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Book review

COMPARATIVE RISK ASSESSMENT
Concepts, problems and applications

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The International Risk Governance Council (IRGC) is delighted to have been able to support the Forschungszentrum Julich GmbH's Man, Environment and Technology Program Group by founding the translation of their original 2004 text into English, hoping that having the report 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, founded in 2003. Its mission is to support governments, industry, NGO's and other organizations in their efforts to deal with major and global risks facing society and foster public confidence in risk governance. 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.

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 companies 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. Comparative risk assessment offers a possible means of providing a scientific basis for such decisions. There is still a need to further study and understand how best comparative risk assessment can fulfill its full potential, and the publication of this book is a most helpful addition to it.

The comparative risk assessment can play an important role in the regulation of risks. The claim of comparative risk evaluation forms a rational foundation for making environmental health-related decision has led, especially in the USA, to a critical debate in which a range of arguments have been brought against comparative risk assessment. 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 environmental health risk and deduces that comparative evaluation of these risks are not possible or, at least, not meaningful. A third argument sees in comparative risk assessment an obstacle to the possible participation of the public in decisions on environmental health risks. Relying on comparative risk assessment 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 non-experts.

In this context, the objectives set for this book were to evaluate existing approaches to comparative risk assessment, 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 results of the study presented herein, are as bellow:

1. Comparative risk assessment can draw upon a range of developed and established instruments. Comparative risk evaluation can

be conceptualized as a multi-attribute evaluation procedure. Thus, it can build upon the approach of multi-attribute 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 strength 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 comparative risk assessment processes in which a variety of evaluators – experts and stakeholders take part. A multitude highly detailed participation procedures and models exist for organizing and implementing such multi-stakeholders 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 comparative risk assessments have already been implemented for which summaries of the experience gained are available.

2. Comparative risk assessment 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 socio-politically 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 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 comparison 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 nanotechnologies 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. Comparative risk assessment 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 in the comparison of a new technology fields, in the comparison of public risk perceptions for different 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. The method of comparative evaluation of nuclear 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 treat are compared.

In the regulatory step of risk evaluation there are four different opportunities for making risk related comparison: (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, is the procedure known as multi-attribute 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 multi-attribute CRA is a ranking of risks on the basis of an assessment of the health consequences and their evaluation. A number of risks – related comparison also lend themselves to risk management, for example in the selection of technological alternatives, or in the sitting search for locations of facilities with potential risks. Cost and benefit aspects are typically included in such comparison.

4. Comparative risk assessment, 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 equivalent, which is derived from the insurance industry, is disputed. Both factors are related 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 ham of health, and, in rare cases, loss of prosperity. The public mostly looks at some of the other dimensions and concomitants circumstance of risks, such as the timeframe in which harmful effects occur, the physical, the unavoidability of risks, evacuations, resettlements, and other conspicuous social aspects. Within the context of specific comparative risk assessment procedures, experts on the one hand and stakeholders on the other hand must clarify which aspects should be taken into account within the CRA. A consensually accepted and successful CRA can therefore only be based in the cooperative of experts (in risk assessment and management) and societal stakeholders as representatives of public opinion.

5. Comparative risk assessment (CRA) requires a risk communication program. An important prerequisite for the success of 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, 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.

The book *Comparative risk assessment. Concepts, Problems and Applications* is structured in 6 main chapters and 4 appendixes. The first chapter *Introduction* presents the tasks of risk assessment and risk management that are in Germany administered by different institutions, and the main objectives of this study which are to evaluate existing approaches to comparative risk assessment, to explore the possibilities of improving such comparisons, to discuss the opportunities for participation, and to design processes that will increase acceptance of political decision making about environmental health risks.

The second chapter *Concepts and Definitions* the major concepts used in the discussions and elaboration of a comparative approach to risk are explained. Additional definitions and comments are found in the appendices and glossary at the end of this book. In this chapter 9 terms are described, such as: risk, danger/potential for damage – hazard, incertitude and uncertainty, risk assessment (understood as the process from identifying a potential danger to the quantitative characterization of risks), risk evaluation (in a procedure built on the results obtained from scientific risk assessment), risk comparison (that has the aim of correlating tow or more risks on the basis of the risk assessments), risk management (that concerns itself with activities that are related to dealing with risks), risk regulation and risk communication. Communication about risk plays a central role in a transparent account of the assumptions, uncertainties, and findings of the individual steps in the process of risk regulation.

In the third chapter *Comparative risk assessment in Practice (CRA in Practice)* approaches to integrated and comparative risk evaluation can only by prosperity appraised when one's perception of their utility includes and considers the varieties of CRA currently existing in practice. This chapter therefore deals firstly with the various evaluations of and positions on CRA in the USA, Europe, and Germany. This is complemented by four examples of comparative risk evaluation that are presented and discussed. The case studies presented that risk comparisons may be differentiated with regard to their goals, formation of risk categories, timeframes, metrics of comparison, and constraints. Typical goals of risk comparisons are the establishment of priorities in environmental health policy, the choice between technological or administrative alternatives, and the setting of threshold values.

