INTRODUCTION TO THE IRGC RISK GOVERNANCE FRAMEWORK

Revised Version 2017

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PREFACE

The International Risk Governance Council (IRGC) is an independent non-profit organisation that provides policy makers, regulators, risk managers and other key decision-makers with evidence-based recommendations about risk governance. Our expertise lies in systemic and emerging risks that threaten human health and safety, the environment, the economy and society at large. IRGC recommendations recognise the scientific, political, social, and economic contexts of risks and opportunities as well as the challenges due to uncertainty, knowledge gaps, time constraints or policy trade-offs.

Many risks are complex, uncertain, and even ambiguous. In most cases, the potential benefits and risks interconnect. Improvements in the management of risks are essential in order to take effective and efficient decisions and to improve public trust in risk management processes, structures and decisions.

The Risk Governance Framework was developed for IRGC by a team of risk experts chaired by Prof. Ortwin Renn, drawing on a broad analysis of evidence-based approaches to risk management. Its purpose is to provide methodological orientation and empirical evidence to use risk governance concepts. This generic and adaptable framework can be tailored to various risks and offers guidance for the development of comprehensive risk assessment and management strategies. A detailed description of the Framework was published in the 2005 IRGC white paper *Risk Governance – Towards an Integrative Approach*.

Building on this work and on feedback from practical applications, IRGC's 2009 report on *Risk Governance Deficits: An analysis and illustration of the most common deficits in risk governance* focused on the sources of governance deficits and their constructive assessment and management. Further to this, IRGC produced a series of publications to address emerging risks, in particular: *Contributing Factors to Risk Emergence* (2010) and *Emerging Risk Governance Guidelines* (2015). These publications expand the main Risk Governance Framework to address issues specific to emerging risks. Work on guidelines for the governance of systemic risks is also under way.

This introduction to the IRGC Risk Governance Framework summarises the main points of the white paper, identifies potential deficits in the risk governance process and illustrates their manifestation with examples.

More information about IRGC and the IRGC Risk Governance Framework is available at www.irgc.org.

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THE NEED FOR RISK GOVERNANCE

Risk can be defined in different ways, for instance based on societal agreements (e.g. organisational, scientific and technical disciplines conventions) or the sector of application (e.g. finance, health, environment, or business). In order to be useful, a definition of risk must enable the evaluation of various dimensions pertinent to the field of that risk (see Box 8) and comparisons between risks and options for managing them.

IRGC has adopted a broad definition relevant to the governance of a wide range of risks: **Risk** refers to uncertainty about and the severity of the consequences of an activity or event with respect to something that humans value. Uncertainty can pertain to the type of consequences, the likelihood of these occurring (often expressed in probabilities), the severity of the consequences or the time or location where and when these consequences may occur[1]. This definition accommodates both desirable (positive) and undesirable (negative) outcomes but most organisations focus on the negative outcomes.

Box 1: From conventional to systemic risks

In today's world, risks and systems are deeply inter-connected. It has proven useful in the risk community to distinguish between conventional and systemic risks. Conventional risks are characterised by a well-known probability distribution over a limited scope of adverse effects. In contrast, the concept of systemic risk refers to the risk or probability of breakdowns in an entire system, because of high levels of connectivity, major uncertainties and ambiguities, and non-linear cause-effect relationships. Risks are increasingly systemic, and can seriously threaten the functionality of critical systems, which are essential to the economy and/or society. Systemic risks are embedded in the larger context of societal, financial and economic change. Such risks cannot be managed through the actions of a single sector, but require the involvement of different stakeholders, including governments, industry, academia, and members of civil society. Some systemic risks can even have 'global' impacts, requiring coordinated management approaches at local, regional, national and international levels. (OECD, 2003)

Governance refers to the actions, processes, traditions and institutions by which authority is exercised and collective decisions are taken and implemented.

Risk governance applies the principles of governance to the identification, assessment, management, evaluation and communication of risks in the

[1] Aven and Renn (2009) and the SRA Glossary (2015) have further defined risk.

context of plural values and distributed authority. It includes all important actors involved, considering their rules, conventions and processes. It is thus concerned with how relevant risk information is collected, analysed, understood and communicated, and how management decisions are taken and communicated. Risk governance mobilises both descriptive issues (how decisions are made) as well as normative concepts (how decisions should be made). In its application as a normative concept it specifies the principles of good governance. These principles include transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law, and the need for the chosen solution to be politically and legally feasible as well as ethically and publicly acceptable.

Decision-makers may defensibly choose to take risks to obtain the associated benefits. Indeed, risk-taking may be crucial to achieving technological innovation, economic development and social welfare. Many risks, and in particular those arising from emerging technologies, are accompanied by potential benefits and opportunities. The challenge of better risk governance lies in enabling societies to benefit from opportunities while minimising the negative consequences of the associated risks.

Therefore, attempts to govern risks often face the following challenges:

- A lack of appropriate **methods**, or differing approaches and protocols for assessing and managing the same risks across countries, organisations and social groups.
- Inadequate consideration of risk-benefit as well as risk-risk **trade-offs**, or inequitable distribution of risks and benefits between stakeholders.
- Failure to understand **secondary consequences** of specific risks and the interconnections among consequences and between risks and opportunities.
- A need to **regulate** and take policy decisions under considerable time pressure, while facing uncertainty, incomplete information, difficult policy trade-offs affecting the various stakeholders differently, and the need to reduce regulatory burden.
- Difficulties to estimate the **cost** of policies, strategies or regulations, which furthermore may sometimes be inefficient or ineffective.
- Inappropriate involvement of different **stakeholder** groups, and lack of consideration for public opinion.
- Loss of public **trust** in risk management, whether by industry or policymakers and regulators.

KEY ASPECTS OF THE IRGC FRAMEWORK

The IRGC Framework recommends a holistic, multidisciplinary and multi-stakeholder approach to risk. It supports processes that aim to provide and structure scientific evidence about a risk in a societal context. It helps decision-makers analyse the major ambiguities and controversies that may affect the management of a risk.

The Framework provides guidance to cope with risks in situations of high complexity, uncertainty or ambiguity. It can support the detection of current or potential deficits within the risk governance process, and provide guidance for their remediation. Its application enables decision-makers to act on the basis of evidence, transparent assumptions, and broad societal values and interests. The IRGC Framework can help analysts raise the relevant questions when dealing with uncertainty and political and cultural ambiguities. Moreover, the Framework is designed to increase the capacity to deal with unanticipated consequences of risk, unknown impacts and social conflicts over trade-offs.[2] While recognising the upside of risk is important, the Risk Governance Framework focuses on managing the negative and unintended consequences of a risk.

Risk governance is not just about risk management. It starts at the earlier stage of **risk pre-assessment**, in which the essential perspectives of the problem are identified early and broadly, particularly regarding how the risk is framed by different stakeholders and whether or not there are any applicable legal or other rules or processes.

While **risk assessment** remains a central (technical) part of risk governance, this approach also urges risk governance institutions to gather not only knowledge about the physical, economic and social impacts of technologies, natural events or human activities but also knowledge about the concerns that people associate with causes and consequences of risks.

[2] The Framework elaborates from earlier and technical work on risk management. The 2005 IRGC white paper includes a list of other initiatives and publications. Since the publication of the IRGC Framework, other guidance documents or frameworks have been published, such as ISO principles for risk management (ISO 31000), some of them in institutional contexts (OECD, UNISDR). Most of those frameworks share similar principles but applied to various contexts. The field of risk management (or risk analysis) is developing to address new challenges in technologies, society or the economy. For example, the Board on Environmental Studies and Toxicology of the Division on Earth and Life Studies, at the US National Academies of Sciences, Engineering and Medicine recognised the need to improve chemical risk assessment by using better new scientific and technical advances. Its publication "Using 21st Century Science to Improve Risk-Related Evaluations" reflects on such advances and suggests recommendation to improve risk assessment. (NAS, 2017) Given the diversity of disciplines involved in risk management and fields of application, a group of risk analysis experts at the Society for Risk Analysis published in 2015–2017 a series of papers and a glossary, to support the development of the risk analysis field in a way that reflects the variety of applications but at the same time aims to bring cohesion to the field. (SRA, 2017).

To help achieve effective risk management and meaningful engagement with stakeholders, IRGC recommends a **characterisation** of risks (whether they originate from natural, technological, economic or environmental causes) depending on the knowledge available to address them: predominantly simple, complex, uncertain, ambiguous or a combination thereof. On this basis, a sound **risk evaluation** will be possible, leading to robust **decision-making** and **implementation** of risk governance measures.

In addition to the standard elements of risk assessment and management, IRGC also emphasises the crucial role of communication and public involvement. This includes not only informing people of a risk or risk management decision, but also establishing the two-way dialogue needed at all stages of the risk governance process – including communication between those responsible for taking risk-related decisions and those responsible for providing the knowledge on which the decisions are based.

An inclusive and open communication process is particularly important for the **engagement of stakeholders** in the assessment of perceptions and concerns and in risk-related decision-making and conflict resolution. It ensures that stakeholders make informed choices about the risk, balancing evidence-based knowledge about it with their own interests, concerns, beliefs and resources.

Finally, the IRGC Framework incorporates considerations to reflect the need to deal with risk in a way that fully accounts for the societal **context** of both the risk and the decision about it. For instance, it is necessary to accept and account for the variety of risk and regulatory cultures and styles around the world, as these will require different methods for, particularly, management and communication processes. Also, as risk cultures vary (for example, over time and according to the level of economic development), timing is a key criterion. Indeed, what is possible now in one environment may not be possible elsewhere; and what is not feasible today may be feasible tomorrow.

The IRGC Risk Governance Framework is a generic resource meant to be tailored to the specific context and needs of each risk governing organisation. The Framework as a whole or specific parts of it are often used as a basis or inspiration for an organisation to develop its own risk management framework (cf. Appendix 2: Application to Institutional Risk Management).

The Framework can contribute to improving risk management practices that go beyond conventional risk analysis and management by incorporating societal values, concerns and perceptions of risk. By looking into the interactions between the various affected stakeholders, it can help achieve more effective risk governance strategies. Eventually, the Framework can contribute to global efforts to harmonise risk governance approaches and find common denominators for risk handling in a globalised and plural world.

THE IRGC RISK GOVERNANCE FRAMEWORK

SUMMARY DESCRIPTION

The IRGC Framework provides guidance for early identification and handling of risks, involving multiple stakeholders. It is a comprehensive approach to help understand, analyse and manage important risk issues for which there can be deficits in risk governance structures and processes. The Framework comprises interlinked elements, with three cross-cutting aspects (see Figure 1 and Figure 2):

1. Pre-assessment – Identification and framing; setting the boundaries of the risk or system.
2. Appraisal – Assessing the technical and perceived causes and consequences of the risk.
3. Characterisation and evaluation – Making a judgment about the risk and the need to manage it.
4. Management – Deciding on and implementing risk management options
5. Cross-cutting aspects – Communicating, engaging with stakeholders, considering the context.

