set firmly in the context of enterprise risk management. The foreword suggests that companies may want to use the Framework to cover both internal control and to *move towards a fuller risk management process*[140].

137 View this document at http://www.fsa.gov.uk/pubs/ukla/lr_comcode2003.pdf.

138 The framework is for purchase at the American Institute of Certified Public Accountants (AICPA) (http://www.aicpa.org/pubs/tpcpa/nov2004/coso.htm); an executive summary can be viewed on the COSO website at http://www.coso.org/Publications/ERM/COSO_ERM_ExecutiveSummary.pdf.

139 Combined Code, p. 15.

140 COSO Framework Summary, p. v.

Overall Approach:

The Combined Code:

The need for an effective internal control system is set out succinctly in paragraph 13 of the Guidance[141]:

A company's objectives, its internal organisation and the environment in which it operates are continually evolving and, as a result, the risks it faces are continually changing. A sound system of internal control therefore depends on a thorough and regular evaluation of the nature and extent of the risks to which the company is exposed. Since profits are, in part, the reward for successful risk-taking in business, the purpose of internal control is to help manage and control risk appropriately rather than to eliminate it.

The Guidance does not prescribe the form of the system of internal control, rather it sets out factors that are important in deciding what form the system should take. Those factors include[142]:

- *The nature and extent of the risks facing the company;*
- *The extent and categories of risk which [the company] regards as acceptable for the company to bear;*
- *The likelihood of the risks concerned materialising;*
- *The company's ability to reduce the incidence and impact on the business of the risks that do materialise;* and
- *The costs of operating particular controls relative to the benefit.*

The Guidance makes clear that the overall process involves[143]:

- Risk assessment (in terms of whether risks are significant);
- Control and mitigation measures;
- Information and communication; and
- Monitoring the effectiveness of the system.

It also sets out the responsibilities of the Board for ensuring the effectiveness of the system of internal control, making it clear that the Board should receive regular reports on internal control and should review the significant risks and the associated control measures. It should report annually.

The COSO Integrated Framework for Enterprise Risk Management:

The Framework describes Enterprise Risk Management as follows[144]:

Enterprise risk management is a process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.

141 Combined Code, Section on 'Guidance on Internal Control (The Turnbull Guidance)', paragraph 13, p. 31.
142 Ibid, paragraph 17, p. 32.
143 See ibid, paragraph 21, p. 33.
144 COSO Framework Summary, p. 2.

The Framework is aimed at addressing[145]:

- *The organisations objectives:*
  - *Strategic*
  - *Operational*
  - *Reporting*
  - *Compliance*
- *[…]*
- *The Components of Enterprise Risk Management:*
  - *Internal Environment (how risk is viewed)*
  - *Objective setting*
  - *Event identification (both external and internal, and identifying risks and benefits)*
  - *Risk assessment (analysis, likelihood and impact)*
  - *Risk response (e.g. avoiding, accepting, reducing, sharing)*
  - *Control activities*
  - *Information and communication*
  - *Monitoring*

The Framework uses a three-dimensional matrix to illustrate the direct relationship between the objectives and the components of enterprise risk management and its application in each of the business's units (which includes the overall business, business divisions, units and subsidiaries).

The Framework says that whether the enterprise risk management is 'effective' will need to be based on a decision on whether all the risk management components are operating effectively in each of the categories of business objectives.

The Framework warns that there are limitations to the effectiveness of enterprise risk management, e.g. through human failures, poor decisions or even simple errors. It emphasises that everyone in an entity should have some responsibility (obviously different at different levels) for enterprise risk management; and that external parties may provide important information that contributes to decision making.

Comment: Other frameworks and approaches contribute to effective corporate governance; for example, the risk management framework adopted by FERMA (the Federation of European Risk Management Associations). It is the responsibility of directors and boards to satisfy themselves that the appropriate measures are in place to identify, assess and deal with significant risks affecting the business (as opposed to putting those measures in place which are not necessarily appropriate to their responsibilities).

