Chapter 5
New Emerging Risks

Siegfried Radandt and Ortwin Renn

In earlier chapters, mention has been made to some new emerging risks in the changing world of work. Here we give a short list of new risks (Section 5.1), combined with a description of strategies and methods on how to deal with those risks within the Risk Management and Risk Governance process, focussing on the "precautionary principle" (Section 5.2).

5.1 New Risks (by Siegfried Radandt)

More and more new risks are emerging in connection with new technologies, such as nanotubes. Globalization brings effects such as mobile transboundary transportation and new network organizations, human interventions in nature, such as the clearance of primaeval forests to obtain land for agriculture.

Today's habitation densities and the predominantly industrial way of life have made people dependent on the technical remodelling of nature and on the development of new technologies, as well as new sources of energy. Goods and services are needed to such an extent that natural resources are constantly diminishing. This has created unknown risks, the complexity of which makes it very difficult to identify and quantify the causal links between a multitude of potential causal agents and the specific effects observed.

The changing conditions of work, new technologies, new substances, new work organizations and working practices are associated with new morbidity

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patterns, and even lead to new occupational and work-related diseases. Similarly, people's social and psychological behaviour may inherently change over time, making assumptions on constancy and stability less realistic.

A number of social conditions, such as current massive rural-urban migration, increased international mobility of workers, new work organizations and mobile work may generate totally new types of morbidity. Examples of such developments are, for instance:

- transboundary transportation leading to the spread of pandemics such as HIV/AIDS, SARS, and avian influenza;
- increased risk of metabolic syndrome, diabetes and cardiovascular diseases aggravated by unconventional working hours;
- increased risk of psychological burnout at work due to a high level of long-term stress; and
- a global epidemic of musculoskeletal disorders among VDU workers with high work load, psychological stress and poor ergonomics.

The incidences of occupational diseases may not decline in the future, but the types of morbidity may change. The trend in industrialized countries is the prominence of work-related morbidity and new diseases, while traditional occupational diseases, such as noise injury, pneumoconiosis, repetitive strain injuries, and chemical intoxications may still continue to be prevalent.

The new ergonomics problems are related to light physical work with a high proportion of static and repetitive work. The recent research points to an interaction between poor ergonomic working conditions and psychological stress as a combined risk of musculoskeletal disorders. The toughening global competition, growing productivity demands, and continuous changes in work, together with job insecurity, are associated with increased stress in work life. Another type of psychological burden is the stress from the threat of physical violence or aggressive behaviour on the part of clients.

One of the new and partly re-emerging occupational health risks is associated with the new trends in microbiological hazards. There are several reasons for these developments, for instance, the generation of new microbial strains, structural changes in human habitations with high population densities, growing international travel, and changes in our microbiological environment as a consequence of global warming.

New or re-emerging biological hazards arise from the transformation of viruses, the increased resistance of some microbial strains (such as tuberculosis and other bacteria) and the rapid spread of contaminants due to extensive overseas travelling. The scenarios of health hazards from the use of genetically manipulated organisms have not materialized, but biotechnolo-

gical products have brought along new risks of allergies. A major indoor air problem is caused by fungi, moulds and chemical emissions from construction materials. New allergies are encountered as a consequence of the increasingly allergic constitution of the population and of the introduction of new allergens into the work environment.

Health care personnel are increasingly being exposed to new microbiological hazards due to the growing mobility of people. High rates of hepatitis B antigen positivity have been shown among health care workers who are in contact with migrants from endemic areas. Along with growing international interactions and mobility, a number of viral and re-emerging bacterial infections also affect the health of workers engaged in health care and the care of the elderly, as well as personnel in migrant and refugee services, in social services and other public services.

5.1.1 Nanotechnologies

Among the new technologies, nanotubes are an important example of new risks. The problems related to nanotechnologies are varied and complex. The risks from these new processes and products are not yet very well understood, but exposure to some nanoparticles, a part of nanotechnology, especially the free insoluble particles, have already been shown to affect human health, and wild life as well. The risks arising from molecular manufacturing are so complex that it is difficult to describe the situation well enough yet, as the field of molecular manufacturing is still in the stage of theory. There is currently no global consensus in defining nanotechnology. However, most of the interest in this new technology seems to be in the range of 100 nm to about 0.2 nm. In this range, materials start to change their behaviour due to the increased surface area (catalytic properties), and the dominance of the quantum effect (no longer dominated by Newtonian Laws), which changes the optical, magnetic or electrical properties of materials. In essence, nanotechnological devices exist in a unique realm, sometimes called the mesoscale, where the properties of matter are governed by a complex combination of classic physics and quantum mechanics.