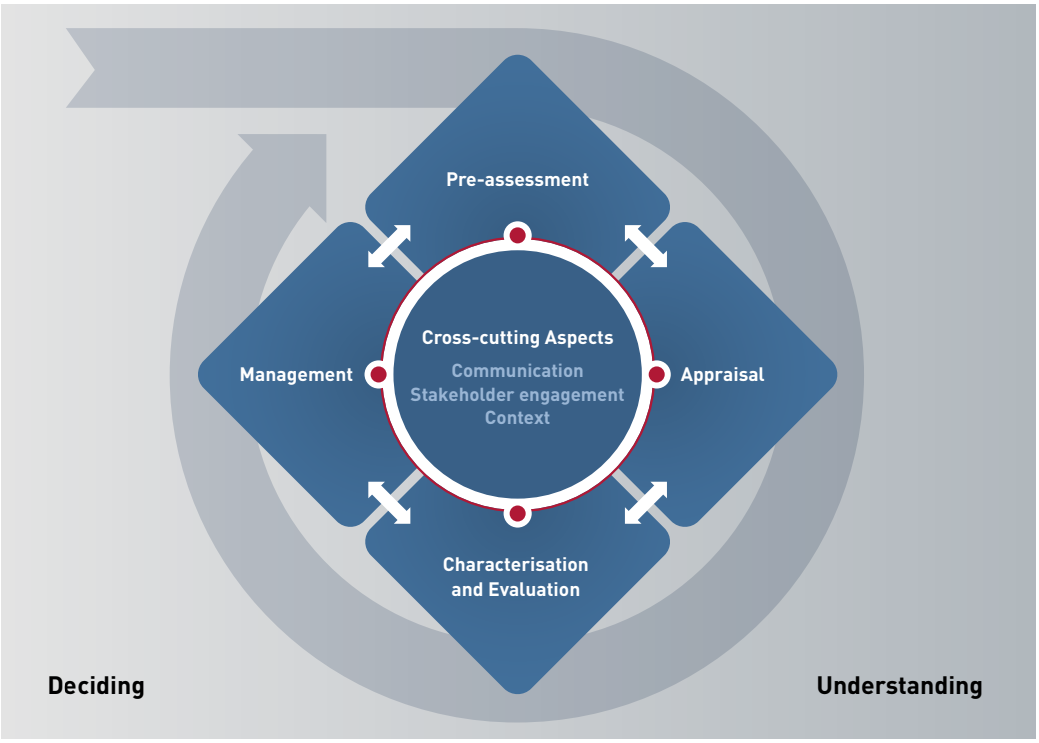


Figure 1: Simplified visual representation of the IRGC Risk Governance Framework.

IRGC's Risk Governance Framework distinguishes between **understanding** a risk (for which risk appraisal is the essential procedure) and **deciding** what to do about a risk (where risk management is the key activity). This distinction reflects IRGC's support for the clear separation of the responsibilities for risk appraisal and management as a means of maximising the objectivity and the accountability of both activities. Those responsible for both should be jointly involved in the other three elements: pre-assessment, characterisation and evaluation, and cross-cutting aspects.

The interlinked elements are summarised in the following pages. Together, they provide a means to gain a thorough understanding of a risk and to develop adequate and appropriate options for governing it.

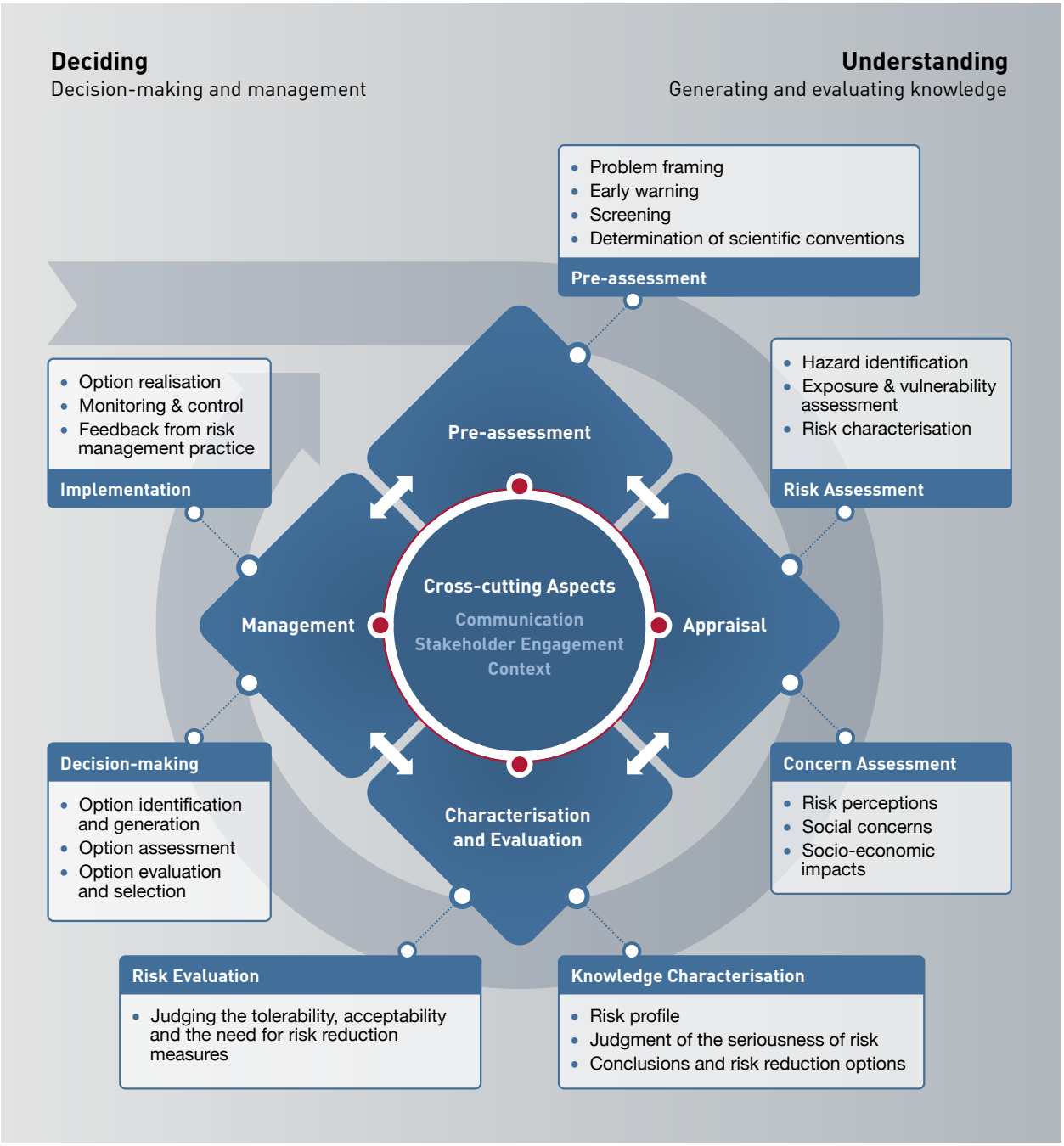


Figure 2: Detailed visual representation of the IRGC Risk Governance Framework.

1.

PRE-ASSESSMENT

IRGC's approach begins with risk pre-assessment, which leads to framing the risk, early warning, and preparations for handling it. Pre-assessment involves relevant actors and stakeholder groups, so as to capture the various perspectives on the risk, its associated opportunities, and potential strategies for addressing it.

Box 2: Pre-assessment – Subprime crisis in the USA

The subprime financial crisis which started in 2007 led to severe recessions in many countries with long-term negative impacts in many sectors. Critics have focused on the inadequacies of the banking sector and failing regulations, but many important issues have been overlooked. A pre-assessment of the risk would have framed financial risks as systemic, or deeply embedded within the economy of many countries. In the US and elsewhere, imbalances were likely created over the years. The numerous factors included weak regulations, political pressure to encourage home ownership among lower-income households, and the opacity of financial products.

It is important to identify these various sources and dimensions of risk as well as the different stakeholders involved, even before full risk assessment starts. Thereby, risk pre-assessment contributes to a broader understanding of a risk and can lead to the development of more integrated solutions than a narrow focus on regulation would propose.

Pre-assessment clarifies the various perspectives on a risk, defines the issues to be looked at, and forms the baseline for how a risk is assessed and managed. It captures and describes both:

- The variety of issues that stakeholders and society may associate with a certain risk (and the related opportunities).
- Existing indicators, routines and conventions that may help narrow down what is to be addressed as the risk, as well as the manner in which it should be addressed.

The main questions in pre-assessment are:

- **What are the risks and opportunities** that we are addressing?
- Who are the **stakeholders**? How do their views affect the definition and framing of the problem? What are the organisational issues and power relations between them?
- Does the risk mobilise different stakeholders?
- What are the **various dimensions of the risk**?
- How are the **boundaries of the evaluation** defined, in terms of scope, scale or time horizon?

- Are there indications that there is already a problem? Is there a need to act?
- What are the established scientific and analytical tools and methods that can be used to assess the risks? Do we need new research protocols to characterise the risks?
- What are the current legal/regulatory systems and how do they potentially affect the problem?
- Does the organisation use foresight or horizon scanning for the identification of emerging risks?
- What is the organisational capability of the relevant governments, international organisations, businesses and people involved?

Potential governance deficits in pre-assessment:

- Warning – Signals of a known risk have not been detected or recognised (complacency bias, false positive and false negative)
- Scope – A risk which is perceived as having only local consequences may in fact be much broader (and vice-versa)
- Framing – Different stakeholders may have conflicting views on the issue (including contesting views about the desirability of the benefits)
- 'Black swans' (surprising extreme events relative to our knowledge) – No awareness of a hazard or possible risk

2.

APPRAISAL (ASSESSMENT)

Risk appraisal develops and synthesises the knowledge base for the decision on whether or not a risk should be taken and/or managed and, if so, what options are available for preventing, mitigating, adapting to or sharing the risk.

Risk appraisal goes beyond the conventional scientific risk assessment and comprises both:

- A risk assessment – An assessment of the risk's factual, physical and measurable characteristics, which aims to identify and describe the possibility of occurrence or a probability distribution over a range of negative consequences, considering the hazard as well as the exposure[3] and vulnerability[4] of the values or assets that must be protected.
- A concern assessment – An assessment of different stakeholders' opinions and concerns about the risk, a systematic analysis of the associations and perceived consequences (benefits and risks) that stakeholders may associate with a hazard, its cause(s) and consequence(s).

Risk and concern assessments need to be based on state-of-the-art scientific methodologies. They involve the physical sciences (such as toxicology, epidemiology, engineering science or natural sciences) as well as human and social sciences (such as sociology, psychology, political sciences, anthropological or behavioural sciences).

