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Foreword

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2013-02-13, the constitution of which was supported by CEN following the public call for participation made on 2011-08-30.

Below is the list of the organizations which officially took part to the development of this CWA:

— EU-VRi - European Virtual Institute for Integrated Risk Management EEIG

— EDF – Électricité de France S.A.

— GDF Suez

— GIE AXA

— INERIS - Institut National de l'Environnement Industriel et des Risques

— KMM-VIN – European Virtual Institute on Knowledge-based Multifunctional Materials AISBL

— MERL - Materials Engineering Research Laboratory Limited

— R-Tech - Steinbeis Advanced Risk Technologies GmbH

— Stiftelsen Sintef

— Swiss Re - Swiss Reinsurance Company Ltd

— Tecnalia - Fundacion Tecnalia Research & Innovation

— TNO Research Group Q&S

— University of Stuttgart

The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members.

The final review/endorsement round for this CWA was started on 2012-12-05 and was successfully closed on 2013-02-12.The final text of this draft CWA was submitted to CEN for publication for public comment phase on 2013-02-14.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN: [list inserted by CCMC].

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

Introduction

This CEN Workshop Agreement document is based on the results of the iNTeg-Risk project [1]. (iNTeg-Risk: Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks) and, in particular, on the deliverable D.2.1.2.1 iNTeg-Risk ERMF (Emerging Risk Management Framework) [2]. The document deals with the particular issue of emerging risk, in a more narrow sense with the emerging risks related to new technologies. The approach adopted here is complementary to the International Standard ISO 31000, Risk Management – Principles and guidelines [3], which is dealing with Risk Management in general. This CEN Workshop Agreement has been a part of the project and its preparation supported by the EU's Seventh Framework Programme for Research (FP7).

Goals

iNTeg-Risk project [1] [5], and this CEN Workshop Agreement are devoted to improving the ability of the EU industry, society and authorities to identify, monitor and manage emerging risks. The project should improve chances of market success of European innovation and new technologies[1)] developed in the EU. Its particular concern is the issue of public trust and confidence in the research efforts promoted by the EU, e.g. in the technologies and solutions - like innovations - developed within European projects. The technologies and solutions developed in these projects should be well accepted by the European society and perceived as a good and just investment of time and effort. On the other hand, mistrust or lack of confidence, lack of fairness and/or transparency of innovation can damage or even stop the innovation in a particular field.

The particular goal of this CEN Workshop Agreement is to improve management of emerging risks in the EU and promote safety, security, environmental friendliness and social responsibility as a trademark of the EU technologies. The approach proposed by the document is based mainly on the results of 17 individual applications of new technologies like nanotechnologies, hydrogen technologies, underground storage of carbon dioxide and new materials, which have been analyzed in iNTeg-Risk project ERRAs (Emerging Risk Representative industrial Applications). The solutions have been generalized and used for the framework presented here. In the project, the overall solution has been made available to the users in the form of the iNTeg-Risk 1StopShop. The shop includes tools for early recognition and monitoring of emerging risks, risk governance, education & training, as well as new tools such as Safetypedia, RiskAtlas, network of stakeholder companies and persons (ENISFER), etc. These tools are supposed to be available as a PPP-service (PPP – public-private partnership) after the end of project in May 2013.

Transparency and precaution

Transparency is required by both public bodies and general public. The transparency is a precondition for having the research and innovation perceived as balanced, fair and beneficial. However, the question if a particular innovation (e.g. a new technology – e.g. nanotechnology, new materials or new energy production technologies) is beneficial for the society often cannot be answered in a simple and straightforward way. It leads to the question "how one can be sure that the innovation related risks are acceptable", which, because of the uncertainty of these risks and their management solutions, calls for application of the precautionary principle. This principle is well rooted in Europe and in the EU policies on the highest level [6] and in a formal way [7]. But when deciding about the best balance between the advantages of a technology and possible risks different approaches are possible. There, for instance, the EU and the US have often followed different ways [8] [9], e.g. in the cases of climate change, toxic chemicals or genetically modified foods.

The emerging risks are the issue of major concern for both precautious and risk-taking stakeholders, especially for new technologies (in the case of iNTeg-Risk project, the technologies dealt with in the ERRAs).

1) Used broadly as a synonym for emerging technologies (http://en.wikipedia.org/wiki/Emerging_technologies), such as those in the list of emerging technologies proposed at http://en.wikipedia.org/wiki/List_of_emer-ging_technologies; in iNTeg-Risk seventeen such technologies are proposed as so-called ERRAs (Emerging Risk Representative Applications), see http://www.integrisk.eu-vri.eu/home.aspx?lan=230&tab=851&itm=852&pag=856

A common framework, such as the one proposed in iNTeg-Risk project, is part of the answer to the question how to reconcile the needs for innovation on one side with the needs for safety and sustainability on the other side.

The framework

The question how one can be sure that the innovation related risks are acceptable is, therefore, in the very root of the ideas which have led to iNTeg-Risk project and in the very root of the project itself. The practical answer to the question, as proposed by the project [1] consists of:

— agreed principles, in the form of iNTeg-Risk Paradigm and iNTeg-Risk Emerging Risk Management Framework (ERMF), tackled by this document;

— reference methodologies, mainly in the form of guidelines (iNTeg-Risk Guidelines) and

— tools supporting application of the above principles and methodologies in form of a software suite (iNTeg-Risk 1StopShop[2)]).

The framework is, thus, envisaged as one of the key elements of the overall iNTeg-Risk solution and it defines the practical agreed way of dealing with emerging risks and managing them. In addition, the ERMF provides the basis for the common EU recommended practices and standardized practices for dealing with emerging risks due to new technologies. The main objective of the framework is to set a transparent agreed way for management of emerging risks and to provide the basis for development of the planned pre-normative guideline documents, in particular by:

— acquiring emerging risk notions/precursors and monitoring their development;

— identifying similarities with known risks or their precursors;

— better identification of the most critical emerging risks;

— better recognition of interdependencies and relations among emerging risks;

— better knowing triggers, factors and drivers of emerging risks;

— better monitoring and optimized follow-up for the emerging risks, and

— systematic interlinking between hazards, vulnerabilities and stakeholders.

Acknowledgements

The research leading to these results has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 213345.

This CEN Workshop Agreement has been coordinated and prepared by the following authors

— Aleksandar Jovanović (EU-VRi and R-Tech, Main Editor, Chairman of the CEN Workshop 67)

— Daniel Baloš (R-Tech)

— Bruno Debray (INERIS, 1st Co-Chairman)

2) iNTeg-Risk 1StopShop registered as eingetragene Marke Nr. 30 2010 058 354 at Deutsches Patent- und Markenamt; Safetypedia is registered as eingetragene Marke Nr. 30 2011 018 399 at Deutsches Patent- und Markenamt;

— Michael Löscher (EU-VRi)

— Roderick Martin (MERL)

— Knut Øien (SINTEF, 2nd Co-Chairman)

— Vladimir Pilić (R-Tech)

— Jerzy Trebicki (KMM-VIN)

— Robert Wilson (MERL)

— Mures Zarea (GDF Suez)

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— Derk H. Brouwer (TNO)

— Yves Dien (EDF)

— Krzystof Dolinski (KMM-VIN)

— Carole Duval (EDF)

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— Hans-Theo Kuhl (AXA)

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— CEN European Committee for Standardization (CEN/CENELEC Management Centre)

— Secretariat: DIN German Institute for Standardization

The CEN/CENELEC Workshop Agreement is a technical agreement, developed by an open workshop structure within the framework of CEN-CENELEC and owned by CEN-CENELEC as a publication, which reflects the consensus of only the registered participants responsible for its contents. The Workshop Agreement therefore does not represent the level of consensus and transparency required for a European Standard (EN) and is not designed to support legislative requirements (e.g. the New Approach) or to meet market needs where significant health and safety issues are to be addressed. It is instead designed to offer market players a flexible and timely tool for achieving a technical agreement where there is no prevailing desire or support for a standard to be developed.