Nanobiotechnology plays a special role within the scope of nanotechnology. Nanobiotechnology deals with the reciprocal relation between nanotechnology, biotechnology, biology and medicine using nature's construction plans and organizing principles, referring to biological components and materials, in combination with or supporting biological processes. It is under-

standable that such technologies also bring along risks. Nanoparticles have size-induced functional characteristics, making it difficult at present to evaluate how they will behave in the environment or after being incorporated. Artificially produced nanoparticles may enter the environment and the human body through emission during production, or during use of the products. Their behaviour, when spreading out, and their effects are not known nor are their potential long-term consequences. Particularly questions concerning mobility, reaction, readiness, persistence, respirable dust, and solubility, still have to be answered. There is a lot of uncertainty that must be cleared up in connection with the precautionary principle. Evidence is necessary, as far as relevant risks are concerned.

Nanotechnology currently presents itself as follows:

Materials that have only one dimension in the nanoscale: layers such as thin films or surface coatings. These have been developed and produced for some time now.

Materials that are nanoscale in two dimensions: nanowires and nanotubes.

Three-dimensional nanoscale materials: e.g., precipitates, quantum dots, and colloids, such as colloidal silver, which is a very effective anti-bacterial and anti-viral agent, and has been used for hundreds of years.

Nanocrystalline materials, other nanoscale materials, are made up of nanometer-sized grains.

Currently, many chemicals display nanoscale features: e.g., polymers are made of a number of smaller subunits. Nanotechnologies have been used to produce features on computer chips.

Nanosized proteins exist in our bodies: this size range is therefore a big part of nature as well.

Nanoparticles have also been produced as the products of combustion, e.g., in diesel exhaust, food cooking and atmospheric photochemistry. The production of red gold fumes is an example of nanoparticles that have been produced for nearly a thousand years.

Zinc fume is another example of the production of nanoparticles, and also a good example of a material in that size range that has a negative effect on the body.

In this book only the term nanotechnology will be used, where otherwise it is also referred to as molecular manufacturing. Although there are nanostructures in nature, here only artificial nanostructures will be dealt with, i.e. materials that are produced by human intervention, such as the production of red gold fume, or zinc fume.

There are two types of nanotechnologies:

1. Top-Down. This means from the top (larger) to the bottom (smaller). Here mechanical structures are miniaturized to a nanometer scale. So far, most of the nanotechnology applications have been in this area. It involves the bulk production of nano-scale particles, such as pure elements and simple compounds produced for the market.
2. Bottom-Up. This means from the bottom (smaller) to the top (larger). Here the assumption is that one starts with a nanometric structure such as a molecule, and through a process of assembly creates a larger mechanism. This form of nanotechnology is more likely to be part of future manufacturing. However, some suggest that the merger of biotechnology, information technology and artificial intelligence with nanotechnology could see advances in this area soon. Nanotubes, which are graphite cylinders with special electric properties, may be the first example of a self-assembled nanostructure. One assumption that illustrates the limits of current nanotechnologies suggests that engineers will not be able to make nano-devices until they comprehend the physical principles inherent in the mesoscale.

Currently, nanotechnological products are in the form of:

- paints (e.g., crack-resistant paint based on antimony-tin oxide);
- fuel cells;
- batteries;
- fuel additives, catalysts;
- lubricants;
- integrated circuitry;
- medical implants;
- machine ceramics;
- water purification and remediation products;
- military battle garments;
- self-cleaning windows;
- sunscreen products and cosmetics;
- explosives, propellants and pyrotechnics;
- disinfectants; and
- abrasives.

In general, free particles in the nanometer range raise health and safety concerns because these tiny particles have a much larger surface to mass ratio compared with larger particles. Consequently, they are likely to penetrate cells in the body and take on different structures than they would in their larger scale.

Unfortunately, very little research has been done to evaluate the toxicity of novel nanoparticles created by these new technologies. Most of the assumptions on the potential adverse health impact come from the evidence in air pollution, in the effects from the inhalation of welding fumes, and extrapolation from the extensive body of knowledge on the health effects of existing micrometer-sized particles.

It appears that one key driver is the link between particulate air pollution episodes and the increase in cardiovascular mortality and morbidity in susceptible individuals. A case in point is the London smog episode in December of 1952, when 4000 excess deaths occurred over a two-week period. It has been suggested that the high level of exposure was mostly due to particles of the nanometer range. One theory suggests that the finer particulates in air pollution, those in the nanoscale range, may be responsible for increasing blood coagulation, leading to increased blood viscosity and consequently causing cardiac ischemia. Other hypotheses include an effect on neutrophil deformity and atherosclerotic plaque progression and destabilization.

There is also a general picture emerging from animal studies, suggesting that on a mass dose basis, pulmonary toxicity is enhanced when the particle size is reduced from the micrometer to the nanometer range. The increased toxicity of the materials appears to be partly linked to the increase in the particles' surface area (causing a catalytic effect and generating free radicals). However, it also seems that there is a difference in toxicity between the materials; i.e., some materials in the nanometer range are more toxic, so that the final verdict on a material's toxicity must be made on a case-by-case basis.

For example, single high exposure to non-fibrous, non-cytotoxic particles, like carbon black, titanium dioxide, talc, can cause transient pulmonary inflammation. Repeated exposure, however, appears to bring on a risk of chronic inflammation, lung damage with hypertrophy, epithelial hyperplasia, and interstitial fibrosis due to overload (exceeding the capacity of the alveolar macrophage to phagocytize, leading to the secretion of inflammatory mediators).

