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Concepts, Problems and Applications

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Foreword

The International Risk Governance Council (IRGC) is delighted to have been able to support the Forschungszentrum Jülich GmbH's Man, Environment and Technology Programme Group by funding the translation of their original 2004 text into English. We very much hope that having the report available in English will help to increase worldwide readership of this contribution to the understanding of risk and its governance.

The IRGC is a private, independent, not-for-profit foundation based in Geneva, Switzerland. The IRGC was founded in 2003. Its mission is to support governments, industry, NGOs, and other organizations 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 endeavor to work and communicate in ways that account for the needs of both developed and developing countries.

The establishment of the 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 were making it ever more difficult for risk managers to develop and implement adequate risk governance strategies. Consequently, the IRGC is committed to promoting a multidisciplinary, multisectoral, and multiregional approach to risk governance. The subject of comparative risk assessment (CRA) was identified as a priority area for the IRGC from the date of its founding, precisely because it offers a means of improving risk decision-making on a global basis.

All those who make risk-related decisions, whether government ministers, regulators, or company directors, require sound knowledge on which to base their decisions, wherever possible including the best scientific knowledge available. Often, decision-makers are confronted by the need to make decisions for which they must allocate resources to one or more of several different problems, and are required to

do so in the absence of any objective means of comparing the risks or the impact of their decisions. CRA offers a possible means of providing a scientific basis for such decisions.

As the authors of this book make clear, there is a need to further study and understand how best CRA can fulfill its full potential. There is a growing body of knowledge, and the publication of this book is a most helpful addition to it. We are pleased to have been able to play a role in helping to bring Forschungszentrum Jülich GmbH's report to a wider audience.

Finally, the IRGC extends its thanks to Simon Milligan for the excellence of his translation of this valuable contribution to the debate about CRA and its place in the total risk governance process.

Pittsburgh PA, USA, April 2006

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The translation was prepared by Simon Milligan and funded by the *International Risk Governance Counsil (IRGC)* [http://www.irgc.org/].

Summary

Decisions dealing with environmental health risks must be made under the most widely differing contexts. These range from decisions of the private sphere through regulatory decisions to those on the global political level. A glance at some contemporary problems in society shows that the spectrum of risk-related decisions is very broad:

- Should the use of a particular substance be regulated (e.g., by setting limit values)?
- Can a substance known to be harmful be replaced by another (e.g., by substituting chemicals)?
- Where should the emphasis of health policy be placed (e.g., cancer prevention)?
- Which energy systems should be used (e.g., fossil fuels, renewable energy sources)?
- Which methods of agricultural production should be preferred (e.g., conventional agriculture, genetically modified crops)?

The solutions to such challenges require regulatory and political decisions that should be based on a thorough and rational analysis of risks and decision options. The above problem statements make it clear that *comparative* risk assessments (CRAs) can play an important role in the regulation of risks.

The claim that comparative risk evaluation forms a rational foundation for making environment health-related decisions has led, especially in the USA, to a critical debate in which a range of arguments have been brought against CRA. Some of the criticisms are of a fundamental nature. One such is that risks are frequently so qualitatively heterogeneous, for instance in respect to their origin or the type of damage they cause, that a meaningful comparison cannot be made. Another argument centers on the considerable knowledge gaps of environment health risks and deduces that comparative evaluations of these risks are not possible or, at the least, not meaningful. A third argument sees in CRA an obstacle to the possible participation of the public in decisions on environmental health risks. Relying on CRA for such decisions is seen to create the danger of an "expertocracy" because the risk assessments upon which a CRA must be based are frequently very complex and, thus, can hardly be followed by nonexperts.

In the light of this situation, the objectives set for this study were to evaluate existing approaches to CRA, to explore the possibilities of improving such comparisons, to discuss the opportunities for participation, and to design processes that will increase public acceptance of political decision-making as regards environmental health risks.

The following questions are addressed:

- What prior efforts of comparative risk evaluations are there? What gaps and problems do these present?
- What types of comparative risk evaluation can be distinguished, and which of these, within existing administrative constraints, are meaningful and worthy of development?
- How are the individual steps of a comparative risk evaluation to be designed, and what advice can be gleaned from the substantial body of literature on social science risk research?
- What special demands does an integrated comparative risk evaluation have, in particular one that involves a variety of evaluators from science and society?
- What are the chances of success for comparative risk evaluations, and where do their limitations lie?

The results of this study are summarized as a number of recommendations, as discussed below.

1. CRA can draw upon a range of developed and established instruments

Comparative risk evaluation can be conceptualized as a multiattribute evaluation procedure. Thus, it can build upon the approach of multiattribute decision-making, which allows for a theoretically sound and structured progression by way of manageable individual steps. For each single step (structuring the problem, structuring and weighting the attributes, sensitivity analysis, etc.) there is a range of practically tested techniques.