With respect to the type and collection of data, risk assessors can be informed by big data (large scale data sets that can provide evidence on correlations between risk elements and thus help understand complex phenomena), the use of predictive analytics (a type of statistical techniques used in predictive modelling, machine learning and data mining that analyse current and historical facts to make predictions about future or otherwise unknown events), or social media (which can provide information about public opinion and the emergence of new phenomena).

[3] The fact of being subject to a risk source/agent.

[4] The degree to which a system is affected by a risk source or agent, or able to withstand specific loads.

Box 3: Risk and concern assessment – Assessing risks and concerns in fisheries depletion

The North Sea herring fishery suffered a severe collapse in 1975 after regulators ignored early warning signs that fish stocks were very low. The fishery was therefore closed. Upon re-opening of the herring fishery in 1981, efforts were made to improve the continuous assessment and management of fish stocks. In 1995, early warning signs once again showed that fish stocks were becoming dangerously low. However, quick and drastic action to impose quotas was taken to avoid another collapse and, by 2003, the stock had recovered without even requiring temporary closures of the fishery. An important reason for the success was the combination of a scientific assessment of the risk, using knowledge gathered and shared from earlier collapses about the behaviour of fish stocks, and an assessment of the concerns of fishermen and industry, which would have been affected by a new collapse, even if in the medium term only. Affected stakeholders were involved in the decision to restore quotas, which led to short-term losses but avoided larger collapse.

2.1 Risk assessment

The IRGC Framework distinguishes between the source of the risk and its impact:

- On the source side, it considers the risk agent (source system), i.e. the hazard that has the potential to cause harm (e.g. a poisonous chemical).
- On the impact side, it considers the risk absorbing system, i.e. the assets that could be exposed to the risk agent.

Risk is hence a composition of the potential to cause harm by the risk agent, the possibilities of being exposed to this agent and the vulnerability of the risk-absorbing system (amount of stress that the system can tolerate). Furthermore, risk expresses the relative likelihood that such harm is experienced.

Scientific risk assessment deals with the following questions:

- What are the potential **damages or adverse effects** associated with the risk? How ubiquitous could the damage be? How persistent? Can it be reversed?
- What are the **processes** that create and control risk?
- How **vulnerable** is the risk-absorbing system with respect to the stress that the risk agent inflicts on it?
- What accident **scenarios** can occur? What about their severity, kinetics, probability of occurrence, etc.?
- Can the risk be **quantified** (e.g. as a function of probability and severity)?
- What is the degree of **confidence in the risk assessment**, including its comprehensiveness (inclusion of all relevant factors) and accuracy? What is the level of robustness and validity of data and knowledge?
- How **reliable** are the probability estimates and how much uncertainty prevails?
- Do risk assessors use **scenario** development for prospective assessment of the risk?

Potential governance deficits in risk assessment include:

- Lack of appropriate methods and models to assess potential harm (e.g. in the case of new technologies or cumulative exposure).

- Scarcity of scientific data about the risk (risk agent and risk-absorbing system) and/or about stakeholders' associated concerns.
- Inappropriate use of advanced assessment methods, such as those deriving from big data analytics, artificial intelligence, social media analysis, or citizen science.

2.2 Concern assessment

The concern assessment is a key feature of the IRGC Framework. It takes into account the values and socio-emotional issues that may be associated with the risks. It explicitly recognises that people's decisions about how to handle risks are influenced by their past experience, their perception as well as their perhaps more emotional and value-based concerns. It is therefore essential to understand perceptions, values and concerns, as they not only determine the social and cultural ambiguity about a risk issue but also influence the attitudes toward risk and risk taking behaviour. With increasing complexity and interconnection between risks and benefits, it is often difficult for people to give meaning to situations or their experience. Attention must be paid to the collaborative process of sense-making, i.e. the process by which people give meaning to their experience, which can create situational awareness and understanding in situations of high complexity or uncertainty in order to make decisions.

Concern assessment deals with such questions as:
- What are different **stakeholders**' opinions, values and concerns about the risk? What is their level of involvement, accountability or responsibility?
- Are there cognitive or heuristic **biases** that affect the risk perception or concern? (see Box 4)
- Are there sociological, organisational and anthropological **constraints** on actors and stakeholders?
- What is the **social response** to the risk? How do people react? Is there the possibility of political or social mobilisation?
- What role do existing institutions, governance structures and the media play in defining and **addressing public concerns**?
- Are risk managers likely to face **controversies** and conflicts due to differences in risk perception, in stakeholder objectives and values, or from inequities in the distribution of benefits and risks?

Potential governance deficits in concern assessment include:
- Misunderstanding about biases that may affect the perception of the risk.
- Low confidence level in the data, the model or their interpretation.
- Inadequate attention given to the concerns of different stakeholder groups, and drivers of their behaviour.

Box 4: Cognitive biases that affect how individuals perceive risks and behave in risk situations

Behavioural insights can be extremely useful in understanding the predispositions that affect how people take decisions and then build on those biases to help obtain a better outcome. Biases and intuitive heuristics relate to processing information on risk aspects such as exposure, probability or uncertainty. Biases that individuals often apply to judge risks or to draw inferences from probabilistic information include (Renn, 2008) (Kahneman, 2013):

- **Availability** – Events that come to people's mind immediately (e.g. events highlighted in the mass media) are rated as more probable than events that are less in their thoughts. In food consumption behaviour, if people have a tendency to grab the first food they see (due to the availability heuristic or satisficing choice strategies), then it is recommended that they see the healthy food first.
- **Status quo or choice avoidance** – People have a tendency not to change their behaviour. If their inclination is to stick with the default option that is proposed to them, then authorities or risk managers need to make sure that the default option is the one that is best suited for them.
- **Anchoring effect** – Probabilities are not adjusted to sufficiently take into account new information when it becomes available. People retain the perceived significance of the initial information so that, for example, if they associate eating fish with heavy metal contamination, they are likely to ignore that eating fish, even lightly contaminated, is still healthier than eating red meat.
- **Personal experience** – Single events either experienced directly by people, or in associated circumstances, are considered more typical than the information related to the actual frequencies of those events. People who, by chance, have observed that woman drivers were involved in the last two accidents they witnessed are likely to infer that women cause more accidents (which, in fact, is not true).
- **Avoidance of cognitive dissonance** – In an attempt to attenuate cognitive dissonance, information which challenges perceived probabilities that are already part of a belief system will either be ignored or minimised. Autonomous cars are perceived to be less safe because the overriding belief is that humans are better drivers than machines, even though experts demonstrate that, in general, machines cause fewer accidents than humans. In the case of autonomous vehicles, industry and regulators will need to communicate more clearly to explain why those can be safer than conventional ones.

3.

CHARACTERISATION AND EVALUATION

Risk evaluation is the process of comparing the outcome of risk appraisal (risk and concern assessment) with specific criteria, to determine the significance and acceptability of the risk, and to prepare decisions. Characterising the knowledge about a risk can help evaluate it.

3.1 Knowledge characterisation

Risks differ in a number of dimensions (see Box 8), which have an influence on the way they are assessed and managed. During the risk appraisal phase a considerable amount of knowledge is developed about a risk. That knowledge is important in order to characterise it as being predominantly simple, complex, uncertain or ambiguous, or (most often) a combination thereof. Doing so can assist in planning for the participation of stakeholders in the risk governance process (see Figure 5), and in designing risk management strategies (see Figure 4).

For relatively simple risks, such as risk of car or plane accidents, the benefits of taking regulatory action may be straightforward and uncontroversial, for example with compulsory seat belts in cars and flight recorders in planes. However, more complex, uncertain or ambiguous risks require a different approach to risk assessment, evaluation and management, with respect to the perceptions and values associated with those risks. In these risk situations, more comprehensive involvement of stakeholders will be needed. It should also be recognised that the characteristics of risks can shift over time, a factor that should be taken into account especially for longer risk governance processes.

Complexity

Complexity refers to difficulties in identifying and quantifying the causes of specific adverse effects, and understanding a sociotechnical system. Examples of complex risks include the risks of disruption of interconnected infrastructures, such as large electricity grids or the Internet. Complex issues can normally be handled by scientific and empirical research and expert technical work.

Box 5: Complexity - Critical infrastructure (CI)

Infrastructures are 'critical' when they provide basic services without which societies and economies cannot function normally. Electricity, gas, water, rail and communication infrastructures are good examples of critical infrastructure that are indispensable. While each of these infrastructures has its own basic weaknesses, their vulnerability is further increased by their mutual interdependence or 'coupling'. For example, the delivery of health care services relies on the electric power network, which itself relies on the availability of energy as a fuel (an increase share of this being from renewable intermittent sources). Although the intrinsic design of CI includes built-in capacity for reliability, CI are increasingly prone to failure because of the high levels of complexity inherent in the design of their systems, interdependency and tight coupling, with little redundancy and back-up. Failure in one infrastructure can rapidly cascade through an entire system and cause a major failure elsewhere. Identifying and quantifying the causes and consequences of disruptions is often difficult and problematic.

Uncertainty

Uncertainty refers to a lack of scientific or technical data, or a lack of clarity or quality of the data. Uncertainty describes the level of confidence that analysts associate with a qualitative or quantitative assessment of a specific risk. Uncertain risks include the effect of some developments in biotechnology, for example if new organisms are released into the open environment before a complete assessment of their potential impact.

Box 6: Uncertainty – Synthetic Biology

Synthetic biology is the design and construction of new biological systems not found in nature. It offers great promise in areas such as health and medicine, chemical manufacturing and energy generation. However, uncertainties about the potential risks and benefits of new products, as well as the effectiveness of future regulatory systems, may raise concerns among stakeholders. The IRGC policy brief "Guidelines for the Appropriate Risk Governance of Synthetic Biology", published in 2010, provides suggestions for identifying the uncertainties and trade-offs that need to be made between enabling innovation, minimising risk to people and the environment, and balancing the interests and values of all relevant stakeholders. The policy brief argues that regulation must not simply prohibit or restrict any development for which uncertainty exists but should seek the right balance between potential benefits and threats. Such an endeavour requires the active participation of many stakeholders potentially affected. In the case of gene drives (a technology that spreads biased inheritance of particular genes to alter entire population) early engagement with stakeholders and adaptive governance approaches are advised (see Appendix 3).

Ambiguity

Ambiguity results from divergent perspectives on the risk, including the likelihood and severity of potential adverse outcomes. Risks that are subject to high levels of ambiguity include issues for which economic or ethical issues matter and where controversies and polemics can emerge, such as in the case of food production, the use of hormones or antibiotics as a growth promoter for cattle, or some developments in genomic research. In these cases, people's values and interests can differ widely and create conditions for contestation or conflict.