Exposure to non-fibrous, cytotoxic particles (e.g. silica) is more likely to directly affect alveolar macrophages. This is due to the surface area chemistry of such particles and their potential to generate free radicals (inducing oxidative stress). Toxicological studies have shown that, for instance, low exposure to micrometer-sized particles of quartz causes severe lung inflammation, cell death, and fibrosis. It has also been shown to cause tumours in rats. The current view is that these effects are related to the surface of quartz, which is reactive and generates free radicals leading to oxidative damage.

Studies on exposure to coal and silicates have found that similar effects can be expected if the dose is sufficiently high, causing overload, and that this depends on the total surface area of the particles inhaled. In essence, cells and organs may display a toxic response even to non-toxic substances when they are exposed to a high enough dose in the nanosized range.

The concern arising from exposure to nanosized fibrous particles is similar to that arising from non-fibrous particles, namely, pulmonary toxicity and/or cytotoxicity. The history of asbestos is still fresh in our minds, and there is a fear that nanosized fibres may introduce similar problems.

The fibres coming from carbon nanotubes could also cause a problem, not only due to their shape and dimension, but also because of their potential to combine with iron or other metals. The addition of these metals could cause catalytic effects with potential to release free radicals and aggravate inflammatory processes.

Recent animal studies using nanosized particles, such as titanium dioxide, barium sulphate, metallic cobalt, and metallic nickel, have found that metallic nickel induced statistically significantly stronger inflammation responses than either cobalt or titanium dioxide, and cobalt was more inflammatory than titanium dioxide. Nickel and cobalt, but not titanium dioxide, caused lipid peroxidation.

Some concern has been voiced about the possibility of nanosized particles to translocate to the liver and other organs. This may nevertheless depend on the differences in exposure conditions, chemical composition and particle size.

A recent study has even suggested that nanoparticles generated by manufacturing processes may penetrate and pass along nerve axons and into the brain.

In addition to respiratory exposure, there has been some fear that nanosized particles may also penetrate the broken skin. This could add to the overall body burden and potentially generate free radicals that could damage DNA. However, this has not yet been confirmed.

The parameters of dust explosion risks are also influenced. Dust explosions can occur in manufacturing plants that use fine particles of sugar, flour, animal feeds, and in operations in which e.g. sawdust, organic chemicals, plastics, metal powders and coal are present.

The ignition sensitivity and explosion violence of the dust cloud are affected mainly by the size of the particles or the total surface area per unit volume. Generally, as the particle size decreases, the actual surface area increases, and the dust explosion risk and ease of ignition also increases. The rate of pressure rises and flame speed can also increase.

It is possible that the increased surface area of nanoparticles could also increase the likelihood that they become self-charged and ignite more easily. Nanopowders, on the other hand, because of their large specific surface area, may become highly charged in use. They may also persist longer in the air.

The traditional filter and gravimetric methods used for particulates cannot be used for particles in this size range. It should be stressed that filter effectiveness for particles smaller than 15 nm is still uncertain.

Traditional respiratory protection at work should also be effective for particles over 15 nm. However, it is crucial that the facemask fits well. It is also important to note that the NPR 100 respirators have not been tested with nanoscale particles.

It is also recommended that impervious gloves and clothing be used to minimize dermal exposure.

5.1.2 Mechatronics

Another example for new emerging risk is the field of mechatronic systems which are in particular new through their growing complexity.[1]

Mechatronics is most frequently defined as a synergistic combination of mechanical engineering, electronic engineering and computer engineering (IT technologies) in the design of products and manufacturing processes. The term synergy is of essential significance in this respect because it means that mechatronics is far more than merely the combination of the individual components (Figure 5.1).

The limits of mechatronics cannot be defined precisely. Therefore, the expression fuzzy limit (see Figure 5.1) is used where "fuzzy" means that the limits are defined on the basis of rational and common sense principles.

For better understanding of the fundamentals of mechatronics, mechatronic systems are classified according to the influence of electronic engineering and IT technology on their system design.

1. Traditional machines are equipped with electronic control units, including IT technologies (e.g. CNC machine tools, electronic ignition of combustion engines).
2. Various functions based on mechanics are replaced by electronic controls (e.g. replacing a mechanical gearbox with an electronically controlled gearbox – a typical mechatronic system).

[1] The part "Mechatronics" was written with strong support from Professor Sinay, Technical University, Kosice, Slovakia.