145 Drawn from ibid, p. 3/4.

A-10 References

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ANNEX B – AN OVERVIEW OF RISK TERMINOLOGY (BY TERMS)

Broadly Acceptable Risk:

The risk is truly negligible in comparison with other risks that the individual or society runs. (HSE Tolerability of Risk)

Damage:

The destruction, diminution or impairment of concrete or abstract values. (German Advisory Council on Global Change)

Danger:

Expresses a relative exposure to a hazard. A hazard may be present, but there may be little danger because of the precautions taken. (SRA)

Disaster:

A serious disruption of the functioning of a community or a society causing widespread human, material, economic or environmental losses which exceed the ability of the affected community or society to cope using its own resources. (UN Living with Risk Report)

Hazard:

A source of potential harm or a situation with a potential to cause loss. (Aus/NZ Standard)

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. (Codex Alimentarius)

The hazard associated with a chemical is its intrinsic ability to cause an adverse effect. (CEFIC)

Any pathogenic agent that could produce adverse consequences on the importation of a commodity. (FAO - EMPRES)

The circumstances of an objective threat posed by a future damaging event that will occur under certain circumstances. (German Advisory Council on Global Change)

Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent. (IPCS)

A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb. (SRA)

A potentially damaging physical event, phenomenon or human activity that may cause the loss of life or injury, property damage, social and economic disruption or environmental degradation. (UN Living with Risk Report)

A source of possible damage or injury. (US Presidential/Congressional Commission)

An inherent property, for example of a chemical, that provides the potential for harm. (WHO World Health Report 2002)

Hazard Assessment:

A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. (IPCS)

Hazard Characterisation:

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable. (Codex Alimentarius)

The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. (IPCS)

Hazard Identification:

The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. (Codex Alimentarius)

Identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity. (FAO – EMPRES)

The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition. (SRA)

The identification of the type and nature of adverse effects that an agent has the inherent capacity to cause in an organism, system or (sub) population. (IPCS)

Mitigation:

Structural and non-structural measures undertaken to limit the adverse impact of natural hazards, environmental degradation and technological hazards. (UN Living with Risk Report)

Precautionary Principle:

A risk management tool designed to provide guidance to policy-makers in cases where scientific uncertainty remains with regard to a risk of serious consequences on public health or the environment. Precautionary measures may be adopted only after a systematic scientific evaluation and must be proportionate, non-discriminatory and duly justified. (CEFIC)

In order to protect the environment, a precautionary approach should be widely applied, meaning that where there are threats of serious or irreversible damage to the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (European Environment Agency)

Decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete. (US Presidential/Congressional Commission)

Prevention:

Activities to provide outright avoidance of the adverse impact of hazards and means to minimise related environmental, technological and biological disasters. (UN Living with Risk Report)

Resilience:

The capability of a system to return after deflection or perturbation to a stable overall or local state of equilibrium. (German Advisory Council on Global Change)

The capacity of a system, community or society potentially exposed to hazards to adapt, by resisting or changing in order to reach and maintain an acceptable level of functioning and structure. (UN Living with Risk Report)

Risk:

The chance of something happening that will have an impact upon objectives. It is measured in terms of consequences and likelihood. (Aus/NZ Standard)

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. (Codex Alimentarius)

Risk is the chance that a given hazardous effect will occur. (CEFIC)

Expected losses (of lives, persons injured, property damaged and economic activity disrupted) due to a particular hazard for a given area and reference period. Based on mathematical calculations, risk is the product of hazard and vulnerability. (European Environment Agency)

The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period. (FAO - EMPRES)

In a technical perspective, risk refers to two variables – the probability of occurrence of a specific instance of damage and the extent of that damage. The social science perspective focuses on aspects of societal and psychological risk experience and risk perception, while socio-economic approaches focus on risks to livelihood, security and the satisfaction of basic needs. (German Advisory Council on Global Change)

(1.) A multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

(2.) The probability of a specific health effect occurring in a person or group as a result of exposure to radiation. (both from IAEA Risk Glossary)

The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent. (IPCS)

The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred. (SRA)

The uncertainty of outcome, whether positive opportunity or negative threat, of actions and events. It is the combination of likelihood and impact, including perceived importance. (UK Government Handling Risk Report)

The probability of harmful consequences, or expected losses (death, injuries, property, livelihoods, economic activity disrupted or environment damaged) resulting from the interactions between natural or human-induced hazards and vulnerable conditions. (UN Living with Risk Report)