Box 7: Ambiguity - Genetically modified crops

Ambiguity is well illustrated by the controversy that surrounds the scientific evidence or lack of evidence regarding consequences of using genetically modified (GM) organisms, and therefore the global debate about genetically modified crops. Europe has been caught between conflicting perspectives from industry, which has been promoting the benefits of this technological innovation, and the public, who have expressed concerns about harmful consequences and doubts about sustainable benefits. As a result of the fundamentally different perspectives, ambiguity has arisen. Evidence produced by companies to support product registration has been regarded as suspect by the public and is carefully scrutinised by regulators. Consequently, the European Commission initially ruled that a precautionary approach was necessary. It is only in 2015 that the EU Directive (2015/412) gave Member States the possibility to restrict or prohibit the cultivation of GM crops authorised by the European Food Safety Authority (EFSA) for their territory.

Box 8: Different dimensions of risk

Several dimensions typically influence the risk governance process.

At the most basic level, risks sources can be of three types, natural phenomena, human activity or a combination of the two[5]:

- Outcomes from natural phenomena become risks (with negative consequences) only when they impact on what is important to basic conditions of life on earth (e.g. services provided by ecosystems), or on the well-being of humans.
- Risks that arise from human activity may be unintended or poorly managed consequences of activities undertaken (or decisions made) for other purposes (e.g. driving a car), or they may derive from intentional harm such as fraud or terrorism (e.g. cyber security risks).

Several dimensions relate to the risk itself, for example:

- Degree of novelty – Is the risk emerging*, re-emerging, increasing in importance, current (topical) or institutionalised (already subject to management decisions)?
- Scope – is the risk local, dispersed, trans-boundary or global?
- Range – Does the risk impact on human health and safety, the environment, capital assets, trade, etc?
- Time horizon – What is the timeframe available for analysing a risk?
- Type of hazard – Is it ubiquitous, persistent and/or irreversible?
- Delay – Is there a long-time span between the trigger of the risk and its effects (latency)?
- For the risks introduced by developments in science and technology – Is the change incremental or breakthrough?

Other dimensions have an influence on the way risks are assessed and managed. These reflect the fact that risk is a human, an organisational and a social construct. According to this, the risk perception differs:

- Does handling the risk require international cooperation?
- Does it meet or violate important societal values, business prospects, equity concerns, security requirements, or trade agreements?
- Is the risk transferable or insurable?
- What is the level of public concern and stakeholder involvement?
- What type of regulatory framework is in place: Regulation/standards/guidelines/laissez-faire? At which level (national/international)? What is the level of compliance?
- Are there public-private partnerships in place for the management of the risk? What is the degree of public (governmental) regulation versus private (industry, self) regulation?

* **Emerging risks**. IRGC defines emerging risks as new risks (e.g. that derive from the use of new materials such as some nanomaterials), or familiar risks that become apparent in new or unfamiliar conditions (e.g. malaria in northern regions). This definition suggests that managers need to focus on the early detection and analysis of emerging risks' triggers, including the development of familiar risks into new threats. Emerging risks are issues that are perceived to be potentially significant but which may not be fully understood and assessed, thus not allowing risk management options to be developed with confidence. Some raise questions of efficiency of conventional risk governance processes, as well as accountability and responsibility.

[5] Cf. for example IRGC report on *Emerging Risks: Sources, Drivers and Governance Issues* (2010).

3.2 Risk evaluation

Risk management requires a prior and careful judgment of whether or not a risk is acceptable to the decision-maker and stakeholders. If it is not acceptable, risk reduction measures may make it more tolerable. To make this judgement, the evidence based on the risk and concern assessment must be combined with a thorough evaluation of other factors such as societal values, economic interests and political considerations. After these considerations, risk is evaluated as:

- **Acceptable**, if risk reduction is considered unnecessary
- **Tolerable**, if the risk can be pursued because of its associated benefits, but subject to appropriate risk reduction measures
- **Intolerable**, if it must be simply avoided, i.e., no risk reduction measures can make it tolerable.

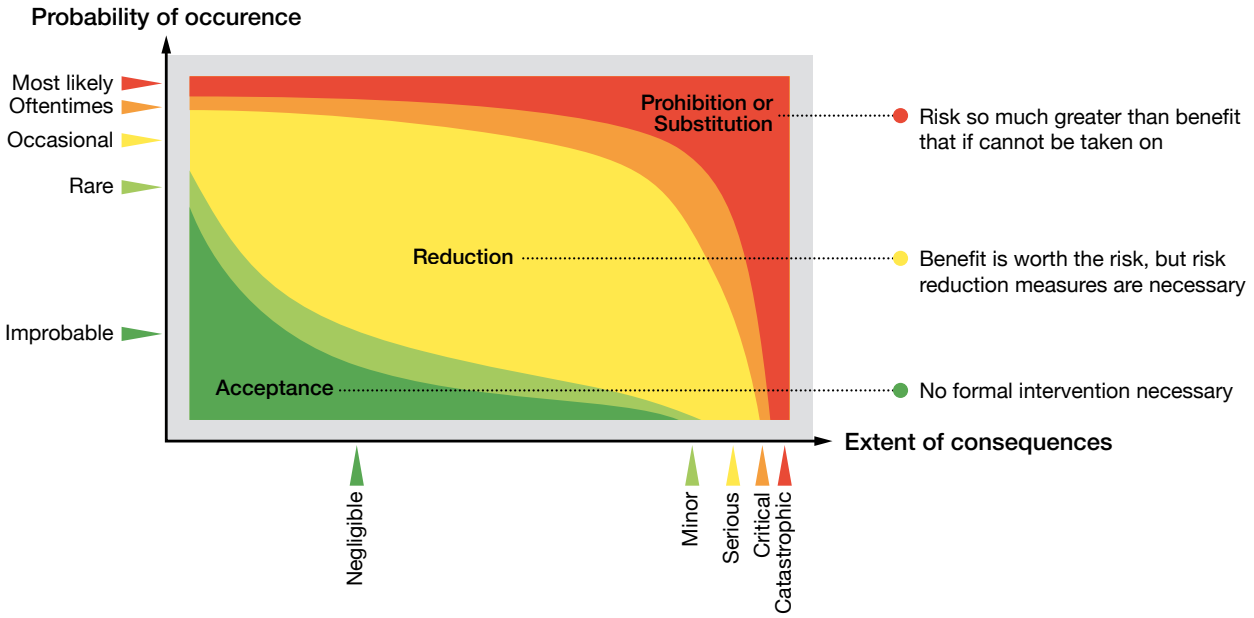


Figure 3: Risk evaluation (IRGC, 2005)

Evaluation involves making **judgments and choices**, which are often social, technical, economic, political or strategic, based on questions such as:

- Are there **ethical issues** to consider, beyond those taken into consideration in the concern assessment?
- What are the **societal values and norms** for making judgments about tolerability and acceptability? Are these values and norms changing?
- Do any **stakeholders** – government, business or other – have commitments or other reasons for wanting a particular outcome of the risk governance process?
- What are the **constraints** (e.g. time, budget, context, etc.)?
- What is the political or **strategic appreciation** of the societal, economic and environmental benefits and risks?
- Is there a **possibility of substitution**? If so, how do the risks compare?

Potential governance deficits in risk evaluation:

- Overlooking outcomes from risk appraisal – Failing to fully consider social needs, environmental impacts, cost-benefit analyses and risk-benefit balances.

- Exclusion – When some stakeholders and their views or significant benefits and other consequences are excluded or omitted, whether advertently or inadvertently.
- Indecision – When there is lack of responsiveness, due to a voluntary act of authority or an involuntary failure in the decision-making process (e.g. overly inclusive process with stakeholders may lead to inertia).
- Lack of transparency and accountability – When trade-offs are not made explicit and resolved, and hidden agendas (including of experts involved) may determine the outcome of the evaluation process.
- Sustainability – When risk decision is not robust and relevant for a long period

Box 9: Acceptable risk – Internet of Things

The Internet of Things (IoT) drastically changes how individuals interact with objects, wherever those may be located. This creates significant opportunities for more efficiency, convenience and comfort and can improve performance and reduce inefficiencies in numerous sectors. Specific promising applications and gains include traffic efficiency thanks to connectivity between vehicles and with infrastructure, the provision of personal health care through implantable or wearable connected medical devices, and smart buildings. However, the safe and secure use of IoT is concerned with cyber security issues and vulnerabilities, with potential direct negative impact on the physical safety and the security of IoT users, through the risk of being hacked, being infected with malware and being vulnerable to unauthorised access, which may trigger risks of a physical accident or adverse outcomes. Dependence on network connected technologies has grown faster than the means to secure applications. The balancing of risk and benefit is very complex, and may change in the future but, overall, users currently evaluate the risks they take, either intentionally or unintentionally, as acceptable. They prioritise comfort and convenience against security and privacy risks, which are generally considered as acceptable.

Box 10: Tolerable risk – Nuclear power generation

Whether or not a risk is perceived to be acceptable, tolerable or intolerable involves issues that go well beyond probabilities and statistics to include societal, political, economic and ethical considerations. This is well illustrated by the case of nuclear power. Most experts consider the risks from nuclear power to be of low probability but potentially devastating. The Fukushima accident in 2011 has refuelled fears of the catastrophic potential of nuclear accidents, and many countries thus responded by imposing moratoria or by phasing out their nuclear program. And yet, what is intolerable in one country may be tolerable in others, which continue to support the development of new nuclear plants to satisfy their energy needs, control air pollution and reduce CO2 emissions. Identifying and understanding the factors and processes that may shape public acceptance of a particular risk is therefore critical for developing and implementing risk management decisions that are effective, legitimate, and in line with societal norms and values.

Box 11: Intolerable risk and ambiguity – Human genome editing

What is considered an intolerable risk may vary across societies and jurisdictions, and may also change over time as technology develops and public perceptions shift. Ongoing advance in medical research make it increasingly likely that scientists will someday be able to genetically engineer humans to possess certain desired traits. However, such interventions may have undesired consequences and bear incalculable risk for humanity. As of 2017, many countries including France, Germany, Canada or Australia, ban gene editing in human embryos. However, some countries and jurisdictions do not view human genome editing per se as an intolerable risk. China, for instance, does not forbid research on non-viable embryos, and in the UK, the Human Fertilisation and Embryology Authority (HFEA) in 2016 approved an application by a London-based research team to carry out genome-editing technique CRISPR–Cas9 in healthy human embryos for the first seven days of development.

4.

MANAGEMENT

Tolerable risks are risks that require appropriate and adequate risk management measures to address them. Risk management is a process that involves the design and implementation of the actions and remedies required to avoid, reduce (prevent, adapt, mitigate), transfer or retain the risks. Risk management includes the generation, assessment, evaluation and selection of appropriate management options, the decision about a specific strategy and options, and implementation.