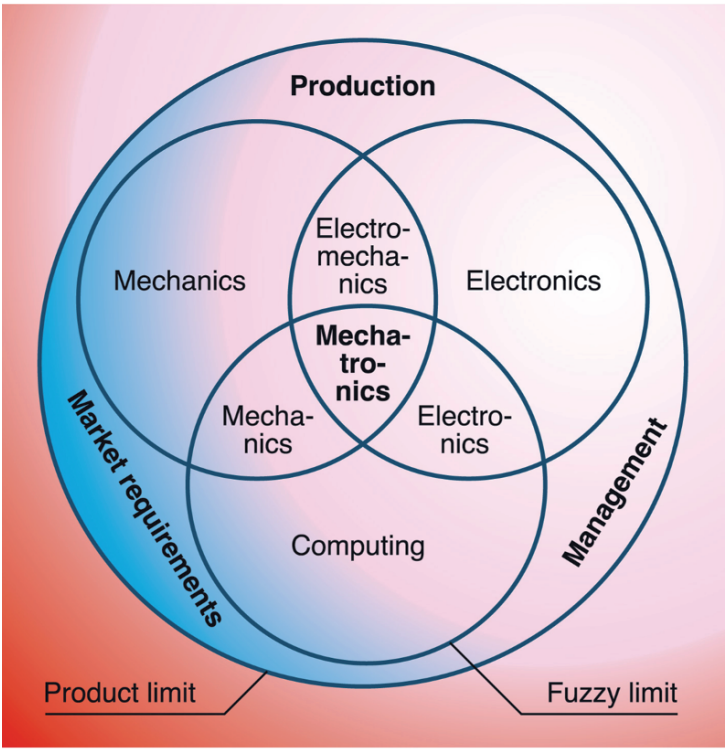

Fig. 5.1 Mechatronic system and its structure.

3. The mechanical control function is substituted by an electronic system incorporating IT systems.

Risks of the Mechatronic System – Associated with Operation

Mechatronic products are found in all fields of technology today. Thus, a wide range of risks may be involved:

- *mechanical risks*: contusions, cuts, blade cuts, winding up, pulling in, absorbing, recoiling, puncture, abrasion, spraying of liquids, etc.;
- *electrical risks*: contact with live parts or with parts which are current-carrying as a result of a fault, electrostatic occurrence, heat radiation;
- *thermal risk*: burns;
- *acoustic risk*: permanent hearing damage, tinnitus, fatigue, stress;
- *radiation risk*: caused by electromagnetic field, infrared light, ultraviolet laser radiation; and

- *risk as a result of failure to observe ergonomics principles*: physiological, psycho-social effects.

Risks of the Mechatronic System – Associated with Technology

The definition of the mechatronic system implies that the risks also occur in three basic categories:

- *mechanical risk*: failure of mechanical components;
- *electronic risk*: power failure, short-circuit, electronic component fault, failure of the sensor system (sensor, limit switch); and
- *software risk*: occurrence of an accidental logical error, intentional or unintentional program change (virus, operation), incorrect data input.

Risk of Loss of Synergy

An important aspect in the assessment of the risk associated with mechatronic systems is the interconnection of the individual component. The incorrect evaluation of a minor fault that is difficult to detect in a component can result in the destruction of the system. The failure of the mechanical part that is not registered due to the non-existence of the sensor, as a consequence of which the control unit is not able to respond to the change of the system status which leads to the subsequent system destruction.

The new consequences come in particular from the complexity and occurrence of the various single risk fields. These risks can be identified and analysed, however, according to risk assessment principles, and they can be treated applying a risk management approach.

Several distinct analytical methods for reliability, availability, maintainability and safety analysis are available for identifying the risks in mechatronic systems. The Markov technique is one suitable method.

Markov techniques make use of a state transition diagram which is a representation of the reliability, availability, maintainability or safety behaviours of a system, from which system performance measures can be calculated. It models the system's behaviour with respect to time.

Markov techniques are especially suited to the investigation of systems with redundancy, or to systems where system failure depends on sequential events. They are also suitable to systems in which maintenance strategies are complex, e.g. systems with restoration priorities or multiple restoration teams, queuing problems, and resource restrictions.

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5.2 Strategies and Methods, the Precautionary Principle in Particular: Application to Integrative Risk Governance (by Ortwin Renn)

5.2.1 Introduction

The precautionary principle has been adopted in a variety of forms at the international, European Union and national levels[2] (Fisher 2002). It is applied in an increasing number of national jurisdictions, economic sectors and environments (Trouwborst 2002, de Sadeleer 2002). It has shifted from the regulation of industry, technology and health risks, to the wider governance of science, innovation and trade (O'Riordan and Cameron 1994, Raffensberger and Tickner 1999, Harding and Fisher 1999, O'Riordan et al. 2001). As it has expanded in scope, it has grown in profile and authority. As Article 174(2) of the EC Treaty of 2002 states, precaution is now the key underlying principle in European Community policy making (European Commission 2002). In the aftermath of a series of formative public health controversies, economic calamities and political conflicts (such as those involving BSE and GM crops), precaution is of great importance in many sectors, including the regulation of chemicals.