1 Scope

The present document gives guidance on steps for applying/implementing the proposed Emerging Risk Management Framework (ERMF) in industrial organizations. The document also formulates the process to follow for better management of emerging risks. In its approach it relies on the International Standard ISO 31000 which provides principles and generic guidelines on risk management.

This CEN Workshop Agreement can be used by any public, private or community enterprise, association, group or individual. Therefore, this CEN Workshop Agreement is not specific to any industry or sector, but its origin and emphasis are in the area of emerging risks related to new technologies and innovation.

The core of the document is its 10 elements/steps procedure for managing emerging risks, which should help improving the communication and alignment of different stakeholders' approaches.

This CEN Workshop Agreement can be applied throughout the life of an organization, and to a wide range of activities, including strategies and decisions, operations, processes, functions, projects, products, services and assets. It can be applied to different types of emerging risks, as a generic guideline, and it is not intended to promote uniformity of emerging risk management across different users and stakeholders. The implementation solutions for emerging risk management in each particular case will need to take into account the specificity of each of these particular cases and the specific features in each of the organizations, with specific contexts, structures, operations, processes, functions, projects, products, services, and/or assets and specific practices employed.

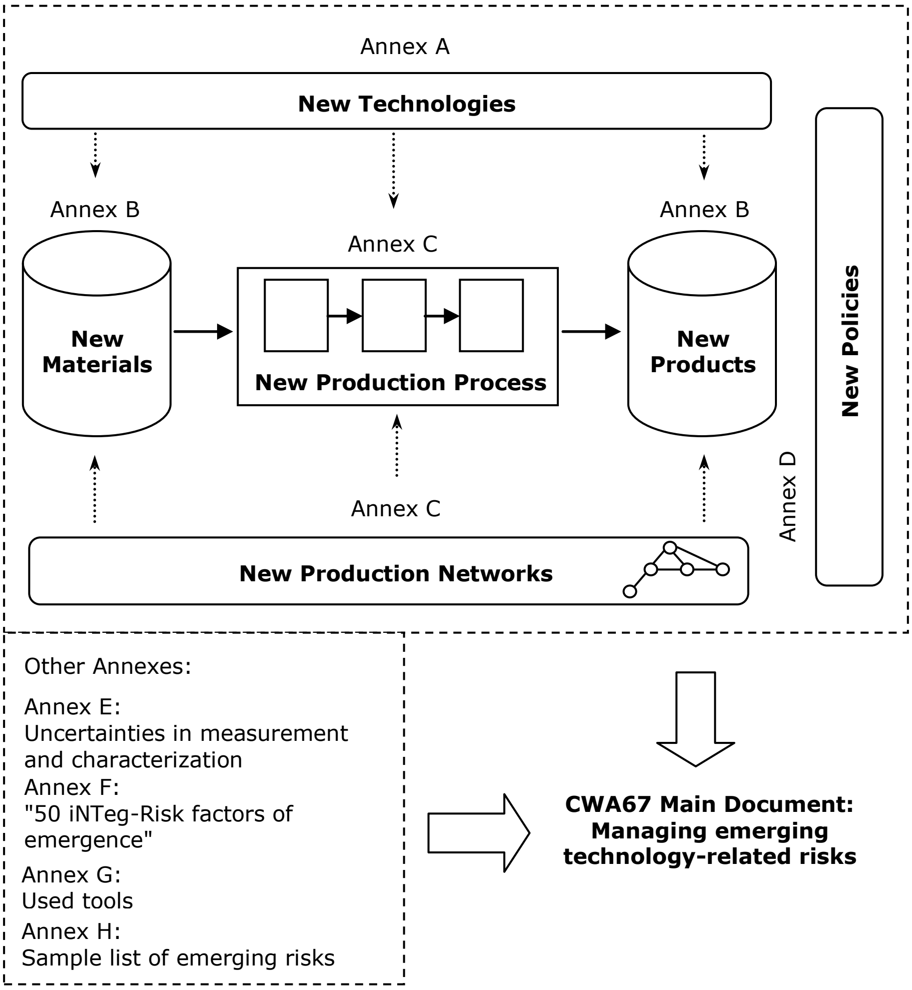

Figure 1 — Relations among the informative Annexes and the main document

It is intended that this contributes to harmonize emerging risk management processes in different countries and across organizations and types of activity and/or sectors, and does not replace the standards already available.

It is expected that this CWA enhance the realization of initiatives like European Emerging Risk Radar (E2R2) Initiative: “Matching the technology challenges of 2020” [4].

This CEN Workshop Agreement is not intended for the purpose of certification.

This CEN Workshop Agreement has a number of additional (informative) parts dealing with emerging risks related to (A) new technologies, (B) new materials, (C) new production processes and new production networks, (D) new policies, (E) uncertainties in measurements and characterization, (F) factors of emergence, (G) used tools and (H) sample list of emerging risk, as shown in Figure 1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this CWA. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this CWA are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies.

BS 31100:2011, *Risk management - Code of practice and guidance for the implementation of BS ISO 31000*

EN ISO 14001:2004, *Environmental management systems - Requirements with guidance for use*

EN ISO 14044:2006, *Environmental management - Life cycle assessment - Requirements and guidelines*

EN ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 51:1999, *Safety aspects – Guidelines for their inclusion in standards*

ISO Guide 72:2001, *Guidelines for the justification and development of management system standards*

ISO Guide 73:2009, *Risk management - Vocabulary*

ISO 26000:2010, *Guidance on social responsibility*

ISO/IEC 27000:2009, *Information technology - Security techniques - Information security management systems - Overview and vocabulary*

ISO 31000:2009, *Risk management - Principles and guidelines*

ISO/IEC 31010:2009, *Risk management - Risk assessment techniques*

NOTE 1 In addition, the CEN Workshop Agreement proposing a management system related standard will take ISO Guide 51 into account carefully, as well as the ongoing development on ISO 31004 (Risk management - Guidance for the implementation of ISO 31000).

NOTE 2 Other cited references in the text of this document are presented as reference documents in the Bibliography.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Definitions often attempts to be very precise, thus they may capture the concept in question rather narrowly. By reading several definitions for the same concept, a richer understanding of the concept may be obtained. In the definitions below, the preferred definition is stated, but in some cases alternative definitions are included as notes.

3.1
assets
items at stake, objects of importance, which are affected by the event where the value is defined by a social group (approximately equivalent concept to stakes)

3.2
communication and consultation
is a continual and iterative process that an organization conducts to provide, share or obtain information, and to engage in dialogue with stakeholders and others regarding the management of risk

Note 1 to entry: The information can relate to the existence, nature, form, likelihood, severity, evaluation, acceptability, treatment or other aspects of the management of risk.