Questions to ask in the management stage include:

- Who are the **actors** and stakeholders that should be involved in the risk management process? What is their level of responsibility for decisions about the risk and its management? Have they accepted this responsibility?
- What management **options** should be chosen (e.g. technological, regulatory, institutional, educational, transfer, compensation, etc.)? How are these options evaluated and prioritised? What are the evaluation criteria? What are the most efficient options for addressing each of the three major characterisations of risks (complexity, uncertainty and ambiguity)?
- What are the likely **impacts** of particular risk-reduction options, their costs and benefits?
- What potential **trade-offs** between risks, benefits and risk-reduction measures may arise?
- Is there an appropriate level of international **cooperation** and harmonisation for global, trans-boundary or systemic risks?
- What measures are needed to ensure **effectiveness** in the long term (compliance, enforcement, monitoring, etc.)? In particular, does the risk management decision account for uncertainty and ambiguity, and does it enable some flexibility and adaptation if and when new knowledge is available?

4.1 Making decisions about risk management strategies

Good risk management relies on a process to facilitate systematic decision-making:

- The generation of a range of risk management options: Different ways to manage the risk.
- The evaluation of those options with respect to pre-defined criteria such as effectiveness, efficiency, sustainability, etc.
- The selection of options to be considered in the decision, based on a weighting of the assessment criteria and the trade-offs involved.
- The determination of a given risk management strategy. In case of high uncertainty or ambiguity, managers should consider the ability of the decision to perform well enough under various circumstances that may unfold in the future. Robust decisions are those that maintain enough flexibility for adaptation in the future and offer good performances for more than one possible development of the risk.

Risk management is confronted with the challenges of complexity, uncertainty and ambiguity. Based on this distinction one can identify four risk management strategies (for simple, complex, uncertain, ambiguous risks). Each of these four strategies is characterised by different processes and requirements for the choice of appropriate instruments, the inclusion of experts, stakeholders and the general public, and specific discourse arrangements (see Figures 4 and 5):

- Simple risks can be managed using a **routine-based** strategy, such as introducing a law or regulation. Traditional decision-making frameworks implemented by risk regulatory agencies may be suitable for simple risks.
- Complex risks should be dealt with by risk-based decision-making involving internal or external experts and relying on scientific models. Complex risks can be addressed by acting on the best available scientific expertise and knowledge, aiming for a **risk-informed** and **robustness-focused** strategy. Robustness refers to the degree of reliability of the risk-reduction measures to withstand threatening events or processes even when those have not been fully understood or anticipated. A system is robust to uncertainty if specified goals are achieved despite information gaps.
- Uncertain risks should be managed using **precaution-based** strategies to avoid exposure to a risk source with large uncertainties, and **resilience-focused** strategies[6] to reduce the vulnerability of the risk-absorbing systems. Precautionary approaches must be considered when the consequences of an activity could be very serious and are subject to high uncertainty. Such approaches aim to ensure the reversibility of critical decisions and to increase a system's coping capacity to the point where it can withstand surprises. Resilience is the ability of the system to sustain or restore its basic functionality following a risk event. Resilience approaches aim to prepare, cope with and recover from unexpected surprises resulting from risk with high uncertainty about causes and impact, and potentially catastrophic consequences. Resilience building may include developing

[6] For resilience, s. also the IRGC Resource Guide on Resilience, available at https://www.irgc.org/irgc-resource-guide-on-resilience/

the ability to adapt to new context conditions. In this context, resilience is a strategy against unknown or highly uncertain hazards, and concerns a whole system.

- Ambiguous risks require **discourse-based** decision-making involving all groups that have special interests or value commitments with respect to the risk or the benefits. Discourse-based strategies seek to create tolerance and mutual understanding of conflicting views and values with a view to eventually reconciling them.

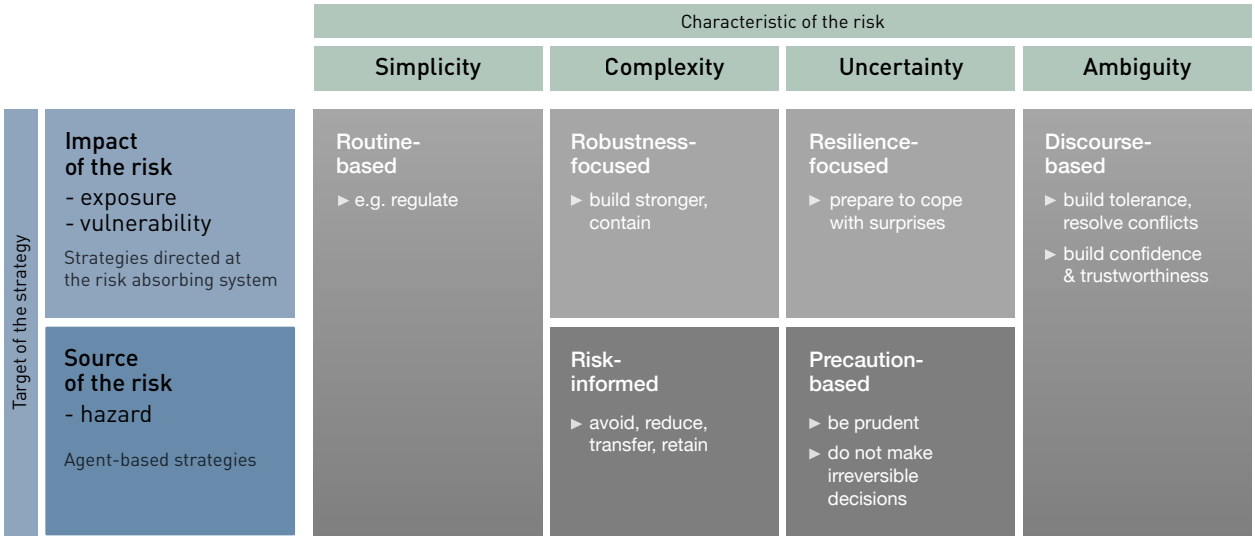


Figure 4: Risk management strategies, adapted from (IRGC, 2005).

Potential governance deficits in the decision about a risk management strategy:

- Lack of responsibility – No entity is legally responsible for failures; risk management and regulation may 'fall between the cracks'
- Lack of accountability – Decision-makers are isolated from the impact of their decision
- Unsustainability – E.g. short-term decisions lead to further longer-term problems
- Short-term expediency – Authority makes a decision on a knee-jerk or ad-hoc basis, for instance as a response to public pressure
- Indecision/lack of timeliness – Delays or inaction make matters worse
- Inequity – Decisions allot the risk and benefits unfairly.

4.2 Implementation, monitoring and review

After the decision is made, mandate is given to implementation agencies to apply the selected measures, monitor their effectiveness, review the decisions if necessary and integrate feedback from the monitoring and review into possible revisions of the assessment and evaluation. It is important to establish a link between the outcome of risk management and the need to revise the initial assessment and the management decisions, if conditions have changed or if performance is lower than expected.

Supportive conditions for effective implementation include appropriate authority and leadership, communication (internal and external), attention

to possible organisational change that may be needed (to overcome frequent resistance to change), clear definition of roles, responsibilities and incentives, and the allocation of necessary resources.

Many governance deficits originate from the lack of an appropriate legal or regulatory framework. Sometimes there is no appropriate structure or process. Alternatively, some regulatory structures overlap and compete with others, creating conflicts which complicate how risks are handled. Of particular interest today is how public and private regulation combine for effective and efficient outcome, and how public regulators can engage in planned adaptive governance to cope with uncertainty and rapid change (see Box 12).

Potential governance deficits in implementation:

- Failing implementation – Decisions are ignored or poorly implemented.
- Lack of evaluation and feedback – Implementation is poorly evaluated, feedback is not integrated into review.
- Inappropriate use of advanced management tools, such as those deriving from artificial intelligence and machine-learning.
- Inflexibility – Failure to revisit a risk decision in the light of new knowledge.

Box 12: Planned adaptive regulation as a risk management approach

Planned Adaptive Regulation (PAR) is an approach in which each regulation is designed from its initiation to learn from experience and update over time. In the face of uncertain or changing evidence that was used to underpin a rule, regulators plan both for scheduled adaptation of the rule and for the production of decision-relevant knowledge that will further characterise or reduce the uncertainties pertaining to the risk regulated. PAR is a policy tool that is too unfrequently considered. It is still rare to see a purposeful combination of (i) planning for future review and revision, (ii) monitoring of regulatory performance and impact, and (iii) funding of targeted research. Such research will be organised in a way that is credibly overseen for quality and relevance, and that explicitly feeds into the reassessment of the knowledge base. PAR is appropriate to risk issues whose comprehensive assessment is evolving because of changes in the technologies or in context conditions. It has been used for the regulation of criteria pollutants in the atmosphere (in the US National Ambient Air Quality Standards (NAAQS) and the European Air Quality Standards), in the US Lautenberg Chemical Safety Act (LCSA) of June 2016, in flood management in the Netherlands, and in adaptive licensing of new drugs by the European Medicines Agency.

5.

CROSS-CUTTING ASPECTS

Cutting across and at the core of the Framework, IRGC adds three aspects that are critical to the success of every risk governance process: the crucial role of open, transparent and inclusive **communication**, the importance of engaging **stakeholders** to both assess and manage risks, and the need to deal with risk in a way that fully accounts for the societal **context** of both the risk and the decision that will be taken.

5.1 Communication

Risk communication is the process of exchanging or sharing risk-related data, information and knowledge between and among different groups such as scientists, regulators, industry, consumers or the general public. It is of the utmost importance for effective risk governance. First, it enables risk assessors and risk managers to develop a common understanding of their tasks and responsibilities (internal communication). Second, it empowers stakeholders and civil society to understand the risk and the rationale for risk management (external communication). It allows stakeholders to make informed contributions to risk governance, recognises their role in the risk governance process and gives them a voice by creating a deliberate two-way process. In many traditional risk management procedures, once the risk management decision is made, the role of communication is to explain the rationale for the policy decisions. In the IRGC Framework, communication is central in the process and crucial at each phase of pre-assessment, appraisal, evaluation and management. Indeed, **effective and early communication is the key to creating long term trust in risk management, in particular when risks are perceived complex, uncertain or ambiguous**.

Questions to address when developing communications:
Process

- Is there a **facilitator** in charge of the risk communication process?
- How can the communication **process** be organised and facilitated between and among regulators, risk assessors and other in-house experts (internal communication)?

- How can communication be facilitated between risk takers, risk affected parties, other stakeholders, the media and risk managers (external communication)?
- How can communication be organised so that **two-way information** is effective, enlightening and timely?

Content

- **What is known** about the risk and the hazard, by whom, and how can it be conveyed to the interested stakeholders and the public?
- Does the communication take into account how the risk is **perceived** by the stakeholders?
- Are there **ambiguities** and controversies about the risk within the public sphere?
- What is the degree of **confidence** in the risk managers responsible for generating or disseminating information, and for organising a dialogue?
- How to deal with confidential and **sensitive information**?
- What are the **demands**, needs and purposes for information and communication among the different stakeholder groups, including members of the general public?
- Are the **concerns** of stakeholders and the public being clearly articulated and are decision-makers listening?
- How is information **interpreted** by those who receive it?
- What has been and can be the role of the **media**, both traditional and social?