Despite the strong political interest, however, a number of serious ambiguities and queries remain. They concern the nature and appropriate role of the precautionary principle in governance (Cross 1996, Morris 2000, Majone 2002, Marchant and Mossman 2004, Löfstedt 2004). These are addressed – if not resolved – in lively academic debate (Sand 2000, Fisher 2001, Klinke

[2] This part includes material from a recent article by Stirling et al. (2006), as well as an article by Elliot and Renn (in press).

and Renn 2001, Stirling 2003, van Zwanenberg and Stirling 2004, Stirling et al. 2006), as well as the more policy-oriented literature (Stirling 1999, Gee et al. 2001). The precautionary approach has been formulated in numerous ways in many different places: One root may be the "foresight principle" in Germany in the 1970s, but the formulation in the Rio Declaration is the most popular one (see Paterson 2005):

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (Rio Declaration 1992 Principle 15)

The meaning of this principle is a topic of debate among analysts and policy makers. In order to understand the debate better, it is helpful to distinguish three positions taken towards risk analysis, as pointed out in the Introduction (see also Resnik 2003).

- Within the first frame of scientific risk analysis, risk management relies on the best scientific estimates of probabilities and potential damage. It uses expected values as the main input for assessing the toleration of risk, as well as for planning risk reduction measures that are cost-effective, proportional to the threat, and fair to the affected population. In this frame, precaution may best be interpreted as being conservative in making risk judgments and in selecting cautious assumptions when one is calculating exposure or determining safety factors (of 10, 100 or more) to cover inter-individual variability.
- Within the frame of "precaution", the concept of risk is seen from the perspective of pervasive uncertainty and, in particular, ignorance and lack of knowledge. Precautious risk management means the prudent handling of decision options in situations where there is high uncertainty about causes and effects and high vulnerability of the population at risk. Instruments of precaution include minimization requirements (such as ALARA or ALARP[3]), diversification of risk agents, containment in time and space, and close monitoring.
- The third frame of deliberation has been advocated as an alternative or an addition to the purely analytical procedures of assessing and managing risks. The task of risk management here is to organize in a structured and effective manner the involvement of stakeholders and the inter-

[3] ALARA = as low as reasonably achievable; ALARP = as low as reasonably possible.

ested public in the designing of risk management strategies based on each stakeholder's knowledge (epistemic community) and value system. This strategy can be used together with both the risk analysis and the precautionary approach, but it has been advocated either as an independent path to risk management, or more often as a policy-oriented implementation of the precautionary approach.

During the past few years, advocates of the classic risk management approach, of the precaution-based approach, and the deliberative approach have launched a fierce debate over the legitimacy of each of these approaches. This debate has been particularly strong between the classic and the precautionary camp. It is argued, on the one hand, that precautionary strategies ignore scientific results and lead to arbitrary regulatory decisions (Cross 1996). On the other hand, the precautionary viewpoint implies that "one should be on the safe side". This could be interpreted as a mandate to ban everything that might result in negative side effects. Such a rule would logically apply to any substance or human activity and would lead to total arbitrariness (Stone 2001; Majone 2002: 101). The principle has been labelled as being ill-defined, absolutist, leading to increased risk-taking, being a value judgment or an ideology, and being unscientific or marginalizing the role of science (Sandin et al. 2002:288; Peterson 2006). Some analysts claim that the precautionary principle entails the risk that science may be held "hostage to interest group politics" (Charnley and Elliott 2002: 66, 103). In addition, policy makers could abuse the precautionary principle as a policy strategy to protect their economic interests and to impede world trade (Majone 2002).

On the other side of the fence, the advocates of the precautionary approach have argued that precaution does not automatically mean banning substances or activities; it is rather a step-by-step diffusion of risky activities or technologies until more knowledge and experience is accumulated (Fisher 2001, Stirling 2003). They have accused their critics of ignoring the complexity and uncertainty of most hazardous situations and of relying on data that often turns out to be insufficient for making prudent judgments. Since the application of the precautionary principle has been associated with stricter and more rigid regulations, environmental groups have usually rallied around the precautionary approach, while most industrial and commercial groups have been fighting for the management-based approach. Again, the issue is not resolved, and the debate has become even more pronounced after the defeat of the European Community in the recent World Trade Organization (WTO) settlement of hormones in beef. The European Community failed to provide

sufficient evidence that the precautionary approach could justify the restriction of imported beef treated with hormones.

It is interesting to note that the first data-driven approach has been widely adopted by the official US regulatory bodies, whereas the precautionary approach has been widely advocated by the EU regulatory bodies. There are, however, also numerous elements of precautionary approaches interspersed into the actual practices of US regulatory agencies, just as there are judgments about magnitudes of risk in the actual practices of regulators in the EU (Löfstedt 2004). A strict dichotomy between "precautionary" in Europe and "risk-based" in the US is therefore too simple for describing the actual practice (Charnley and Elliott 2002).