Note 2 to entry: Consultation is a two-way process of informed communication between an organization and its stakeholders or others on an issue prior to making a decision or determining a direction on a particular issue. Consultation is a process which impacts on a decision through influence rather than power and an input to decision making, not joint decision making.

[SOURCE: ISO 31000:2009, definition 2.12]

3.3
consequence
combination of the intensity of the event, items affected by the event and vulnerability

Note 1 to entry: Consequences are subjective, as the affected items have symbolic or economical values that are a function of the utility that a social group draws from them. An equivalent concept is outcome. Consequences are measured by their severity.

Note 2 to entry: outcome of an event affecting objectives

Note 2.1 to entry: An event can lead to a range of consequences.

Note 2.2 to entry: A consequence can be certain or uncertain and can have positive or negative effects on objectives.

Note 2.3 to entry: Consequences can be expressed qualitatively or quantitatively.

Note 2.4 to entry: Initial consequences can escalate through knock-on effects.

3.4
current risk
conventional risk
those related to activities and equipment typically found in most industries

Note 1 to entry: An example is the risk of electrocution in a conventional understanding

3.5
early warning
is the provision of timely and effective information, through identified institutions, that allows individuals exposed to hazard to identify the emergence of a risk

3.6
emerging risk
has been defined as any risk that is both new and/or increasing

Note 1 to entry: The definition follows the principles set by OSHA.

Note 2 to entry: New means that the risk did not previously exist and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or that a long-standing issue is newly considered as a risk due to a change in social or public perceptions; or that new scientific knowledge allows a long-standing issue to be identified as a risk.

Note 3 to entry: Increasing means that the number of hazards leading to the risk is growing; or that the exposure to the hazard leading to the risk is increasing; or that the effects/impacts of the hazards are getting worse (e.g. seriousness of health effects and/or the number of people affected).

3.7
event
occurrence or change of a particular set of circumstances

Note 1 to entry: An event can be one or more occurrences, and can have several causes.

Note 2 to entry: An event can consist of something not happening.

Note 3 to entry: An event can sometimes be referred to as an incident or accident.

Note 4 to entry: An event without consequences can also be referred to as a near miss, incident, near hit or close call.

[SOURCE: ISO 31000:2009, definition 2.17]

3.8
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO Guide 51:1999]

3.9
hazard
potential source of harm

[SOURCE: ISO Guide 51:1999]

3.10
hazardous event
event in which a situation may result in harm

[SOURCE: ISO Guide 51:1999]

3.11
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazards

[SOURCE: ISO Guide 51:1999]

3.12
indicator
something that provides an indication especially of trends

Note 1 to entry: a measurable/operational variable that can be used to describe the condition of a broader phenomenon or aspect of reality

[SOURCE: http://www.eionet.europa.eu/gemet; 2013-01-21]

3.13
intended use
use of a product or system in accordance with information provided by the supplier

[SOURCE: ISO Guide 51:1999]

3.14
(key) performance indicators
(K)PIs
measures by which the performances of organizations, systems, technologies and/or persons are periodically or continuously assessed

3.15
level of risk
magnitude of a risk or combination of risks, expressed in terms of the combination of consequences and their likelihood

[SOURCE: ISO 31000:2009, definition 2.23]

3.16
likelihood
chance of something happening

Note 1 to entry: In risk management terminology, the word likelihood is used to refer to the chance of something happening, whether defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and described using general terms or mathematically (such as a probability or a frequency over a given time period).

Note 2 to entry: The English term likelihood does not have a direct equivalent in some languages; instead, the equivalent of the term probability is often used. In English, probability is often narrowly interpreted as a mathematical term. Therefore, in risk management terminology, likelihood is used with the intent that it should have the same broad interpretation as the term probability has in many languages other than English.

[SOURCE: ISO 31000:2009, definition 2.19]

3.17
(emerging risk) notion
any evidence indicating that a risk may emerge in a given context or situation

3.18
occupational safety and health
is a cross-disciplinary area concerned with protecting safety, health and welfare of people engaged in work or employment, aiming to foster a safe work environment

Note 1 to entry: largely based on EU OSHA definition

[SOURCE: https://osha.europa.eu/en; 2013-01-21]

3.19
precautionary principle
is a principle adopted by the UN Conference on Environment and Development (1992) saying that in order to protect the environment, a precautionary approach should be widely applied, meaning that where there are threats of serious or irreversible damage to the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation

Note 1 to entry: Within the frame of precaution - the concept of risk is seen from the perspective of pervasive uncertainty - and even ignorance. Precautious risk management means ensuring prudent handling of decision options in situations of high uncertainty about causes and effects and where high vulnerability of the population under risk is present. Instruments of precaution include minimization requirements such as ALARA (as low as reasonably achievable) or ALARP (as low as reasonably practicable), diversification of risk agents, containment in time and space, and close monitoring. In severe cases a ban of the activities may be warranted.

3.20
risk
combination (product) of the probability of an event and its consequences

Note 1 to entry: effect of uncertainty on objectives

Note 1.1 to entry: An effect is a deviation from the expected — positive and/or negative.

Note 1.2 to entry: Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).

Note 1.3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination.

Note 1.4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

Note 1.5 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

[SOURCE: ISO 31000:2009]

Note 2 to entry: combination of the probability of occurrence of harm and the severity of that harm

Note 2.1 to entry: The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event, and the possibility to limit the harm.

3.21
risk acceptance
informed decision to take a particular risk

3.22
risk analysis
process to comprehend the nature of risk and to determine the level of risk

Note 1.1 to entry: Risk analysis provides the basis for risk evaluation and decisions about risk treatment.

Note 1.2 to entry: Risk analysis includes risk estimation.

Note 2 to entry: systemic use of available information to identify hazards and to estimate the risk

3.23
risk assessment
overall process of risk identification, risk analysis and risk evaluation

Note 1 to entry: The decision may be taken based on the result of risk evaluation.

[SOURCE: ISO 31000:2009, definition 2.14]

3.24
risk based approach
related to safety, the risk based approach is a process for ensuring safety of products, processes and systems through consideration of hazards and their consequent risks

3.25
risk criteria
terms of reference against which the significance of a risk is evaluated

Note 1 to entry: Risk criteria are based on organizational objectives, and external and internal context.

Note 2 to entry: Risk criteria can be derived from standards, laws, policies and other requirements.

[SOURCE: ISO 31000:2009, definition 2.22]

3.26
risk communication
is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties

Note 1 to entry: It is an integral and ongoing part of the risk analysis exercise, and ideally all stakeholder groups should be involved from the start.

Note 2 to entry: the exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc.

3.27
risk evaluation
process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude are acceptable or tolerable

Note 1 to entry: procedure based on the risk analysis to determine whether a tolerable risk has been achieved

3.28
risk identification
process of finding, recognizing and describing risks

Note 1 to entry: Risk identification involves the identification of risk sources, events, their causes and their potential consequences.

Note 2 to entry: Risk identification can involve historical data, theoretical analysis, informed and expert opinions, and stakeholder's needs.