Potential governance deficits in risk communication:

- One-way information instead of two-way communication prevents building a dialogue.
- Communication from experts is often too technical to be understood by lay people and stakeholders. Such communication may not address what stakeholders need and want to know. It may not account for how different stakeholders receive and accept information.
- Communication is not adapted to the category of risk (simple, complex, uncertain, ambiguous). For example, it does not convey uncertainty.

Box 13: Risk communication – The case of the 2009 L'Aquila earthquake

Six days before an earthquake hit the central Italian town of L'Aquila in 2009, seven members of the National Commission for the Forecast and Prevention of Major Risks took part in a meeting organised by the local authorities and civil protection. The meeting was called to analyse the danger posed by minor shocks that had been occurring for several weeks. While officials were hoping that the scientists would reassure the public, scientists informed the authorities about the uncertainty of the scientific evidence. On that basis, authorities urged the local residents to stay calm, stating that it was impossible to predict earthquakes and that the scientists had concluded that a major earthquake was not impending. The meeting and subsequent communication thus served to reassure the public and to reassert scientific authority in the public discourse. In the aftermath of the earthquake, the members of the commission were indicted and handed jail terms on charges of manslaughter for providing unjustifiably reassuring advice. But in November 2015, the ruling was overturned on the grounds that the scientists could not be faulted for stating that there was no reason to think that the risk of a major earthquake had increased following the smaller tremors.

This case raises the issue of the role of scientists in risk communication as well as the difficulty to convey scientific uncertainty to both decision-makers and the general public, in particular regarding low-probability high-impact events.

- People's or organisations' concerns are treated as irrelevant or irrational; this may cause incomplete understanding of the full nature of risks as well as social mobilisation against the institution or the final decision.
- Low level of confidence or trust in the decision-making process, the information given or the communication channel weakens the whole process.

5.2 Stakeholder engagement for inclusive risk governance

Engaging stakeholders for assessing plural values and interests, designing effective risk management strategies, and managing risks can improve the relevance of the decision and performance of the outcome.

IRGC recommends that, beyond technical scientific risk assessment, a concern assessment should inform decisions about risk. A concern assessment examines how relevant stakeholders, including members of the general public, perceive the risk and its potential consequences. Both are relevant inputs to risk evaluation and risk management.

Stakeholders who could be impacted by the risk and the risk management measures should be involved in the process, because they have useful insights to contribute to the process of risk governance and the resulting management decisions. By systematically engaging stakeholders, risk governance becomes an inclusive exercise that incorporates a wide range of perspectives. It improves the knowledge about risk and its management and can thus increase the effectiveness, the fairness and the acceptability of the decisions that are made.

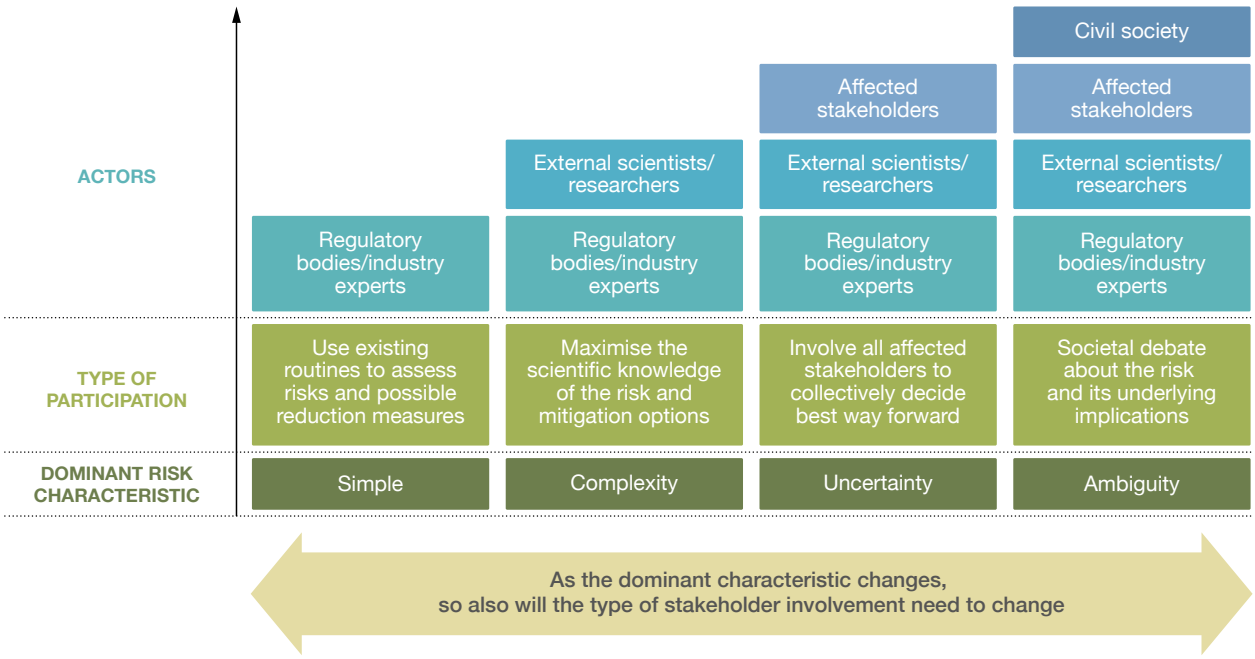


Figure 5: Stakeholder engagement 'escalator' (IRGC, 2005).

In order to assess when and how to engage different stakeholders, and particularly the general public, IRGC recommends that decision-makers consider using the dominant characteristic of a risk as the basis for deciding on the appropriate level of stakeholder involvement in the process:

- When a risk is considered as simple, it may require relatively basic consultation with experts to decide which management option should be adopted. The risk governance response can be straightforward and routine.
- By contrast, when a risk is evaluated as complex and uncertain, decisions about its management may benefit from a wider dialogue amongst a broader range of experts and affected stakeholders.
- For risks that are marked by high levels of ambiguity, involving civil society is recommended, in part to capture and reconcile the various existing perceptions of a risk and options for its management.

Potential governance deficits in stakeholder involvement:

- Exclusion – Accidental or deliberate exclusion of stakeholders and/or their views.
- 'Authority knows best' – A deliberate refusal to communicate with other interested parties leads the stakeholders with power to make the decisions, irrespective of the need for consultation and dialogue.
- Ignoring the composition of complexity, uncertainty and ambiguity and designing a process that is either too inclusive (for rather trivial risks) or not inclusive enough (for ambiguous risks).
- Insufficient attention to changes in context and to stakeholders' nature and expectations.
- 'Paralysis by analysis' – Selection of an overly inclusive process leads to inertia or indecision.
- Time pressure and time delay – The deliberative process is under time constraint or is diluted.

Box 14: Reaching agreement through stakeholder engagement – Chlorofluorocarbons (CFCs) and the Montreal Protocol

A decisive, coordinated international action involving governments and industry was instrumental in the success of both the Montreal Protocol conclusion and its implementation. The discovery and monitoring of the Antarctic ozone 'hole' raised concerns about negative impacts on the climate, environment and public health. In 1985, CFCs were found responsible for the depletion of the stratospheric ozone layer. Only two years later, the Montreal Protocol was signed to regulate the production of ozone-depleting substances and schedule their phasing-out. As a consequence, the 2005 levels of ozone-depleting gases in the stratosphere showed an 8-9% decrease from their peak values in 1992-94. The success of the Montreal Protocol can be attributed to international organisations engaging with all actors with a stake in the issue, including the industrial, scientific and political groups, who came together to work out a solution and negotiated a specific, detailed, and forward-looking agreement.

Box 15: The importance of engaging stakeholders – The case of unconventional gas development

One of the key factors surrounding the risk governance of unconventional gas development is that various interest groups frame very differently the issue, and therefore the associated opportunities and risks. Their opinions, concerns and expectations vary widely. For example, the oil and gas industry is driven by economic motives, national policy makers are often driven by considerations of energy security, sustainability and affordability issues, and local communities are concerned about the possible impact on the local environment, public health, displacement and employment. The various actors and their different objectives, needs and constraints must be identified before specific risk assessment can start. The case of how pilot testing of hydraulic fracturing was stopped in Germany (as well as other countries or US states) in the years 2014–2016 illustrates the role of local communities. Operators underestimated the importance of involving those in their assessment of context conditions for the exploitation of shale gas resources. Local communities mobilised against pilot projects, and operators cancelled their plans.

Inclusive risk management decisions require a balancing of various interests and views held by different stakeholders. The neglect of any important factor, group or evidence can lead to an inappropriate decision and the failure of risk management actions.

Box 16: IRGC Stakeholder Engagement Resource Guide

In order to provide further guidance to practitioners and academics, for developing and implementing science-based stakeholder involvement in research, policy, strategies and practices, in 2013, IRGC produced an annotated resource guide for stakeholder engagement. The guide reviews existing manuals, providing background information on the various perspectives. It emphasises the importance of determining the main objective and the expected outcome or contributions that engaging with stakeholders aim to achieve, before choosing the type of method that will be used to involve stakeholders. stakeholder.irgc.org.

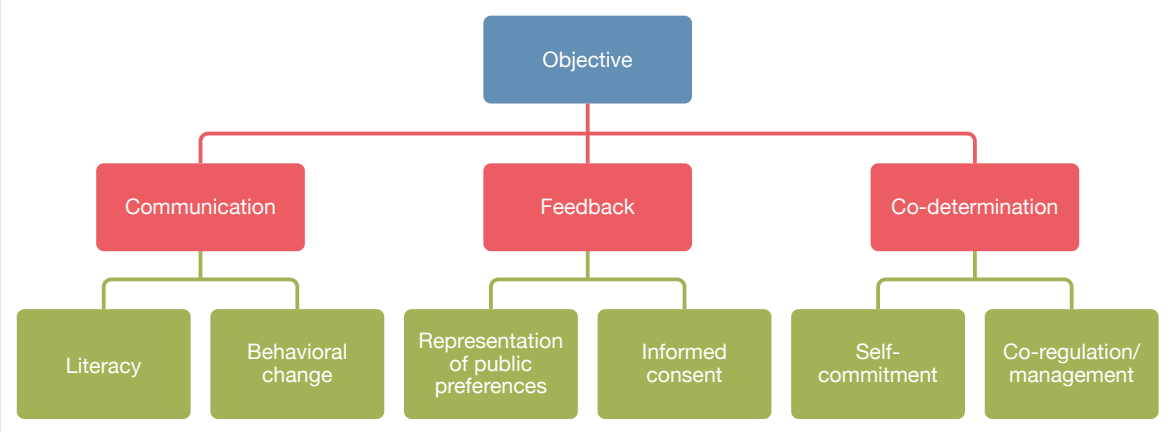


Figure 6: Objectives of engaging stakeholders.