The third approach has found wide acceptance among social scientists and risk analysts from academia, but so far has had little impact on the institutional design of risk analysis (Renn 2004). There are, however, isolated examples of community participation in risk decisions, such as in selecting the remedy under the Superfund clean-up program or negotiated rulemaking in the US (Harter 1982, Coglianese 1997). In recent years, however, risk policy makers have acknowledged that participation in risk analysis brings many advantages because it transforms difficult issues of resolving epistemic uncertainty into topics that can be tackled at the negotiation table. "If society participates in the production of policy-relevant scientific knowledge, such 'socially robust' knowledge is less likely to be contested than that which is merely reliable" (Funtowitz et al. 2000: 333–334). Accordingly, the EU communication on good governance (2001) has emphasized the need for more stakeholder involvement and participation in risk management. How to implement this requirement in day-to-day risk management decisions is still being debated. Many scholars have also questioned the value of deliberative approaches in some settings, arguing that "when there is trust in the regulator, a top-down form of risk communication (information transfer) may be better than dialogue" (Löfstedt 2005: 3; see also Rose-Ackerman 1994, Coglianese 1997).

5.2.2 The Precautionary Approach as Part of Integrative Risk Governance

The risk governance model outlined in Chapter 4 states that the main task of risk managers is to reduce identified undesirable effects of human activities or natural events by appropriately modifying causes or, though less de-

sirable, by mitigating the consequences. Since there are more risks in the world than can ever be handled at the same time, risk management always implies the setting of priorities. The conventional solution to this problem has been to create risk reduction policies in proportion to the severity of the potential effects (Crouch and Wilson 1984). Severity has been defined as a linear combination of the magnitude of harm and the probability of occurrence. Risk-risk comparisons constitute the most appropriate instrument in this perspective for setting risk management priorities (Merkhofer 1987, Cohen 1991).

The underlying rationale of this approach is based on the assumption that risk should be reduced in proportion to the expected or modelled harm to humans or ecosystems. This assumption is, however, highly contested in the wider risk community: social actions to cope with risk are not confined to the single goal of risk minimization, but rather include other objectives such as equity, fairness, flexibility, or resilience (Vlek 1996). The strongest argument against the proportional risk management approach comes from the analysis of uncertainty (Cooke 1991, van Asselt 2000). Most risk data consist of aggregate results on large segments of the population over a long time (Funtowicz and Ravetz 1987).

It is essential to note in this context 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 1992, van Asselt 2000: 93–138, RIVM/MNP 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 number of variables and parameters); and
- *ignorance or non-knowledge* (uncertainties derived from lack or absence of knowledge).

Risk analysts consequently distinguish between *aleatory* and *epistemic uncertainty*: Epistemic uncertainty can be reduced by more scientific research, while aleatory uncertainty will remain a random variable where only distributions over long time periods can be deducted (Shome et al. 1998). The first two components of uncertainty qualify as epistemic uncertainty and can therefore be reduced by augmenting 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 characterized to some extent by using scientific approaches, but cannot be further reduced to probabilities. If uncertainty, particularly the aleatory components, plays a big role, then the estimation of risk becomes fuzzy. Accordingly, the validity of the end results is questionable, and additional information is needed for risk management purposes. This necessary information can be e.g. a subjective confidence level in the risk estimates, potential alternative pathways of cause-effect relationships, ranges of reasonable estimates, loss scenarios, and others. Based on the distinction between epistemic and aleatory uncertainty, 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 – complex risk problems – risk problems due to high unresolved uncertainty – risk problems due to interpretative and normative ambiguity.

For more details concerning different risk strategies according to risk class as well as a list of instruments and tools appropriate for respective risk treatment please turn to Chapter 3.8.2.

5.2.3 Stakeholder Involvement and Participation

Any type of 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. *Inclusion and selection* are therefore the two essential parts of any decision or policy making activity. Classic decision analysis offers 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, compared to the conventional strategies of decision analysis. Our understanding of risk governance includes the notion that the four major actors in making risk decisions, i.e. the *political*, *economic* (*business*), *scientific and civil society* players need to be involved in the process of problem framing, generating and evaluating options, and coming to a joint conclusion. Inclusive governance requires that:

- There has been a serious attempt to involve representatives of all four actor groups (where appropriate).
- There have been major efforts to empower all actors to participate actively and constructively in the discourse.
- There has been a serious attempt to co-design the framing of the (risk) problem or the issue in a dialogue with these different groups.
- There has been a concerted effort to generate a common understanding of the magnitude of the risk (based on the 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.
- There has been a clear connection between the role of participatory bodies in decision making and the process of political implementation.

If these conditions are met, evidence shows that actors, in addition to strengthening their faith in their own competence, use the opportunity and start to trust each other more, and have greater confidence in the management process (Kasperson et al. 1999; Viklund 2002). 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 imply reaching a "final say" on an initiative or regulation. Rather, it represents the outcome of a deliberation, i.e. the agreement that the participants reached. The problem is that the more actors, viewpoints, interests and values that are represented in an arena, the more difficult it is to reach either a consensus or some other joint agreement. With respect to the closure of debates (whether they are final or temporary) a second set of criteria is needed to evaluate the closure process, as well as the quality of the decision or recommendation that is generated through this process.