The combined answers to (1) What can go wrong? (2) How likely is it? and (3) What are the consequences? (US Nuclear Regulatory Commission)

The probability of a specific outcome, generally adverse, given a particular set of circumstances. (US Presidential/Congressional Commission)

A probability of an adverse outcome, or a factor that raises this probability. (WHO World Health Report 2002)

Risk Analysis:

A systematic use of available information to determine how often specified events may occur and the magnitude of their consequences. (Aus/NZ Standard)

A process consisting of three components: risk assessment, risk management and risk communication. (Codex Alimentarius)

A process comprising four components: hazard identification, risk assessment, risk management and risk communication. (FAO-EMPRES)

Method of evaluating the probability of the adverse effects of a substance, industrial process, technology or natural process. (European Environment Agency)

Efforts to ascertain […] the probability of occurrence of concrete damaging events or the probability function of magnitudes of damage. Risk analyses aim to determine the expected value of a risk. (German Advisory Council on Global Change).

A process for controlling situations where an organism, system or (sub) population could be exposed to a hazard. The risk analysis process consists of three components: risk assessment, risk management and risk communication. (IPCS)

Systematic use of information to identify sources and to estimate the risk. (ISO/IEC Risk Management Vocabulary Guide)

A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks. (SRA)

Risk Assessment:

An overall process of risk analysis and risk evaluation. (Aus/NZ Standard)

A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. (Codex Alimentarius)

A process to determine the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation. (CEFIC)

Comprises release assessment, exposure assessment, consequences assessment and risk estimation. (FAO – EMPRES)

The procedure in which the risks posed by inherent hazards involved in processes or situations are estimated either quantitatively or qualitatively. (European Environment Agency)

Assessment of the radiological risks associated with normal operation and possible accidents involving a source or practice. (IAEA)

A process intended to calculate or estimate the risk to a given target organism, system or (sub) population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment and risk characterisation. (IPCS)

Overall process of risk analysis and risk evaluation. (ISO/IEC Risk Management Vocabulary)

The process of establishing information regarding acceptable levels of a risk and/or levels of risk for an individual, group, society, or the environment. (SRA)

An organised process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps are hazard identification, dose-response assessment, exposure assessment and risk characterization. (US Presidential/Congressional Commission)

The characterization of the potential adverse health effects of human exposure to environmental hazards. (US Red Book)

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. (WTO Agreement on Sanitary and Phytosanitary Measures)

Risk Assessment/Analysis:

A methodology to determine the nature and extent of risk by analysing potential hazards and evaluating existing conditions of vulnerability that could pose a potential threat or harm to people, property, livelihoods and the environment on which they depend. (UN Living with Risk Report)

Risk Characterisation:

The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub) population, under defined exposure conditions. (IPCS)

The process of organizing, evaluating and communicating information about the nature, strength of evidence, and likelihood of adverse health or ecological effects from particular exposures. (US Presidential/Congressional Commission)

The process of estimating the incidence of a health effect under the various conditions of human exposure described in the exposure assessment. (US Red Book)

Risk Communication:

Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups and the general public. (IPCS)

Exchange or sharing of information about risk between the decision-maker and other stakeholders. (ISO/IEC Risk Management Vocabulary)

Risk Evaluation:

The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria. (Aus/NZ Standard)

Establishment of a qualitative or quantitative relationship between risks and benefits, involving the complex process of determining the significance of the identified hazards and estimated risks to those organisms or people concerned with or affected by them. It is the first step in risk management. (European Environment Agency)

Comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection. (First component in risk management). (FAO – EMPRES)

A set of techniques used to arrive at rational judgements about a risk in terms of its acceptability for society as a whole or for certain groups or individuals. (German Advisory Council on Global Change).