One of the strengths of this approach is that it facilitates an explicit examination of assumptions and values and thus aids in a transparent comparative risk evaluation. This approach is therefore suitable for precisely those CRA processes in which a variety of evaluators – experts and stakeholders – take part. A multitude of highly detailed participation procedures and models exists for organizing and implementing such multistakeholder evaluations.

In addition, as regards the practical organization and implementation of CRAs, a rich store of experience can be called upon. In the USA in particular, more than 100 CRAs have already been implemented for which summaries of the experience gained are available.

2. CRA requires scientific expertise and must be developed further

An important prerequisite for a CRA is the harmonization of methods of risk assessment and evaluation from different fields. To this end, the characterization of risks should be regarded as a separate step. The entire process requires scientific

expertise and needs to be further developed to allow for an efficient implementation.

Risk assessment begins with the identification of hazards. Three problem areas are of significance here: (a) the degree of evidence required to substantiate a causal link between the causes and effects in question, (b) the classification of an effect as adverse or undesirable, and (c) possible exposure of subjects of protection.

The evaluation of evidence is a substantial problem. Here categories ("how strong is the suspicion?") must be developed that can be unambiguously operationalized. Worst case scenarios are, due to their arbitrary nature – it is always possible to imagine even more severe scenarios – no workable basis for the assessment and evaluation of risks. Dose–response assessments should be determined in accordance with standardized and harmonized methods. In the light of the importance of hazards, exposure assessments are also of considerable significance.

The risk characterization thus brings together the results of the identification of hazards, dose–response assessments, and exposure assessments. This examination of the data is also a factual prerequisite for comparative analyses. Hence the risk characterization should be regarded as a special stage in the process.

Risk evaluation constitutes the link between the predominantly scientific/technical risk assessment and a sociopolitically oriented valuation of risks. A consensus on what are tolerable risks, reached through societal debate, can be the basis for an evaluation of quantifiable risks. Many deliberations must cope with (as yet) unquantifiable risks, and thus criteria for differentiating – again on the basis of scientific expertise – between averting a substantiated danger (with unambiguous regulatory requirements, primarily through limit values) and precautionary measures need to be developed. It is, furthermore, undetermined which suspicions of risk are strong enough to justify the application of the precautionary principle as a way of reaching an initial basis for making comparisons with other risks. However, standards of quality neither for individual studies nor for the overall scientific understanding of risk suspicions have yet been developed.

Another problem area is the evaluation of risks involving new or developing technologies (such as nanotechnology or genetic manipulation). Special methods, including prognostic procedures, for the early recognition of potential hazards and their relevance need to be developed. To this end, it should be ensured that the conceptualization of such methods be consistent and provide for the ability to compare different technologies.

3. CRA can provide important information for all stages of risk regulation

In the risk regulation process, different individual steps with their own specific objectives can be differentiated. CRA can provide substantial information at all stages; thus, it is clear that even individual components of a CRA – in the sense of risk-related comparisons – can prove useful for the respective objectives.

The *preliminary analysis* is concerned with the analysis of a novel risk potential, with a new technology's public mobilization potential, and with an initial analysis of the urgency for a risk evaluation. The benefit of a CRA lies here in the comparison of new technology fields, in the comparison of public risk perceptions for dif-

ferent cases, and in the comparison of hazardous substances with regard to their emission data, exposure characteristics, and toxicity.

Risk assessment is focused on the evaluation of evidence. This is where scientific controversy is often found and a comparison of different evidence evaluations, for instance with the use of tried and tested guidelines and categories of evidence, could contribute considerably to the solution of the problem. Of note here is the method of *comparative evaluation of unclear risks* in which similarities and differences that are demonstrable between different experts or groups of experts in the evaluation of evidence of the existence of a threat are compared.

In the regulatory step of *risk evaluation* there are four different opportunities for making risk-related comparisons: (a) the evaluation of a pollutant's potency, (b) the evaluation of exposure to such a pollutant, (c) the evaluation of the vulnerability of populations, and (d) the comparative evaluation of the various risks.

At the center is the opportunity for comparative evaluation of various risks. Particularly noteworthy here is the procedure known as *multiattribute comparative risk evaluation*, in which the evaluative dimensions (attributes) of known risks are compared by one or more evaluators (stakeholders). This essentially follows the classic approaches of CRA. The outcome of such a multiattribute CRA is a ranking of risks on the basis of an (preferably quantitative) assessment of the health consequences and their evaluation.

A number of risk-related comparisons also lend themselves to *risk management*, for example in the selection of technological alternatives, or in the siting search for locations of facilities with potential risks. Cost and benefit aspects are typically included in such comparisons.