[SOURCE: ISO 31000:2009, definition 2.15]

3.29
risk indicator
a measurable aspect (event/condition) of a system or an activity that affects the risk level of this system/activity

3.30
risk management framework
set of components that provide the foundations and organizational arrangements for designing, implementing, monitoring, reviewing and continually improving risk management throughout the organization

Note 1 to entry: The foundations include the policy, objectives, mandate and commitment to manage risk.

Note 2 to entry: The organizational arrangements include plans, relationships, accountabilities, resources, processes and activities.

Note 3 to entry: The risk management framework is embedded within the organization's overall strategic and operational policies and practices.

[SOURCE: ISO 31000:2009, definition 2.3]

3.31
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO 31000:2009, definition 2.2]

3.32
risk matrix
tool for ranking and displaying risks by defining ranges for consequence and likelihood

3.33
risk maturation
process starting with early warnings, weak signals, precursors or other form of collected evidences or indications that a given phenomenon can emerge to a fully recognized risk

Note 1 to entry: The process of risk maturation may but not necessarily have to lead towards a “fully recognized risk”, e.g. in a case of false warnings.

Note 2 to entry: Evolution of risk with time correlated with the evolution of the technology causing the risk, its context and environment, the scientific knowledge on the risk and perception and acceptance of stakeholders.

3.34
risk owner
person or entity with the accountability and authority to manage a risk

[SOURCE: ISO 31000:2009, definition 2.7]

3.35
risk perception
way in which a stakeholder views a risk, based on a set of values or concerns

Note 1 to entry: Risk perception depends on the stakeholder’s needs, issues and knowledge.

Note 2 to entry: Risk perception can differ from objective data.

Note 3 to entry: a subjective appreciation by individuals which may often bear little relation to the statistical probability of damage or injury

3.36
risk profile
description of any set of risks

Note 1 to entry: The set of risks can contain those that relate to the whole organization, part of the organization, or as otherwise defined.

[SOURCE: ISO 31000:2009, definition 2.20]

3.37
risk reduction measure (protective measures)
any action or means to eliminate hazards or reduce risks

Note 1 to entry: Examples include inherently safe design, risk reduction measures and information for use

[SOURCE: ISO Guide 51:1999]

3.38
residual risk
risk remaining after risk reduction measures (protective measures) have been taken

[SOURCE: ISO Guide 51:1999]

3.39
safety
freedom from unacceptable risk

Note 1 to entry: In other publications slightly different definitions may apply for the same terms, but the concepts are broadly the same.

[SOURCE: ISO Guide 51:1999]

3.40
screening
establishing a procedure for screening hazards and risks and determining assessment and management route

Note 1 to entry: A screening procedure is typically applied in pre-assessment.

3.41
stakeholders
person, group or organization that has interest or concern in an organization's activity

Note 1 to entry: The decision-maker is also a stakeholder.

Note 2 to entry: The term stakeholder includes but has a broader meaning than interested party (which is defined in ISO 9000:2000).

Note 3 to entry: person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity

3.42
tolerable risk
risk which is accepted in a given context based on the current values of society

Note 1 to entry: For the purposes of ISO Guide 51, the terms acceptable risk and tolerable risk are considered to be synonymous.

3.43
vulnerability
possible incapacity of a system (e.g. society or environment) to cope with a major event (hazard) threatening its normal functionality or existence

Note 1 to entry: Vulnerability is a concept having its origins in the medical, defense and cyber security areas, expanding to the management of major natural or industrial hazards.

Note 2 to entry: The concept may include various elements such as anticipation of the event, protection measures, preparation to crisis situations, crisis management, and recovery. It depends on social, economic, institutional, technological and cultural adaptive mechanisms. An increasing amount of research develops the correlation between the hazard, the consequences and vulnerability.

4 Symbols and abbreviations

ALARP	As low as reasonably practicable
C	governance/communication[3)]
CCS	Carbon Capture and Storage
CNTs	Carbon Nanotubes
CSF	Contributing Success Factor
CWA	CEN Workshop Agreement
D	Deliverable
DyPASI	Dynamic Procedure for Atypical Scenarios Identification

3) in ERMF framework

EDF	fr.: Électricité de France
EN	European Standard
ENISFER	European Network of Industrial Systems and Facilities for Exploration of Emerging Risks
ERMF	Emerging Risk Management Framework
ERRAs	Emerging Risks Representative (industrial) Applications
EU	European Union
FMEA	Failure Mode and Effect Analysis
GAMAB	fr: Globalement Au Moins Aussi Bon[4)]
GUM	Guide to the expression of Uncertainty in Measurement
H	Human/management[3)]
HARN	High aspect ratio nanomaterials
HAZOP	Hazard and operability study
HEPA	High Efficiency Particulate Air filter
HiPco	High pressure carbon monoxide
HILP	High-impact-low-probability
HSE	Health, Safety, Environment
HSE-UK	Health and Safety Executive (institution UK)
HSSE	Health, Safety, Security and Environment
IEC	International Electrotechnical Commission
INERIS	fr.: Institut National de l'Environnement Industriel et des risques
iNTeg-Risk	Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks
IRA	Integrated Risk Assessment
IRGC	International Risk Governance Council
ISO	International Organization for Standardization
KPI	Key Performance Indicator
KMM-VIN	European Virtual Institute on Knowledge-based Multifunctional Materials AISBL
LCA	Life Cycle Analysis

4) practised in France

MCDM	Multi Criteria Decision Making
MEM	Minimum Endogenous Mortality (practiced in Germany)
MIMAH	Methodology for the Identification of Major Accident Hazards
MSDS	Material Safety Data Sheet
MWCNT	Multiwalled CNTs
NGO	Non-Governmental Organization
OECD	Organisation for Economic Co-operation and Development
PoF	Probability of Failure
PPP	Public –private partnership
R	Policies regulations/standardization[3)]
REWI	Resilience based Early Warning Indicator (method)
RICAF	Risk Communication Assessment Framework
SINTEF	SINTEF (Research Institute in Norway)[5)]
SME	Small and Medium sized Enterprise
SWCNTs	Single walled CNTs
T	Technology/technical[3)]

NOTE The abbreviations referred to in the document, including Annexes, are listed above – others are explained in the text when/where used.

5 Emerging risks

5.1 Emerging risks, innovation and engineering

Safety in a modern society is to a large extent obtained by means of compliance. Respecting the rules and the rule of law is the proven way for dealing with majority of known hazardous phenomena and respective “conventional” risks. Rules and regulation in such cases reflect the society's concern related to risk, defining what risk to accept or not, and foresee the way how to manage these risks and, usually, assigning the responsibilities. However, if society has to deal with the potentially dangerous phenomena not considered or regulated so far, the concerns are raised and the agreed ways of dealing with these “emerging” phenomena need to be established. If the knowledge about the phenomenon itself is incomplete, ambiguous or burdened by uncertainties then the society’s concern about them is generally magnified [10], especially in the cases when this deficiencies in knowledge about the phenomenon result in surprising events, deemed impossible to happen, analogous to the "discovery" of the black swan[6)] [11]. These potentially dangerous phenomena may arise as part of engineering innovation. The approach of focusing on progress first, and consider potential

5) acronym being full name

6) Black swan refers to an extremely rare event that have never been encountered before (to the best of the observers knowledge) and in principle cannot be anticipated.

trouble later has often been in the core of engineering innovation [12]. Clearly, such an approach can be and has been in the root of many emerging risks and problems in history, hence innovating first and looking at risk afterwards cannot be compatible with the precautionary principle and respective policies. As most of the applications and technologies looked at in the iNTeg-Risk project are strongly related to engineering innovation, it has been, therefore, deemed necessary to tackle the balancing of engineering innovation and emerging risks in the iNTeg-Risk ERMF. In addition, as the issues of uncertainty, fear, threat and perception of risks play an increasingly important role in society [12], these aspects have also been included into the iNTeg-Risk ERMF.