Process of comparing the estimated risk against given risk criteria to determine the significance of the risk. (ISO/IEC Risk Management Vocabulary)

Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, including the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought by the agent. (Risk Evaluation is synonymous with Risk-Benefit Evaluation). (IPCS)

A component of risk assessment in which judgements are made about the significance and acceptability of risk. (SRA)

Risk Management:

The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects. (Aus/NZ Risk Standard)

The sum of measures instituted by people or organisations in order to reduce, control and regulate risks. (German Advisory Council on Global Change)

Decision making process involving considerations of political, social, economic and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk Management involves three elements: risk evaluation; emission and exposure control; risk monitoring. (IPCS)

Coordinated activities to direct and control an organisation with regard to risk. (ISO/IEC Risk Management Vocabulary)

All the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress. Good risk management helps reduce hazard and builds confidence to innovate. (UK Government Handling Risk Report)

The process of analysing, selecting, implementing, and evaluating actions to reduce risk. (US Presidential/Congressional Commission)

The process of evaluating alternative regulatory actions and selecting among them. (US Red Book)

Safety:

Relative protection from adverse consequences. (SRA)

Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. (IPCS)

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards. (IAEA for Nuclear Safety)

Tolerable Risk:

A risk is tolerable if it is not unacceptable (see below) and risk reduction is impracticable or if its cost is grossly disproportionate to the improvement gained. (HSE Tolerability of Risk)

Uncertainty:

The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed. (FAO-EMPRES)

Imperfect knowledge concerning the present or future state of an organism, system or (sub) population under consideration. (IPCS)

Unacceptable Risk:

A risk which cannot be justified except in extraordinary circumstances. (HSE Tolerability of Risk)

Vulnerability:

The condition determined by physical, social, economic and environmental factors or processes, which increase the susceptibility of a community to the impact of hazards. (UN Living with Risk Report)

ANNEX C – AN OVERVIEW OF RISK TERMINOLOGY (BY ORGANISATIONS/PUBLICATIONS)

Australia/New Zealand Risk Management Standard:

Hazard: A source of potential harm or a situation with a potential to cause loss.

Risk: The chance of something happening that will have an impact upon objectives. It is measured in terms of consequences and likelihood.

Risk Analysis: A systematic use of available information to determine how often specified events may occur and the magnitude of their consequences.

Risk Assessment: An overall process of risk analysis and risk evaluation.

Risk Evaluation: The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.

Risk Management: The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.

Codex Alimentarius:

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

European Chemical Industry Council (CEFIC):

Hazard: The hazard associated with a chemical is its intrinsic ability to cause an adverse effect.

Precautionary Principle: A risk management tool designed to provide guidance to policy-makers in cases where scientific uncertainty remains with regard to a risk of serious consequences on public health or the environment. Precautionary measures may be adopted only after a systematic scientific evaluation and must be proportionate, non-discriminatory and duly justified.

Risk: Risk is the chance that a given hazardous effect will occur.

Risk Assessment: A process to determine the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation.

European Environment Agency:

Precautionary Principle: In order to protect the environment, a precautionary approach should be widely applied, meaning that where there are threats of serious or irreversible damage to the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Risk: Expected losses (of lives, persons injured, property damaged and economic activity disrupted) due to a particular hazard for a given area and reference period. Based on mathematical calculations, risk is the product of hazard and vulnerability.

Risk Analysis: Method of evaluating the probability of the adverse effects of a substance, industrial process, technology or natural process.

Risk Assessment: The procedure in which the risks posed by inherent hazards involved in processes or situations are estimated either quantitatively or qualitatively.

Risk Evaluation: Establishment of a qualitative or quantitative relationship between risks and benefits, involving the complex process of determining the significance of the identified hazards and estimated risks to those organisms or people concerned with or affected by them. It is the first step in risk management.

FAO-EMPRES:

Hazard: Any pathogenic agent that could produce adverse consequences on the importation of a commodity.

Hazard Identification: Identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity.

Risk: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period.

Risk Analysis: A process comprising four components: hazard identification, risk assessment, risk management and risk communication.

Risk Assessment: Comprises release assessment, exposure assessment, consequences assessment and risk estimation.

Risk Evaluation: Comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection. (First component in risk management).

Uncertainty: The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.

German Advisory Council on Global Change:

Damage: The destruction, diminution or impairment of concrete or abstract values.

Hazard: The circumstances of an objective threat posed by a future damaging event that will occur under certain circumstances.

Resilience: The capability of a system to return after deflection or perturbation to a stable overall or local state of equilibrium.

Risk: In a technical perspective, risk refers to two variables – the probability of occurrence of a specific instance of damage and the extent of that damage. The social science perspective focuses on aspects of societal and psychological risk experience and risk perception, while socio-economic approaches focus on risks to livelihood, security and the satisfaction of basic needs.