4. CRA, as a combination of scientifically based risk assessments and value judgments, requires the cooperation of experts and societal stakeholders

Experts – such as the authors of scientific risk assessments – and the general public frequently have very different understandings and interpretations of risk assessments. One substantial problem, from the point of view of experts, is that the final results of analyses are separated from their principal constraints, methodological uncertainties, and scope, of which the public remains unaware.

What is basic to the understanding and role of risk assessments is, furthermore, the idea of risk itself. It has been shown that the technical conception of experts is, from the public's point of view, extremely narrow and encompasses only a fraction of the aspects and values that the general public – broadly represented by societal stakeholders – consider important to an appraisal of risk. Even the consideration of frequency and loss as equivalent, which is derived from the insurance industry, is – as it is among experts – disputed. Both factors are treated by lay people (i.e., those who are not risk experts) individually; in particular, the upper limit of potential damages is seen as an independent issue and is increasingly demanded.

In addition, the concept of risk underlying risk assessments usually encompasses only a few of the dimensions of loss, often only loss of life and harm to health, and, in rare cases, loss of property. The public mostly looks at some of the other dimensions and concomitant circumstances of risks, such as the timeframe in which

harmful effects occur, the physical, i.e., spatial, extent of losses, the unavoidability of risks, evacuations, resettlements, and other conspicuous social aspects. Within the context of specific CRA procedures, experts on the one hand and stakeholders on the other must clarify which aspects should be taken into account within the CRA.

A consensually accepted and successful CRA can, therefore, only be based on the cooperation of experts (in risk assessment and management) and societal stakeholders as representatives of public opinion.

5. CRA requires a risk communication program

An important prerequisite for the success of a CRA project is good communication. What are essential here are the setting of clear objectives, explicit and comprehensible definitions of the risks being compared and of the assessment criteria and units of measure, and a comprehensible characterization of risk.

Every CRA assumes that the parties involved are sufficiently well informed that they are able to deal with the comparative assessment of risks. Beyond this, however, several aspects of the process of communication are to be noted. Chief amongst these is the realization of fairness, competence, and trust.

The following aspects need to be distinguished for the public communication of the results of a CRA: (a) acceptance of CRA methods, (b) the clarification of a CRA's contribution to the understanding of the scale of a risk, and (c) acceptance of the results of a CRA.

Acceptance of a CRA is only possible when it succeeds in creating a mature understanding of risk so that it can be rationally weighed. The clarification of a CRA's contribution to the understanding of a risk depends upon whether and how existing information gaps are filled. The exchange of viewpoints and attitudes plays an important role in this. Such an exchange is also essential for the acceptance of CRA results.

1
Introduction

Decisions dealing with environmental health risks must be made under the most widely differing contexts. These range from decisions of the private sphere through regulatory decisions to those on the global political level. While such risk-related decisions in one's private life (for instance, engaging in dangerous or extreme sports or taking out an accident insurance policy) are mostly made without a precise analysis of risks or of the advantages and disadvantages of the available alternatives, regulatory and political risk-related decisions should be based on a thorough analysis of risks and decision options.

A glance at some contemporary problems in society shows that the spectrum of risk-related decisions is very broad:

- Should the use of a particular substance be regulated (e.g., by setting limit values)?
- Can a substance known to be harmful be replaced by another (e.g., by substituting chemicals)?
- Where should the emphasis of health policy be placed (e.g., cancer prevention, AIDS awareness)?
- Which energy systems should be used (e.g., fossil fuels, renewable energy sources)?
- Which methods of agricultural production should be preferred (e.g., conventional agriculture, genetically modified crops)?

The tasks of risk assessment, risk evaluation, and risk management are, in Germany, administered by different institutions.[1)] Thus, the responsibility is distributed among various ministries at the federal level (e.g., BMU, BVEL, BfG) which each consult the expert knowledge of subordinate federal agencies (e.g., BfS, UBA, RKI), private legal entities (e.g., Senatskommission zur Bewertung Maximaler Arbeitsplatzkonzentrationen der DFG), and expert committees (e.g., SSK) which are assigned to them. Numerous committees (e.g., LAI, LAUG) are also involved at the state level. This profusion of competencies and administrative levels may lead to a loss of clarity and confusion. In its final report on the reorganization of the methods and structures for risk evaluation and standard-setting in environmental

1) See the German Risk Commission's analysis (2003) for details.

health protection of the Federal Republic of Germany, the German Risk Commission came to the conclusion that

> *The result of all this is that the way potential health risks are dealt with is usually determined by a fortuitous or interest-driven perception of the problem on the part of the public or the media. In the recent past a number of conflicts of objectives have made it clear that there is a lack of effective crisis management. Participation by the public and by interest groups in risk regulation tends to be the exception, and it is unsystematic and ponderous. Hesitant and contradictory regulation by the governmental bodies involved, selective information of the parties concerned, and communication deficits combine to produce a situation where on the one hand relatively minor risks occupy an important position in public perception, whereas on the other, serious risks are underestimated or even "swept under the carpet".* (German Risk Commission 2003, p. 18)

This appraisal makes it clear that comparative risk assessments can play an important role in the regulation of risks.