In summary, the considerations related to emerging risks, captured in ERMF, are based on the following general assumptions:

— The issue of emerging risk has to be made a compulsory part of innovation policies (innovation risk governance, if done in a systematic and agreed way, does not have to slow down innovation).

— The issue of emerging risks is a very open one – we have neither well established and accepted culture of discussing emerging risks, nor established overreaching mechanisms for discussing emerging risks.

— The issue of emerging risks is not likely to be closed soon – it evolves with the society.

— Frameworks for tackling emerging risks are needed.

5.2 Emerging risks definition

When iNTeg-Risk project was proposed in 2008, the definition of emerging risks proposed by OSHA in 2005 [13], adapted to major accident risk, was stipulating that a risk was to be considered new and emerging if:

a) the risk was previously not recognized and is caused by new processes, new technologies, new ways of working, or social or organizational change (e.g. risks linked with nanotechnology, biotechnology, ICT technologies, new chemicals, effects of globalization etc.) or

b) a long-standing issue is newly considered as a risk due to a change in social or public perceptions (e.g. stress, bullying) or

c) a new scientific knowledge allows a long-standing issue to be identified as a new risk, e.g. in the situations where cases have existed for many years without being identified as risk because of, e.g., lack of scientific knowledge.

The risk was considered to be increasing if the number of hazards leading to the risk is growing, or the likelihood of exposure to the hazard leading to the risk is increasing, (exposure level and/or the number of people exposed), or effect of the hazard is getting worse (e.g. seriousness of health effects and/or the number of people affected).

Current OSHA definition [14] of emerging risks stipulates that an emerging risk is any risk that is new and/or increasing. In this context (and adapted to major accident and technological risk) "new" means that the risk did not previously exist and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or that a long-standing issue is newly considered as a risk due to a change in social or public perception; or that new scientific knowledge allows a long-standing issue to be identified as a risk. The risk is increasing[7)] if the number of hazards leading to the risk is growing, or if the exposure to the hazard leading to the risk is increasing, or that the effects/impacts of the hazards are getting worse (e.g. seriousness of health effects and/or the number of people affected). In iNTeg-Risk project the above definition [15] applies generally, and is taken as a starting reference point.

The ERMF assumes that other definitions of emerging risks should constantly be monitored in order to be sure that the understanding of emerging risks tackled by ERMF is up to date and shared with other

7) The term "increasing" is understood as something which can represent an industry wide, regional or global challenge.

stakeholder groups. As more and more industrial technologies necessarily involve the IT aspects (e.g. for process control and monitoring) it is considered essential to keep abreast with the definition used in the IT field. The respective relevant definition for ERMF is the one provided by ENISA stipulating that [16] emerging risks are those risks that may have an impact between one and five years into the future, while the future risks are those risks that may have an impact in more than five years.

On the governance side, the definition of emerging risks provided by IRGC is [17]: "[...] a risk that is new, or a familiar risk that becomes apparent in new or unfamiliar conditions. Of particular interest to IRGC are emerging risks of a systemic nature, which typically span more than one country, more than one economic sector, and may have effects across natural, technological and social systems. These risks may be relatively low in frequency, but they have broad ramifications for human health, safety and security, the environment, economic well-being and the fabric of societies."

For the extension of the original OSHA definition used for ERMF, the following issues mentioned by IRGC have been taken into account:

— the systemic nature of emerging risks;

— link of emerging risks to high-impact-low-probability-events (HILP events, HILPs);

— multidisciplinary character;

Both the ENISA and IRGC definitions of emerging risks have provided useful inputs for the definition of the approach proposed by ERMF. ISO 31000 basic definition of risk as effect of uncertainty on objectives is essentially including the emergence of emerging risk. The emergence, in that context, becomes just one aspect (or factor, or driver) of the overall uncertainty affecting the achieving of the objectives.

5.3 Extending and implementing the definition in ERMF

The OSHA definition of emerging risk primarily considers the cases of:

a) Risks that did not exist previously and are caused by, e.g., new processes, new technologies, new types of workplace, or social or organizational change, leading to <u>new (adverse) impacts</u>, and/or

b) Risks related to long-standing issues which get newly considered as a risk due to a change in social, or public perception or new scientific knowledge allowing a long-standing issue to be identified as a risk (e.g. because their potential effects are getting worse and/or the severity of potential or perceived (adverse) <u>impact on human values affected change</u>, and/or

c) Risks related to <u>issues/events the likelihood of which changes/increases</u>, e.g. if number of hazards leading to the risk is growing, or the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/or the extent of human values exposed).

For the emerging risks it is necessary to consider the two main characteristics describing their emerging character, namely their “emergence” and their “maturation” with time (see Figure 2).

Furthermore, current considerations in industry tend to comprise possible negative/adverse impacts (consequences) paired with possible positive impacts (benefits) (see Figure 3). Correspondingly, the proposed extension of the OSHA definition would include:

1) likelihood of both negative and positive impacts;

NOTE different, in general

2) both negative (adverse) and positive impacts;

NOTE the negative impacts defining risk and the positive ones, benefits, defining opportunity

3) emergence of both risk(s) and opportunity(ies);

NOTE different, in general

In addition, the extension should include:

— scenario for which risks/opportunities are assessed;

— scales (expressed in classes/categories) for impacts (negative and positive), likelihood and emergence;

— use of Indicators for providing measures for the scale.

Emergence, as a new term (dimension) in the consideration, is understood and defined as the act or an instance of emerging or the act of becoming known or coming into view: the act of emerging; e.g. "his surprising emergence [= arrival, appearance] as a leader", or, e.g., "the emergence of the Internet as an important means of communication” or “the economy's emergence from a recession". In the philosophy, systems theory, science, and art, emergence is often considered [18] as the way complex systems and patterns arise out of a multiplicity of relatively simple interactions including concepts like novelty, surprise, spontaneity, agency, even creativity itself. Emergence is central to the theories of integrative levels and of complex systems.

In this document emergence is understood as a feature of a risk (scenario) characterized by a set of factors, drivers, issues, indicators and/or other elements that make a risk qualify as more or less emerging. Practically, for two risks having the same impact and likelihood, the emergence defines which of the two risks may deserve to be handled with higher priority.