Risk Analysis: Efforts to ascertain […] the probability of occurrence of concrete damaging events or the probability function of magnitudes of damage. Risk analyses aim to determine the expected value of a risk.

Risk Evaluation: A set of techniques used to arrive at rational judgements about a risk in terms of its acceptability for society as a whole or for certain groups or individuals.

Risk Management: The sum of measures instituted by people or organisations in order to reduce, control and regulate risks.

Health and Safety Executive (HSE) (UK):

Broadly acceptable risk: The risk is truly negligible in comparison with other risks that the individual or society runs.

Tolerable risk: A risk is tolerable if it is not unacceptable and risk reduction is impracticable or if its cost is grossly disproportionate to the improvement gained.

Unacceptable risk: A risk which cannot be justified except in extraordinary circumstances.

International Atomic Energy Agency (IAEA) Risk Glossary:

Risk:

(1.) A multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

(2.) The probability of a specific health effect occurring in a person or group as a result of exposure to radiation.

Risk Assessment: Assessment of the radiological risks associated with normal operation and possible accidents involving a source or practice.

Safety: The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

International Programme on Chemical Safety (IPCS):

Hazard: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.

Hazard Assessment: A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed.

Hazard Characterisation: The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects.

Hazard Identification: The identification of the type and nature of adverse effects that an agent has the inherent capacity to cause in an organism, system or (sub) population.

Risk: The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent.

Risk Analysis: A process for controlling situations where an organism, system or (sub) population could be exposed to a hazard. The risk analysis process consists of three components: risk assessment, risk management and risk communication.

Risk Assessment: A process intended to calculate or estimate the risk to a given target organism, system or (sub) population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment and risk characterisation.

Risk Characterisation: The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub) population, under defined exposure conditions.

Risk Communication: Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups and the general public.

Risk Evaluation: Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, including the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought by the agent. (Risk Evaluation is synonymous with Risk-Benefit Evaluation).

Risk Management: Decision making process involving considerations of political, social, economic and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk Management involves three elements: risk evaluation; emission and exposure control; risk monitoring.

Safety: Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances.

Uncertainty: Imperfect knowledge concerning the present or future state of an organism, system or (sub) population under consideration.

ISO/IEC Risk Management Vocabulary Guide:

Risk Analysis: Systematic use of information to identify sources and to estimate the risk.

Risk Assessment: Overall process of risk analysis and risk evaluation.

Risk Communication: Exchange or sharing of information about risk between the decision-maker and other stakeholders.

Risk Evaluation: Process of comparing the estimated risk against given risk criteria to determine the significance of the risk.

Risk Management: Coordinated activities to direct and control an organisation with regard to risk.

Society for Risk Analysis (SRA):

Danger: Expresses a relative exposure to a hazard. A hazard may be present, but there may be little danger because of the precautions taken.

Hazard: A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb.

Hazard Identification: The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition.

Risk: The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred.

Risk Analysis: A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks.

Risk Assessment: The process of establishing information regarding acceptable levels of a risk and/or levels of risk for an individual, group, society, or the environment.

Risk Evaluation: A component of risk assessment in which judgements are made about the significance and acceptability of risk.

Safety: Relative protection from adverse consequences.

UK Cabinet Office Report on Risk:

Risk: The uncertainty of outcome, whether positive opportunity or negative threat, of actions and events. It is the combination of likelihood and impact, including perceived importance.

Risk Management: All the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress. Good risk management helps reduce hazard and builds confidence to innovate.

UN Living with Risk Report:

Disaster: A serious disruption of the functioning of a community or a society causing widespread human, material, economic or environmental losses which exceed the ability of the affected community or society to cope using its own resources.

Hazard: A potentially damaging physical event, phenomenon or human activity that may cause the loss of life or injury, property damage, social and economic disruption or environmental degradation.

Mitigation: Structural and non-structural measures undertaken to limit the adverse impact of natural hazards, environmental degradation and technological hazards.

Prevention: Activities to provide outright avoidance of the adverse impact of hazards and means to minimise related environmental, technological and biological disasters.