Comparisons of risks are, in and of themselves, nothing new. Indeed, every evaluation of a risk implies some comparison: either a comparison of the risk under consideration with an environmental standard (a threshold, benchmark, etc.) or a comparison with other risks.

Examples of comparisons with environmental standards include occupational exposure limits (OEL), acceptable daily intake (ADI) values for various substances, or technical reference concentration values. In these cases, emissions and exposures are compared with standards so as to decide on risk management measures. The number of currently enforceable environmental standards in Germany is very large and these standards are extremely heterogeneous in both their rationales and their aims.[2)] This is not to disparage the practice of such comparisons but to indicate that such a method of evaluation lacks transparency and can also be inconsistent.

Besides the comparisons with environmental standards, there are comparative evaluations of different risks with the goal of creating a risk ranking. This type of evaluation, termed comparative risk assessment (CRA), has been both discussed and applied in practice in the USA since the end of the 1980s. The most well known and perhaps most ambitious CRA project is the ranking of environmental risks carried out by the US Environmental Protection Agency (US EPA). In addition, numerous CRA projects have been, and are being, carried out in the USA, mostly on behalf of particular states or at the local level. The goal of these efforts was, and is, to lay the foundation for a more rational establishment of priorities in environmental health policy. Using scientific risk assessments, risks from entirely differ-

2) In its analysis of environmental standards the German Advisory Council on the Environment (SRU) recorded 154 lists of environmental standards with a total of approximately 10,000 individual environmental standards; see SRU (1996).

ent areas are to be evaluated and compared so as to arrive at an estimation of their relative significance.

In contrast to the USA, comparative risk evaluations have as yet been only rarely used in Germany (and Europe), either in the field of risk assessment and evaluation or in risk management.[3)] There are multiple reasons for this: for one the methodological difficulties inherent in CRA are cited, while another is the completely diverging estimation of the benefit of CRA for environmental policy.

This neglect of CRA is perhaps also a reflection of the density of regulations and the philosophy of regulation followed in Germany, in which risks from various regulatory areas (nonionizing radiation, ionizing radiation and chemicals, transport, etc.) and in various fields of environmental policy (protection of wildlife, soil, water. and climate, as well as air purity conservation, waste disposal, and the treatment of hazardous materials) are not considered concomitantly. This sector-by-sector consideration has disadvantages, not the least of which is the insecurity perceived by citizens when a risk, which is not tolerated in one field, is accepted in another. This public insecurity also results from the basic principle followed in Germany of regulating technical facilities through safety certifications without producing any quantitative reference to risks. In particular, the isolated approaches of individual environmental health sectors regardless of a sufficient consideration for the overall context of safety and risk need to be changed. This is where CRA, when properly integrated into the process of risk regulation, can perform a useful service.

The claim that comparative risk evaluation forms a rational foundation for making environmental health-related decisions has led, especially in the USA, to a critical debate in which a range of arguments have been brought against CRA. One set of arguments relates to the use of CRA in the context of the USA's regulation of environmental health risks (in particular on the part of the US EPA). It is, for instance, argued that the use of CRA would be accompanied by a "tyranny of the rational", which would reduce the flexibility of the existing system of regulation in the USA and that this flexibility is precisely the result from the fact that risk assessment and risk management are not separated from the political processes (Silbergeld 1995, p. 422).

Other criticisms are of a more fundamental nature. In addition to the accusation of the trivialization of risks – especially of environmental risks which, by being compared to so-called "lifestyle risks" (e.g., smoking, or nutritional habits) are often accorded a minor fraction of the risks facing human health – three arguments in particular are brought against CRA (e.g., Hornstein 1992; Shrader-Frechette 1995; Silbergeld 1995).

3) Morgenstern et al. (2000) in their international comparison of CRA methods and results mention a series of developing countries, but find no use of CRA with the aim of developing risk ranking in Europe or, indeed, the OECD countries. CRAs on specific themes have, in the meantime, been attempted in single research projects, for instance the GaBE Project on the Risks of Energy Supply Systems (Projekt zu Risiken von Energieversorgungssystemen); cf. Hirschberg et al. (1998). See Section 3.2.5 of this book.