5.3 The importance of context

Alongside the conventional elements of risk assessment, risk management and risk communication, the IRGC Framework stresses that the broader social, institutional, political and economic contexts must be taken into account in risk-related decision making. It is important to recognise the organisational capacity, which refers to the capability of key actors in the risk governance process to fulfil their roles, the network of actors, and the political cultures or the governmental and regulatory 'styles.' Also important is the risk culture, which impacts on the level of risk tolerance (or risk aversion), and the degree of trust in the institutions responsible for risk governance.

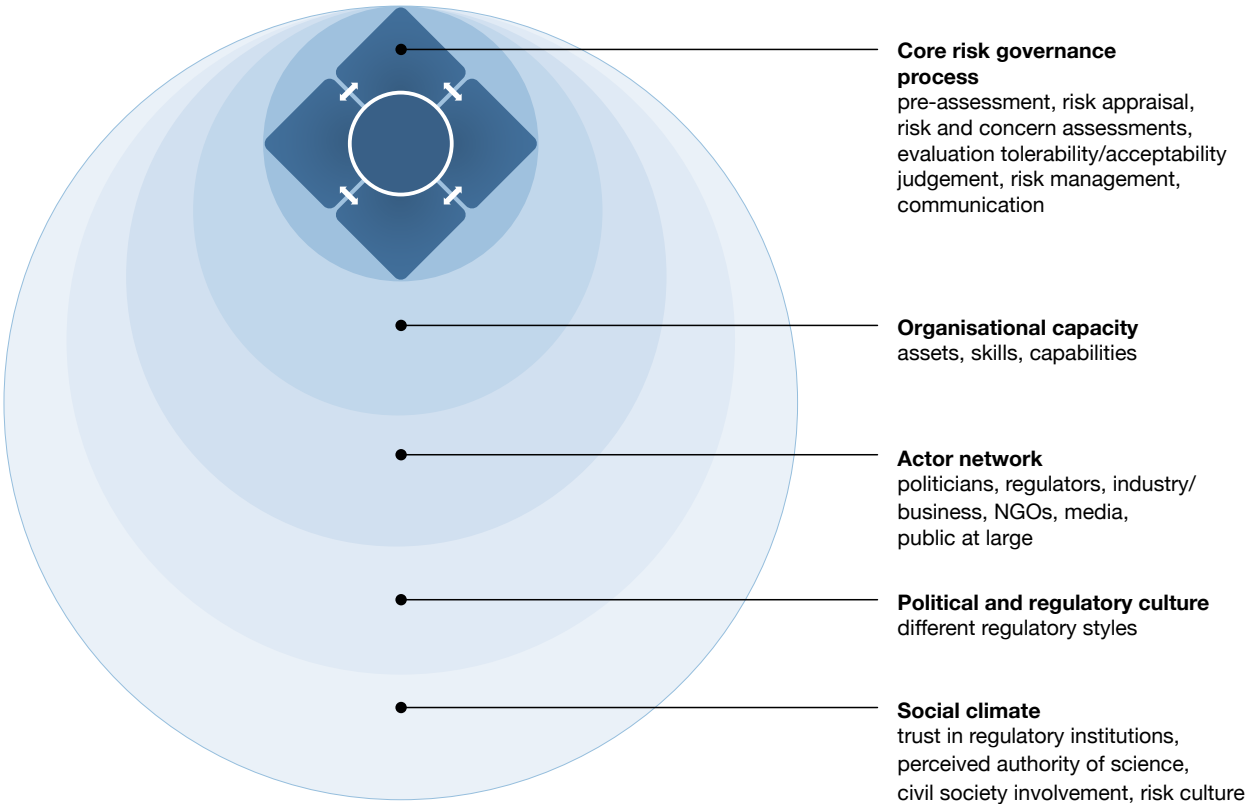


Figure 7: Risk governance in context.

Box 17: Importance of context – Risks related to the production of biomass for energy

Growing biomass for producing energy (heat, electricity or liquid fuel) has been the focus of great interest in the years 2000-2010. After much enthusiasm in many countries, research, experimentation and deployment, scientists, policy makers and industry have finally come to the conclusion that it is important to have a full understanding of the context in which biomass could be produced. Practices and policies will thus need to differ between countries. Countries vary in their energy needs and production capacity, agricultural and forestry practices, climate change impact, technological capacities, and economic and social conditions. Therefore, policies must rely on sound and comprehensive environmental, climate, economic and social impact assessments, and may prioritise different objectives, such as reducing carbon emissions, enhancing national energy security and independence, or catalysing rural economic development. It is also important to recognise that the involved stakeholders may defensibly have different values and priorities. In the face of the same scientific data, some may for example view bioenergy as a threat to the security of food supplies while others may view bioenergy as a potential source of new income. Policies may thus vary widely across countries.

CONCLUSION

The IRGC Risk Governance Framework provides guidance to risk assessors, risk managers and overall those who organise the process by which risks can be identified, analysed, understood, and eventually addressed in a fair and effective manner. It can help institutions to structure their tasks, and design their own specific frameworks, adapted to their own sectoral or organisational contexts and specificities. The Famework is modular, compatible with and complementary to other models for risk management. It can be used as both a 'meta-model' or as a set of dynamic guidelines for implementing comprehensive, inclusive and flexible risk governance processes.

In particular, it recommends the integration of knowledge and action across silos and various levels of governance. It goes beyond conventional risk analysis and management by incorporating societal values, concerns and perceptions of risk. By looking into the interactions between the various affected stakeholders, it can contribute to achieving more effective risk governance strategies.

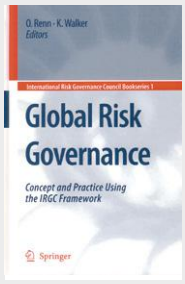
Readers of this introduction can also find some assistance to diagnose deficits in current risk governance processes and suggestions for how to prevent them or improve their remediation.

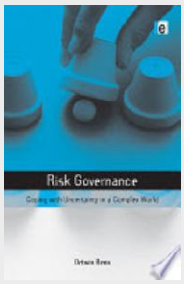
APPENDIX 1

ADDITIONAL INFORMATION AND FOLLOW-UP WORK ABOUT THE FRAMEWORK

Interested readers can learn more about the basis for the development of the IRGC Risk Governance Framework, including a detailed description of the Framework, in the IRGC White Paper No.1 (2005), available from www.irgc.org/risk-governance/irgc-risk-governance-framework.

Additional information is available in *Global Risk Governance – Concept and Practice Using the IRGC Framework* (IRGC, 2008). This volume includes critiques of the Framework provided by internationally renowned experts on risk governance, applications of the Framework to specific risk issues, and a chapter in which Prof. Ortwin Renn – who has led this area of work by IRGC – itemises the lessons learned from the critiques and case studies as well as from IRGC's experience.





The concept was further developed in the book *Risk Governance – Coping with Uncertainty in a Complex World* (Renn, 2008).

In 2012, the original IRGC approach was modified by Klinke & Renn (2012) to add a dynamic, adaptive component, and capture the iterative and relational nature of risk governance. The adaptive and integrative quality of the process requires the capacity to learn from previous and similar risk-handling experiences to cope with current and future risk problems. Figure 8 illustrates this dynamic risk governance process. This model suggests four core functions:

- Systematically and consistently complementing the relevant risk-handling functions in a risk governance cycle.
- Coping with vulnerabilities evoked by generic challenges of different orders of uncertainty
- Providing adaptability and flexibility in risk governance institutions in response to actual outcome or expected consequences which may moderate the estimates about the risk.
- Enhancing the resilience of the risk governance system by increasing the capacity to retain the basic functions and structures of risk handling and to absorb disturbance in the risk handling components.

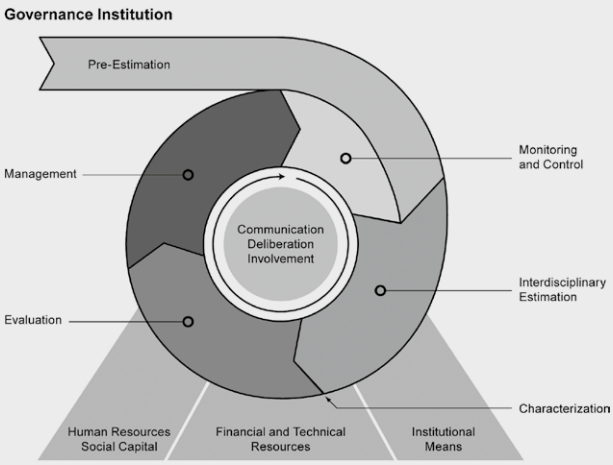


Figure 8: Revised risk governance model (Klinke & Renn, 2012)

In 2014, Rosa, Renn & McCright (2014) shared some of their considerations about society, risk and risk governance in their book *The Risk Society Revisited*. They focus in particular on new forms of governance that are needed in response to rapidly changing societal conditions such as globalisation and the rising phenomenon of systemic risks, which threaten to undermine entire systems. This suggests that societies further develop their institutional and political means for governing and managing such risks effectively, using an analytic-deliberative process.

APPENDIX 2

APPLICATIONS TO INSTITUTIONAL RISK MANAGEMENT

Since its publication in 2005, the IRGC Risk Governance Framework has been applied to various risk governance issues in a number of case studies. Those test the applicability, efficacy and practicability of the Framework. They illustrate that the Framework is a worthwhile basis for diagnosing governance deficits, and is broad and flexible enough to be adapted to diverse governance issues and contexts.[7]

Various organisations use the Framework to structure their thinking and inspire guidelines, roadmaps or models. For example:

- **US Joint Chiefs of Staff**. The Chairman of the Joint Chiefs of Staff manual on Joint Risk Analysis (2016) establishes a Joint Risk Analysis Methodology and provides guidance for identifying, assessing, and managing risk. It introduces and describes a common risk lexicon to promote consistency across the US Department of Defense and Joint Force risk-related processes. "Documents from the International Risk Governance Council (IRGC) were particularly informative in developing this manual. The IRGC white paper, 'Risk Governance: Towards an Integrative Approach' provided key background and substantiated fundamental concepts used when producing this Manual."
- **United States Nuclear Regulatory Commission**. The Commission included a review of the IRGC Risk Governance Framework under "A.2.3 Risk Governance Framework International Risk Governance Council", US NRC (April 2012). A Proposed Risk Management Regulatory Framework.
- **US Department of Homeland Security**. US-DHS DHS Risk Lexicon (2010): IRGC white paper nr 1 and in particular definitions of risk and risk management were used to validate work by the DHS Risk Steering Committee (RSC), to produce a lexicon fundamental to the practice of homeland security risk management. RSC is the risk governance structure for DHS.
- **European Commission / Institutions of the European Union**. The IRGC Risk Governance Framework is a source of information for the development of the European Commission Better Regulation, Toolkit #12: Risk Assessment & Management.
- **CEN Workshop Agreement DIN CWA 16649** on managing emerging technology-related risks. CEN workshop agreements are reference documents elaborated under the supervision of the European Committee of Standardization. DIN CWA 16649 builds upon the Risk Governance

[7] IRGC case studies are available at http://www.irgc.org/publications

Framework developed by IRGC and the International Standard ISO 31000. It sets the base for a European standard for emerging technology-related risks.