The first aspect, the quality of the closure process itself, can be subdivided into the following dimensions:

- Have all arguments been properly treated? Have all truth claims been fairly and accurately tested against commonly agreed standards of validation?
- Has all relevant evidence, in accordance with the actual state of the art and prevailing knowledge, been collected and processed?
- Was systematic, evidence-based 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 judgments made explicit and explained thoroughly? Were normative statements deducted from accepted ethical principles or legally prescribed norms?
- Were serious efforts undertaken to preserve the 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 desired outcome?

Turning to the issues of outcome, additional criteria need to be addressed. As introduced earlier, these involve issues of effectiveness, efficiency, accountability, legitimacy, fairness, acceptance and acceptability. The potential benefits that derive from the involvement of stakeholders and the public depend, however, on the quality of the participation process. It is not sufficient to gather all interested parties around a table and rest all hopes in some kind of cathartic effect. In particular, it is essential to consider the investment of time and effort on the part of participating actors as scarce resources that need to be handled with respect. The participation process should be designed in such a way that the various actors are encouraged to contribute to the process on all issues in which they feel they are competent and can offer something to improve the quality of the final result.

Figure 5.2 provides an overview of the different requirements for participation and stakeholder involvement for the different management strategies. As with all classifications, the scheme gives an extremely simplified picture of the involvement process. Categorizing different threats according to the quality and nature of the available information will, of course, be contested among the stakeholders. Often a consensus may not be reached on a specific case. In such cases, application of the precautionary principle at an "architectural level" in this framework would entail a detailed (worst-case) appraisal. Here, measures such as post-market monitoring and surveillance constitute

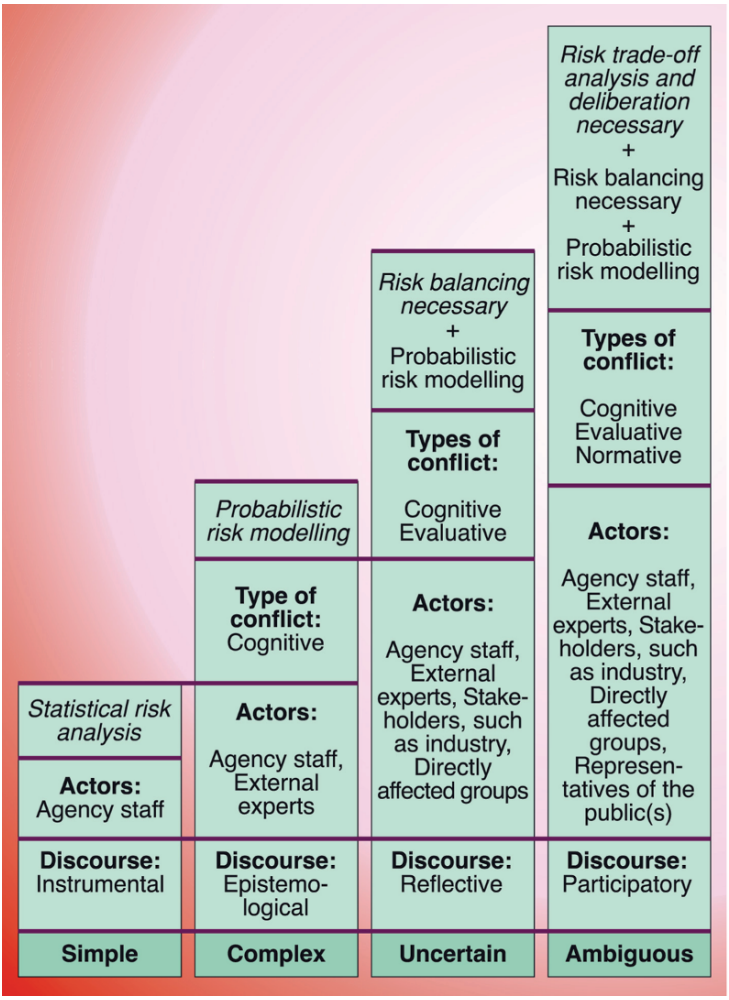

Fig. 5.2 The risk management escalator and stakeholder involvement (from simple via complex and uncertain to ambiguous phenomena). Adapted from Renn (2004b: 300).

important possible bases for compromise, by providing for timely detection, confident scoping and reversible reduction of threats. Such a situation may also require a design discourse in order to reach closure on the appropriate appraisal process.

It now remains to reflect on the extent to which the proposed integrative risk governance framework pursued in this volume addresses the various problems and principles that relate to the precautionary approach. In this regard, it is useful to refer again to the main challenges to risk as outlined

in Chapters 1 and 3. This required, *first* and foremost, that any proposed new framework for the articulation of conventional and more precautionary approaches in an area such as occupational health and safety should display enhanced compliance with the European Commission's own principles of "good governance". These comprised: participation and accountability; accessibility and openness; coherence and consistency; proportionality and non-discrimination; and effectiveness, timeliness and subsidiarity. *Second*, it was argued that compliance with these governance criteria requires a high degree of specificity over the way in which an appropriate balance may be struck between the roles played by different interests, constituencies, disciplines, methods, institutions and modes of engagement. *Third*, the initial conceptual discussion showed more specifically that the framework should (in addition to the conditions of "risk" and "complexity" addressed in established approaches to "risk analysis"), fully engage with the distinct, intractable and somewhat neglected problems of "complexity", "uncertainty", and "ambiguity".