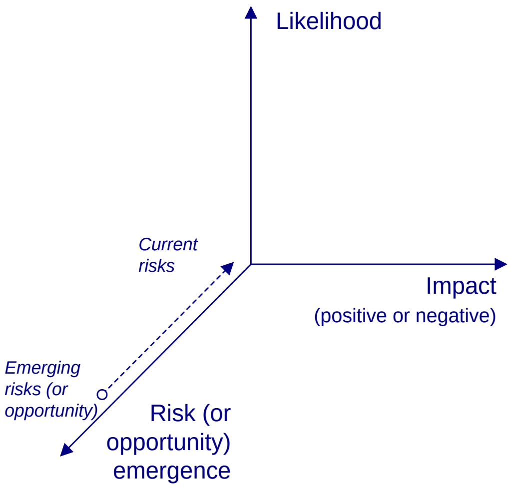

Figure 2 — Emergence as 3rd dimension of emerging risks

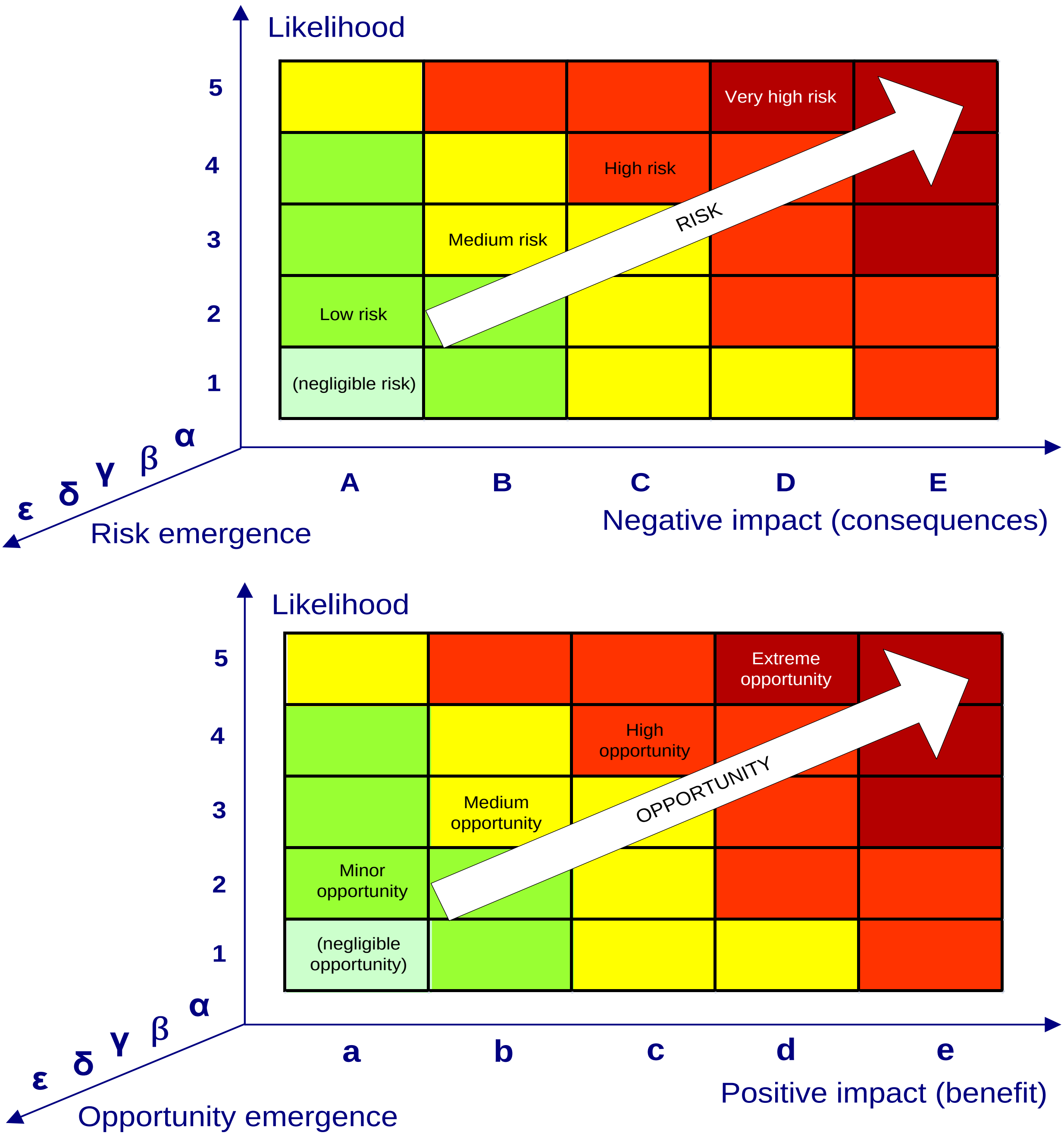

Figure 3 — Risk-opportunity based representation, combined with emerging character (emergence) of risks (and opportunity)

The issue of a common metric to measure and compare negative and positive impacts has to be defined for each particular case and it can be questionable.[8)] It should also be applicable to complex risks where risk receptors (those affected by the risk) are different from the beneficiaries (those benefitting from the risk). The convention also allows defining similar categories for benefits. Following the usual practice in many engineering approaches the technical definition of an emerging risk would, then, consist of, e.g., a 5x5 risk matrix (5x5 classes of negative impact and likelihood, respectively) and, e.g. 4 categories of non-negligible risk (low, medium, high, very high), as well as 5 classes of risk emergence.

8) e.g. from an ethical point of view – impact is often measured as a number of expected fatalities and it is generally impossible to state "how many fatalities is progress worth"

The difference in respective likelihood classes should be noted. Generally, ERMF is designed in such a way, that the values on each of the axes can be expressed in different ways, e.g. as numbers (crisp, rational), statistical distributions (probabilistic, stochastic), linguistic variables and/or fuzzy numbers.

5.4 Scales of emerging risks

Risk communication has been a critical issue in risk analysis and management. In relation to emerging risks it is even more critical than in relation to current risks, because in addition to all difficulties pertinent to the current risk communication, emerging risks have the difficulties related to assumptions about the phenomenon in question due to lack of knowledge. The significance of the assumptions is often very difficult to explain, let alone quantify. Formalizing the process, e.g. by means of a framework like ERMF, helps to make the analysis of different cases more comparable, and an important part of this is to use a clear convention for assessing and expressing/communicating emerging risks. This includes application of specific scales and scoring systems (such as the examples in Table 3 and Table 4). The scale and proposed scoring system below relies very much on the one proposed for the current risks (known risks, not considered as emerging, see [19]). The practical use of the scoring system generally requires the definition of application specific scales/scores. It should also be clearly indicated at which level they should be applied since e.g. an adverse effect to local communities may be a benefit at a regional level. In practical use, conventions such as using (e.g.) 5x5 risk matrices and/or the color-code as per Table 1 can be beneficial.

Table 1 — Example of Color-code for scoring emerging risks (and opportunity)

Color-code for two emerging risks scales			Meaning [a]
	3-level	5-level	
light green (CCFFCC)		1	very low importance (negligible)
green (99FF33)	1	2	low importance
yellow (FFFF00)	2	3	medium importance
red (FF3300)	3	4	high importance
dark red (B40000)		5	very high importance
[a] e.g. resulting from the assessment based on Annex F			

Table 2 is a special case for screening during pre-assessment, prior to assigning values for likelihood and impact.