A typical example for the problems of category formation is the US EPA Unfinished Business Project. Here the comparative categories are oriented on the lines of the internal structure of the EPA, which in turn must be oriented on its role as laid down in law. In projects with the aims of establish priorities in environmental health policy and technical or administrative alternatives are risks that distinguish between the types of harm or damage, timing of damages, and groups of people of varying sensitivity. In the project with the aim setting threshold values, a criterion of comparison (risk of cancer) is at hand for which an established metric (unit risk) is available.

The risk under investigation depends on many constraints such as spatial distribution of the subjects of protection in the vicinity of the sources of risk, previously existing burdens from other sources of risk, interactions which lead to the decomposition or formatting of pollutants, such as that established in ExternE between SO_2, NO_x and NH_3.

The Empirical Foundation of CRA, chapter four describes the starting point for risk comparison, risk comparisons as a means of risk communication, procedural challenges and the comparative risk assessment negotiations under conflict.

The next chapter *Conceptual Framework for an Integrated Comparative Risk evaluation* underlines the methodological problems of comparative risk assessment, the methodology of comparative risk evaluation which consists in multi-attribute risk evaluation: quantitative and qualitative approaches.

The final chapter of this book, *The practical Implementation of CRA* presents four factors that need to be taken into consideration for the practical implementation of CRA. Firstly, the limits of comparison must be defined. This also involves dealing with meaningful possibilities fro comparative evaluation of risk. Secondly, it must be made clear who should compare risks; there are actors to be defined and their roles to be determined.

Thirdly, the sequential order of CRA procedures must be specified. Fourthly, the communication problems between participants must be minimized. From a factual point of view, communication is particularly difficult if there are signs that a CRA is based in risk concepts and perspectives that deviate fundamentally from the public's risk perception. This problem can never be completely solved.

A degree of tension always remains. If a CRA fully meets the public's risk perception, it fails to meet its aim and becomes a study in risk perception. A CRA that masks all aspects of public risk perceptions and touches only on scientific facts can go astray in society: the acceptance of its results will not take place. From this springs the task of explaining precisely the procedure of the CRA and in particular the applied attributes.

Appendix 1 describes risk metrics for characterization dose – response relationships, referring to NOAEL, benchmark dose, reference dose. The appendix 2 presents multi-attribute comparative risk evaluation (MCRA). The preparation and structuring of the evaluative process have a significant impact on the conduct of a multi-attribute comparative risk assessment, particularly when stakeholders groups contribute alongside various experts. The profile of a multi-attribute comparative risk evaluation presented herein follows from this. The MCRA procedure for environmental, health and life quality risks follows 5 steps: establishing the MCRA teams, determining the cornerstones of the CRA, risk assessment, risk characterization, and ranking.

Appendix 3 follows an example fro comparative evaluation of unclear risks. In the evaluation of unclear risks (EUR) the essential problem is that various evaluators can arrive at different outcomes even in the appraisal of scientific findings. For this reason, these circumstances should occupy the central point in the design of the EUR.

The purpose of EUR is the comparison of evaluations of an unclear risk by various evaluators with the aim of formatting a consensus regarding the evidence for the existence of a hazard. The transfer to the comparative evaluation of several unclear risks occurs relatively simply. The aim of an EUR is determination of a hazard, determination of dissent/consensus between various evaluators in the identification of a hazard. The field of application is unclear risks, and is focused on evidence of hazard. At this process, experts with various hazard evaluations, citizens' advisory council can participate. The output of an EUR process is the evidence evaluations and evidence rankings.

A comparative evaluation of the risks of hazardous incidents is described in Appendix 4. In the case of risks associated with hazardous incidents, the uncertainty typical of risks mainly has less to do with whether exposure leads to harm or damage but rather whether an emission takes place. In contrast to normal risks, the probability of the occurrence of the pollutant (the emission) is to be considered as a further attribute in the characterization of risk.

Their scale reaches from events which though far from everyday, are within the realm of human experience, to events which are so improbable that one

does not practically anticipate, and which one can therefore describe as hypothetical. In this appendix just a few of the problems specific to risk arising from hazardous incidents are presented as an example of the comparative evaluation of technical risks.

Further risk communication problems with the public can arise from a lack of resources, as well as a lack of consultation between the CRA projects team and the CRA project management. Whether a CRA is successful depending on how it is communicated to the decision makers. Besides, situational factors, the presentation format plays a role. Overall, the experience with CRAs in USA offers a rich source of material on the variety of implementation possibilities, but due to administrative, political, and not least cultural differences to Germany, or indeed Europe, this is of only limited transferability. If one wishes comparative risk evaluation to have a firm place in the process of risk regulation, practical trials of procedures such as those that have been laid out in this book are indispensable.

Comparative risk assessment offers a possible means of providing a scientific basis for decisions concerning environmental components and health related. There is still a need to further study and understand how best comparative risk assessment can fulfill its full potential, and the publication of this book is a most helpful addition to it.

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