Notwithstanding the many remaining challenges, qualifications and queries, then, it may be cautiously concluded that a framework such as that described here, does warrant further critical scrutiny and constructive attention as a potential basis for addressing the many intractable challenges in the governance of risks, such as those encountered in the field of food safety. In this way we may hope to mitigate the present confusion and controversy over the relationship between "science" and "precaution" and understand the possibility for measured and effective practical implementation of precaution in the appraisal – as well as the management – of risk.

5.2.4 Conclusions

All regulatory regimes are faced with the question of how to make regulatory decisions under uncertainty or even ignorance. It may be helpful in this respect to resort to the differentiation that Resnik (2003: 332) has proposed:

- Decisions under certainty: the outcomes of different choices are known.
- Decisions under risk: probabilities can be assigned to the outcomes of different choices.
- Decisions under ignorance: it is not possible to assign probabilities to the outcomes of different choices.

A similar distinction has been made by Stirling (2003). One of the main conclusions of our analysis in this section has been that using precaution for the

first two cases is neither necessary nor prudent, given that regulations need to meet both objectives, namely, protection of workers and public health, as well as of the environment. Precaution can be used legitimately in the case of ignorance or other forms of remaining uncertainties (such as system boundaries or truly stochastic events). In order to avoid misunderstanding, some analysts have proposed to avoid the term precaution and replace it with the more adequate term of *principle of insufficient reason* (see Peterson 2003: 71). This is the place where precaution is required. The main purpose of precaution in this respect is to avoid irreversible decisions. Although highly critical about the use of the precautionary principle, policy analyst G. Majone conceded that the precautionary principle does have a role, namely, where "losses (or utilities) are unbounded" and where it is "clearly impossible to calculate expected values", e.g., where there is a threat of "serious and irreversible damage" (Majone 2002: 104). In this Chapter we made a strong plea for screening chemical risks according to the degree of remaining uncertainties, and then using those risk reduction methods that are most suited for the type of risk under scrutiny.

Charnley and Elliott have argued that regulatory decisions, whether in the US or the EU, involve both a factual component ("how great do we think that the risk of harm is?") and a value or policy component ("are we willing to accept the risks, including the unknown risks?") (Charnley and Elliott 2002). What changes from one decision to another decision are the relative weights assigned to each component. There is widespread perception on both sides of the Atlantic that Europe tends to place more weight on the second component (acceptability), whereas many US agencies, under the pressure to build a record for judicial review, tend to place more emphasis on the first component (extent of demonstrated risk). One should note, however, that there is little actual empirical evidence supporting these stereotypes, and there are wide variations within and among agencies in the USA and Europe. For example, the now-repealed Delaney clause banning any carcinogens in US food safety regulation was certainly inspired by a strong link to the value component and precaution, while traffic safety regulation in most European countries is clearly guided by risk assessments.

The issue of whether Europe or the USA is really "more precautionary" is ultimately less important than how regulatory decision makers in both systems can strike the most appropriate balance in particular areas of regulation between the components of facts (risk) and values (precaution). Elliot has suggested that this problem becomes more tractable when viewed diachronically (over time) rather than analysing what relative weights should properly be given to facts (risk) and values (precaution) synchronically and

in the abstract (Elliott 1992). Thus, the practical question that every regulator must ask is: "Shall I act to address this particular problem now, basing my decision on what is currently known (or more accurately, *believed* to be known), or shall I instead defer action until a later date, when more may be known, but at the cost of what occurs in the meantime"? Viewed from this practical, diachronic perspective, which is the situation that a regulator actually faces in trying to decide on concrete actions, the problem of the relative weights to be assigned to fact (risk) and to value (precaution) may become much more tractable. As a matter of common sense, a regulator may be well-advised to wait until later to act if, but only if, (1) it seems unlikely that much preventable harm will occur in the meantime, but (2) it also seems likely that enough useful information will be developed in the meantime, so that making a better decision in the future will be substantially less difficult than it is today. Because these quantities are incommensurable (i.e. they exist in different realms and implicate different values), and because they involve predictions about the future, they cannot be reduced to a precise formula. But it may nonetheless be helpful to frame the issues in this way, because there are many "easy cases" in which it is clear that the harm that may occur in the meantime is far greater than any likely benefit that may result from waiting for more information, and vice versa.

For most of these "new emerging risks" there is insufficient or no knowledge concerning consequences and probabilities to use the classical risk management approach. As something has to be done, however, recourse to the precautionary principle is necessary in these cases. But it has to be added that often adequate measures to apply this precautionary principle still have to be developed. A high priority in this respect is to be given to generated knowledge.

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