- **SAFE FOODS**. The EU-funded research project SAFE FOODS, *Promoting Food Safety through a New Integrated Risk Analysis Approach for Foods*, applied the Risk Governance Framework. The result is the General Framework for the Precautionary and Inclusive Governance of Food Safety (Dreyer & Renn, 2009) which adapts IRGC's Risk Governance Framework to the specific needs of the European Food Safety Authority (EFSA) (Ely et al., 2009).
- **Health Council of the Netherlands**. In 2006, the Health Council of the Netherlands published the advisory report Health Significance of Nanotechnology, which explores governance issues and potential adverse effects of nanotechnology. In its advisory report the committee adopts the description used by the IRGC: "The IRGC recently presented a general framework for risk governance. It corresponds closely with our national ideas on dealing with risks and the Committee believes it can also be used for dealing with the risks of nanotechnologies." (Health Council of the Netherlands, 2006).

APPENDIX 3

TWO EMERGING ISSUES WHOSE GOVERNANCE CAN BENEFIT FROM THE IRGC APPROACH (APPLICATION CASES)

Gene drives[8]

In sexually reproducing organisms, most genes have a 50% chance of being inherited by offspring. However, in some cases natural selection has favoured certain genes that are inherited more often. For the past decade or so, research[9] has been exploring how this could be triggered. The 'gene drives' method is a gene editing technique that 'drives' a gene through a population. It stimulates a gene to be preferentially inherited. Then this gene can spread through a given population, whose characteristics could thus be modified by the addition, deletion or edition of certain genes.

"Gene drives could be used to assist in the eradication of insect-borne diseases, for example, reducing mosquito populations to prevent them from transmitting malaria". (http://cser.org/625)

Pre-assessment – Gene drives could have large benefits. For instance, applications are foreseen in malaria control, where the reprogramming of mosquito genomes could potentially eliminate malaria and other insect-borne diseases from entire regions. Other potential applications include combating herbicide and pesticide resistance or eradicating invasive species, where indigenous species provide the basis for local ecosystems diversity but are not equipped to resist the new additions.

Although gene drives hold the promise to cure some of the most severe risks to health and the environment, scientists and regulators need to work together at an early stage. While there are some technical challenges that need to be overcome, there are also some risks that need to be addressed. Lastly, all this should not be done without a clear view of the governance regime that would apply to gene drives.

Appraisal: Risk assessment – The technical challenges relate first to the difficulty of editing genomes for programming drives in a way that is precise (only the targeted gene should be affected) and reversible (to prevent and overwrite possible unwanted changes). Much progress is being made in this area and one can expect the development of purpose-built, engineered gene drives in the next few years.[10] However, gene drives could also carry potential

[8] Based on (Oye et al., 2014); (Esvelt et al., 2014); (Committee on Gene Drive Research in Non-Human Organisms et al., 2016)

[9] In particular by Prof. Austin Burt, Imperial College London.

[10] CRISPR-Cas9 is a tool to accelerate the technology to edit genomes- it enables to rewrite an organism's DNA.

risks to wild organisms, crops and livestock. What if an engineered gene drive triggers a cascade of unintentional damage in connected ecosystems? At this point, risk assessment may have to include the development of various scenarios.

Appraisal: Concern assessment – Given the uncertainty about benefit and risk, it is important to take into consideration societal perceptions, concerns and expectations from gene drive technologies. The discussion of values and public engagement is likely to frame the societal, political and regulatory response to the risk, and the balancing of potential negative consequences with expected benefits. Early engagement could prevent things from spiralling out of control.

Evaluation – After assessing the opportunities and the risks, researchers, regulators and society will be better equipped to understand the challenges involved. They will make a decision about whether to implement the technology or not, i.e. whether the risks are acceptable, unacceptable, or tolerable, in which case risk management measures must be put in place to avoid, prevent or reduce negative consequences. Stakeholders need to agree on a governance regime that would govern research, testing and release. Like with most technologies that interact with the environment and human health, there is high uncertainty as to how the ecosystems will react, so the risk will be evaluated in terms of trade-offs. However, there must be research into areas of uncertainty, public discussion of security and environmental concerns, and development and testing of safety features.

Management – Regulatory frameworks to deal with gene drives vary between countries (with different regulatory cultures) and are challenged by the evolving technology and supporting science. In January 2017, The US published an update of the Coordinated Framework for the Regulation of Biotechnology, which addresses specific regulatory issues, with the aim to make it more adaptable and responsive to change. Sound and proactive governance implies that the potential opportunities of new technologies are accompanied by the development of governance standards or regulatory regimes to oversee both unintentional and intentional damage caused by the technology. In the absence of scientific certainty and to account for the fast-moving development of the science, regulations and conventions must be adaptive to new information on benefits, risk and governance deficits.

Adaptive and flexible regulatory frameworks are being tested in other fields (see Box 11), and could provide both sufficient stability and room for adaptation before gene drives are released in the open environment. Such frameworks should also include a multi-stakeholder view on benefits and risks, cutting across organisations with diverse interests, allowing an inclusive and informed public discussion to determine when and how gene drives should be used.

Automated and connected cars[11]

Automated driving and car connectivity is being developed by numerous car manufacturers and service operators, and in in many countries, with expected benefits in car and road safety, and traffic fluidity. Technologies for sensing the car environment are developing fast, with the potential for large scale deployment. However, there are risks that must be considered. Applying the IRGC Risk Governance Framework can help identify the important steps and tasks for governing the risks.

Pre-assessment – In order to establish the context and frame the issue, the following questions could guide decision-makers: Why do some stakeholders wish to develop autonomous driving? For what benefits? Who are the stakeholders? Are some stakeholders opposed to autonomous driving? What do we know about safety issues and other risks? Do current regulations allow autonomous driving? The outcome of the pre-assessment could be in the form of mapping the issues at stake, including the stakeholders and their interests, constraints and views.

Appraisal: Risk assessment – There are a number of technical risks involved, including safety risks, risks associated with geo-localisation and connectivity between vehicles and with infrastructure, risks related to processing data from sensors and from infrastructure, cybersecurity, privacy issues, legal issues and business risks.

Appraisal: Concern assessment – Public perception surveys indicate that while most people are generally in favour, some people would prefer not to use autonomous cars themselves. However, attitudes are changing very rapidly.

Evaluation – Allowing autonomous cars on the roads will be a question of trade-offs between risks and opportunities. It will depend on the safety level that road users accept and on expected benefits in mobility and transportation. Decisions about the pace and conditions of authorisation (and/or mandating devices and features for sensing, automation, connectivity and autonomy) of automated cars on the roads will thus result from resolving the trade-offs between various types of issues including national priorities and preferences (competitiveness of national industry), consumer preferences and mobility services. A critical determinant of the decision will be how authorities and individuals will answer the question of *When will autonomous cars be safe enough to be fully authorised on public roads?* Those evaluating these conditions will also identify and prepare risk management options, considering the role of insurance to determine the acceptability of the remaining risk, the role of public regulation / litigation, and the role of private standards, certification, and homologation.

Management of the risks and opportunities – A diverse set of measures will most probably be put in place. These measures will affect public road traffic regulation, vehicle safety, standards, certification, product and criminal liability laws, data security / privacy and cybersecurity, among other aspects.

The European Commission provides support for more connectivity, cooperation and automation to address challenges and reap benefits on mobility in Europe. Cooperative, connected and automated mobility and digitisation promise to address challenges and expectations on mobility such as:

- growing demand for more safety and sustainability.
- environmental concerns.
- economic concerns.

https://ec.europa.eu/digital-single-market/en/cooperative-connected-and-automated-mobility-europe

[11] Analysis based on discussions at an IRGC workshop on autonomous cars. See https://www.irgc.org/issues/autonomous-cars.

APPENDIX 4

OTHER IRGC PUBLICATIONS ON CONCEPTS AND INSTRUMENTS FOR RISK GOVERNANCE[12]

Since 2005, IRGC has continued to develop concepts and instruments to support the work of risk assessors, managers, regulators and decision-makers.

Assessing and managing risk governance deficits

IRGC defines a risk governance deficit as a failure or deficiency in the identification, framing, assessment, management and communication of a risk issue or of how it is being addressed. Governance deficits are common and their recognition often serves to understand why risk management does not perform as expected. They can be remedied or mitigated. IRGC has identified 10 common deficits in risk assessment and 12 common deficits in risk management.

- Risk Governance Deficits (Report, 2009)
- Risk Governance Deficits (Policy Brief, 2010)

Governance of emerging risks

IRGC defines emerging risks as new risks or familiar risks that become apparent in new or unfamiliar conditions. Emerging risks are issues that are perceived to be potentially significant but which may not be fully understood and assessed, thus not allowing risk management options to be developed with confidence.

- IRGC Guidelines for Emerging Risk Governance (Report, 2015)
- Appendix to the IRGC Guidelines for Emerging Risk Governance (Appendix, 2015)
- Improving the Management of Emerging Risks (Concept Note, 2011)
- The Emergence of Risks: Contributing Factors (Report, 2010)

Systemic risks

Based on work on 'slow-developing catastrophic risks' and resilience, IRGC is currently developing guidelines for the governance of systemic risks in the context of transitions, which complement the IRGC Risk Governance Framework on specific aspects.

Specific issues

IRGC also works in-depth on a number of issues that benefit from a risk governance approach, such as cybersecurity, precision medicine, or synthetic biology.

[12] All IRGC publications are available on www.irgc.org/publications

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Boxes

The examples used in the boxes are mainly based on previous IRGC work on the same topic (in bold).

Box 1: From conventional to systemic risks
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Box 2: Pre-assessment – Subprime crisis in the USA
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Box 4: Cognitive biases
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Box 5: Complexity – Critical infrastructures
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Box 6: Uncertainty – Synthetic biology
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Box 8: Different dimensions of risk
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Box 11: Intolerable risk and ambiguity – Human genome editing
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Box 12: Planned adaptive regulation
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Box 15: Stakeholder engagement – Unconventional gas development
IRGC report **Risk Governance Guidelines for Unconventional Gas Development** (2014)
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Box 17: Importance of context – Risks related to the production of biomass for energy
IRGC policy brief **Risk Governance guidelines for bioenergy policies** (2008)
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About IRGC

The **International Risk Governance Center** organises IRGC activities, emphasising the role of risk governance for issues marked by complexity, uncertainty and ambiguity, and focusing on the creation of appropriate policy and regulatory environments for new technologies where risk issues may be important.
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More information on irgc.org.

EPFL International Risk Governance Center
International Risk Governance Council

EPFL IRGC
Station 10
1015 Lausanne
Switzerland

Tel +41 21 693 82 90

irgc@epfl.ch
irgc.epfl.ch
irgc.org

ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

international risk governance center