Resilience: The capacity of a system, community or society potentially exposed to hazards to adapt, by resisting or changing in order to reach and maintain an acceptable level of functioning and structure.

Risk: The probability of harmful consequences, or expected losses (death, injuries, property, livelihoods, economic activity disrupted or environment damaged) resulting from the interactions between natural or human-induced hazards and vulnerable conditions.

Risk Assessment/Analysis: A methodology to determine the nature and extent of risk by analysing potential hazards and evaluating existing conditions of vulnerability that could pose a potential threat or harm to people, property, livelihoods and the environment on which they depend.

Vulnerability: The condition determined by physical, social, economic and environmental factors or processes, which increase the susceptibility of a community to the impact of hazards.

US Nuclear Regulatory Commission:

Risk: The combined answers to (1) What can go wrong? (2) How likely is it? and (3) What are the consequences?

US Presidential/Congressional Commission on Risk Assessment and Risk Management:

Hazard: A source of possible damage or injury.

Precautionary Principle: Decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete.

Risk: The probability of a specific outcome, generally adverse, given a particular set of circumstances.

Risk Assessment: An organised process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps are hazard identification, dose-response assessment, exposure assessment and risk characterization.

Risk Characterization: The process of organizing, evaluating and communicating information about the nature, strength of evidence, and likelihood of adverse health or ecological effects from particular exposures.

Risk Management: The process of analysing, selecting, implementing, and evaluating actions to reduce risk.

US Red Book:

Risk Assessment: The characterization of the potential adverse health effects of human exposure to environmental hazards.

Risk Characterization: The process of estimating the incidence of a health effect under the various conditions of human exposure described in the exposure assessment.

Risk Management: The process of evaluating alternative regulatory actions and selecting among them.

WHO World Health Report 2002:

Hazard: An inherent property, for example of a chemical, that provides the potential for harm.

Risk: A probability of an adverse outcome, or a factor that raises this probability.

WTO Agreement on Sanitary and Phytosanitary Measures:

Risk Assessment: The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

ANNEX D – DIFFERENT USES OF TERMINOLOGY

Australia/New Zealand Risk Management Standard

Risk assessment	=	Risk Analysis + Risk Evaluation

Codex Alimentarius

Risk Analysis	=	Risk Assessment + Risk Management + Risk Communication
Risk Assessment	=	Hazard Identification + Hazard Characterization + Exposure Assessment + Risk Characterization

EMPRES

Risk Analysis	=	Hazard Identification + Risk Assessment + Risk Management with Risk Communication involved in all three components
Risk Assessment	=	Release Assessment + Exposure Assessment + Consequence Assessment + Risk Estimation
Risk Management	=	Risk Evaluation + Option Evaluation + Implementation + Monitoring and Review

FERMA

Risk Analysis	=	Risk Identification + Risk Description + Risk Estimation
Risk Management	=	Risk Assessment + Risk Analysis + Risk Evaluation + Reporting + Decision + Risk Treatment + Residual Risk Reporting + Monitoring

International Programme on Chemical Safety

Risk Analysis	=	Risk Assessment + Risk Management + Risk Communication
Risk Assessment	=	Hazard Identification + Hazard Characterisation + Exposure Assessment + Risk Characterisation
Risk Management	=	Risk Evaluation + Emission and Exposure Control + Risk Monitoring

ISO/IEC Risk management vocabulary guidance (ISO/IEC Guide 73)

Risk Assessment	=	Risk Analysis + Risk Evaluation

Nuclear Safety (from HSE Tolerability of Risk)

Risk assessment	=	risk from normal operations + risk from accidents

Risk from accidents	=	risks from plant failure + risks from natural events + human factor risks

UK Cabinet Office Report on Risk

Risk Management	=	Identifying and Judging Risks + Assigning Ownership + Taking action to anticipate or mitigate the risks + Monitoring and Reviewing

USA Presidential/Congressional Commission on Risk Assessment and Risk Management

Risk Characterization	=	Organising information on risk + Evaluating that information + Communication the information and evaluation
Risk Management	=	Analysing possible actions to reduce risk + Selecting preferred option + Implementing + Evaluation

US Red Book

Risk Assessment	=	Hazard Identification + Dose-Response Assessment + Exposure Assessment + Risk Characterization

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