Table 2 — Example of Color-code for the status in the (pre)assessment process

Color-code for status		Meaning
white (FFFFFF)		not yet assessed
blue (0070C0)		discarded in pre-assessment [a]
[a] e.g. for the item set onto the backlist or watch-list in the pre-assessment, see the flowchart in Figure 11		

Table 3 — Examples of likelihood scale – 5 classes

Classes	Values (time between events)	Values (events/year)	Likelihood category
Very probable	< 1 year	$>1\times10^{-1}$	5
Probable	$1 \leq 5$ years	$1\times10^{-1} \geq 1\times10^{-2}$	4
Possible	$5 \leq 25$ years	$1\times10^{-2} \geq 1\times10^{-3}$	3
Unlikely	$25 \leq 100$ years	$1\times10^{-3} \geq 1\times10^{-4}$	2
Very unlikely	>100 years	$\leq 1\times10^{-4}$	1

Table 4 — Examples of negative impacts (consequences) scale – 5 classes

Classes	Values	Examples	Consequence category
Negligible negative	(-1) < 0	Negligible negative impact on human health, livelihoods, community facilities/utilities, wider economy	A
Minor negative	(-2) < (-1)	Limited impact on human health and well-being (e.g. occasional dust, odors, traffic noise), livelihoods of individuals (e.g. isolated incidents related to ethnic tensions and some restrictions on access to income source)	B
Moderate negative	(-3) < (-2)	Modest impact on human health and well-being (e.g. noise, light, odor, dust, injuries to individuals), individual livelihoods (e.g. restricted access to income source)	C
Major negative	(-4) < (-3)	Emergency situation with harmful consequences to human health (e.g. fatalities), or disastrous consequences on the livelihoods of individuals (e.g. curtailment of access to primary Income sources)	D
Extreme negative	(-5) < (-4)	Extreme adverse events, affecting several sectors at the same time (e.g. human health, environment, economy, etc.)	E

5.5 Maturation of emerging risks

Defining the starting point of an emerging risk can be a challenging task because at the very beginning, there is nothing emerging and no risk. Theoretically, it can be very challenging to define the point where an emerging risk starts to emerge. Practically, however, it is assumed that a risk would start its existence as an emerging risk, when the first indication of that risk is recorded for the first time. After that moment, any new evidence (notion, in terms of ERMF), early warnings, indications, weak signals, signals, precursors, incidents, etc., recorded and processed will contribute to emerging risks maturation (see Figure 4 and Figure 5). In most of the cases, the evidence collected will be heterogeneous and incomplete, often contradicting, and it is therefore necessary to ensure that each piece of evidence is stored in a structured manner, in order to obtain a meaningful and consistent picture of an emerging risk as soon as possible. As shown in Figure 4 the process usually starts with weak signals, leading to the first anticipated scenarios, usually formulated by the potentially involved stakeholders, who start to feel threatened by the scenario(s). If the occurrences of the scenarios or their parts start appearing, further development (maturation) might lead to the creation of interest groups taking the stance in the situation and undertaking actions in order to clarify and/or prevent the emerging risk. Once this process leads to e.g., new or changed regulation, legal decisions and similar, one can talk about fully emerged risk, fully included into the scope of known, and thus conventional, risks. The "signal strength", in such a case, as shown in Figure 11 (left part), increases towards the end of the maturation process.

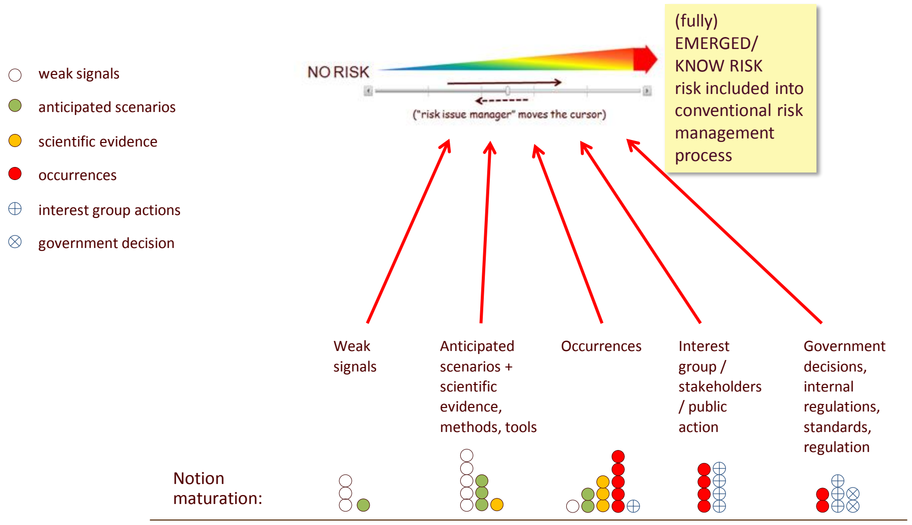

Figure 4 — Maturation of emerging risk through accumulation of knowledge

The maturation of a risk notion does not necessarily need to have a constantly ascending character: if the initial threat indication ends up by becoming false (e.g. no occurrences happen or counter evidence becomes available) the maturation process can start decaying and the emerging risk may, eventually, disappear at the end (Figure 5).

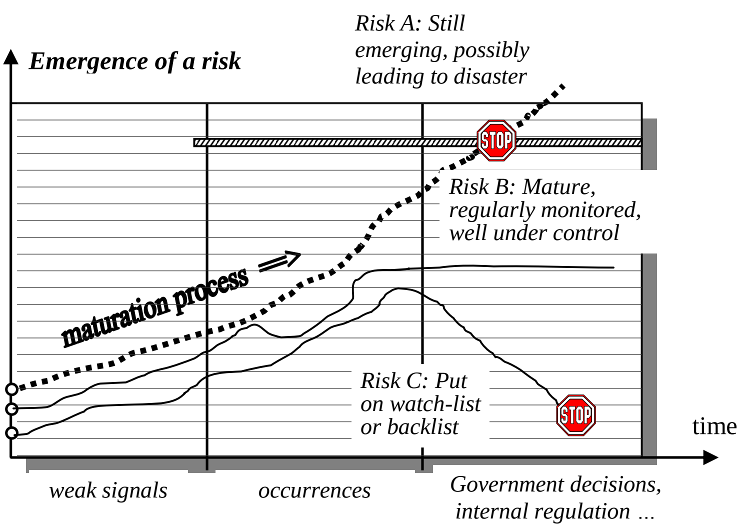

Figure 5 — Example of three different maturation paths for emerging risks: archived or back-listed notion (C), emerging risk which have achieved stable (mature) status (B), and risks still emerging (A)

An emerging risk notion (a notion) is, thus, any piece of evidence indicating that a risk may emerge in a given context or situation. The notions can include weak signals, precursors and other forms of collected evidence about possible or imagined threats. Press releases about unknown health problems in the areas where new gas exploitation technologies are taking place (unconventional gas) can represent sources of notions related to possible emerging risks related to a topic such as fracking. The notions need to be processed in order to obtain clearer ideas about possible scenarios (denoted as iNTeg-Risk ERIs, emerging risk issues, in iNTeg-

Risk project) of how things could go wrong. In the example of fracking, these could be separate scenarios leading to water pollution or micro-seismicity.

These scenarios are generally taking place within a specific application area (denoted in iNTeg-Risk as ERRAs, emerging risks representative applications). A collection of assessed scenarios helps to better judge the acceptability of the technology (e.g. unconventional gas) considered. The technology, on the other hand, can be a part of a broader risk issue, e.g. one raising more global attention (new technologies), those denoted as super ERRAs in iNTeg-Risk project. The levels defined above mark steps in the process of risk maturation. From the vague idea that something could be a risk (notion), considered by single persons or small stakeholders' groups, one goes toward a globally recognized risk (super ERRA) considered at the highest global levels, such as United Nations of World Economic Forum. Along this risk maturation process it may then be necessary to proceed to several scale-ups of the risk management framework and significant changes among of the risk owners and other stakeholders may occur.

6 Requirements

6.1 General requirements

The technical, human/communication, governance/management and regulation related requirements to analysis and management of emerging risks (consequently also the requirements for defining ERMF) should be:

a) well defined in scope;

b) non-contradicting;

c) realistic;

d) applicable to different business areas, activities, industries, etc.

The ERMF itself should take into account:

e) stakeholders' interest and/or priorities;

f) regulatory/legislative requirements;

g) technical and other influencing factors;

h) agreed metrics and accepted methodologies.

In addition:

i) the objectives of the analysis and risk criteria should be clearly defined as early as possible in the process but also revised continuously along the process to accompany the evolution of knowledge about the emerging risk;

j) the level of input information should be improved throughout the process of emerging risk management;

k) the assessment should be performed by a multidisciplinary team with required competence. The composition of this team should also evolve with time according to the evolution of knowledge, objectives and risk criteria.

From the ISO 31000 perspective ERMF should be seen as a part of the overall working process consisting of activities such as defining objectives, goals and requirements, establishing a general risk management system, reporting about failures and status, performing corrective action, active management, management of change, safe work practices, emergency response and controls, investigation of incidents, training, quality assurance.

6.2 Requirements resulting from iNTeg-Risk project

The initial iNTeg-Risk project proposal and the project plan [1] have set the requirements that ERMF should be developed starting from integration and generalization of results of iNTeg-Risk project, follow the conclusions and recommendations from the iNTeg-Risk paradigm, be the basis for the internal common guidelines for emerging risk management, use the key performance indicators defined and ensure the holistic approach to performance assessment, thus preventing risk shift to other receptors or to other process life steps.

Main single requirements resulting from the iNTeg-Risk paradigm document [2] are:

a) **Life-cycle:** All dimensions of emerging risks should be considered along the life cycle of new technologies and products in order to prevent and reduce adverse effects and avoid problem shifting;

b) **Integration:** The management of emerging risk should be based on integrated assessment and management procedures and methods. Integration should be taken into account;

c) **Holistic assessment:** When introducing a specific framing of a risk management problem, a holistic vision should be maintained to avoid risk shift to other spheres and partialization;

d) **Precaution:** When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically;

e) **Continuous improvement:** Emerging risk management processes should be constantly evaluated and improved in the light of their efficiency, effectiveness and flexibility.

6.3 Implementation related requirements

For implementation of the ERMF the following should be taken into account.

a) Various techniques such as fault tree analysis, event tree analysis, cause-effect methods and bow-tie modeling could be used, but in such a way not to mislead the scenario analysis in the sense that what cannot be modeled can be omitted (from the analysis).

b) Special attention should be devoted to atypical scenarios which must be duly considered and not be omitted in scenario development concerning emerging risks just because they, e.g., cannot be modeled.

c) It is not recommended to combine likelihoods and impacts related to different scenarios (e.g. different failure modes) even if they refer to the same system. At the same time, cumulative effects and common failure modes should not be omitted. Efficiency of the risk mitigating activities shall be connected to identify failure modes and the projected risk reduction shall be taken into account.

d) General requirements for performing likelihood analysis are:

— Conservatism of simplified approaches;

NOTE 1 The results from the risk screening may be on average conservative compared to the results from a detailed analysis. Available methods for determining likelihood may vary in the level of detail. A method with less detail (e.g. qualitative analysis) can be conservative, in other words it may yield higher or equal average probability of failure compared to a more detailed approach;

— Possibility to audit the results;

NOTE 2 The results should be auditable to peer experts.

— Multi-level approaches: Both qualitative and quantitative approaches (ranging from screening to detailed) may be used;

- Procedural character: The assessment shall be structured as a procedure with well-defined boundary conditions;
- No averaging: The likelihood rating should be such that the highest rating for one of the individual aspects of different risk mechanisms and trigger events should control the final rating score in order to prevent averaging of the ratings for various aspects;
- Additional aspects to be considered: Effectiveness of the methods used to identify emerging risks, confidence in the inputs used, possible interaction or synergy effects, possible interaction between likelihood and acceptance criteria.

e) General requirements for performing consequence analysis are:

- The consequence/impact (adverse consequence or benefit) analysis should address various types of consequences, the main ones being those related to HSSE and business continuity;
- In general, for the HSE related impacts/consequences the impact assessment results shall be documented and approved by the responsible authorities recognized by the national regulations, if necessary.
- If models are to be used, one should take all the provisions to avoid underestimating the consequences. Models should be used within their validity boundaries and/or with extreme caution.
- The use of expert judgment is allowed both for likelihood and consequence analysis, but this use should be transparent and preferably involve several experts with relevant acknowledged qualifications.

f) General personnel-related requirements: Emerging risk analysis and management require experienced personnel at all levels as well as appropriate routines for the execution of the work. Particular cases may require special competencies. In addition, local rules and legislation, and the type of industry may set detailed requirements to competencies involved. Due consideration should be given to the width of background skills and expertise collated in the team. One or more of the skills may be possessed by one person, but it is emphasized that emerging risk management is a team effort. Generally ERMF and the respective tools should take at least three types of users into account:

- layman, general public user[9];
- intermediate level user[10];
- risk analyst[11].

In practice, the above list can be elaborated into much more details, e.g. shown in Table 7.

9) Can view results of the emerging risk analysis; e.g. an interested citizen.

10) Can view and combine, partly edit the results of the emerging risk analysis, e.g. a decision maker using ERMF results.

11) Creates an emerging risk analysis.

7 ERMF – Emerging risk management framework

7.1 Main principles of ERMF

Main single requirements resulting from the iNTeg-Risk paradigm document [2] are presented in 6.2.

For risk management in general ISO 31000 [3] has defined eleven principles that also can be seen as requirements applicable to the ERMF:

a) create and protect value;

b) be an integral part of all organizational processes;

c) be part of decision making;

d) explicitly address uncertainty;

e) be systematic, structured and timely;

f) be based on the best available information;

g) be tailored;

h) take human and cultural factors into account;

i) be transparent and inclusive;

j) be dynamic, iterative and responsive to change;

k) facilitate continual improvement of the organization.

Learning from successful governance and communication methods and models, such as these of IRGC [20] or those from the previous EU projects, ERMF provides the basis for handling emerging risks in terms of:

a) pre-assessment;

b) risk appraisal;

c) tolerability and acceptability (incl. classification);

d) risk communication and

e) governance and communication strategies.

ERMF is designed in such a way, that it supports comparison of different approaches and helps in their alignment and/or integration when needed. ERMF provides decision support and guidance to implement risk management process at the levels of governance, policies, principles, organization, management and operation. ERMF is, thus, an extension of existing approaches and practices. Figure 6 shows the iNTeg-Risk pyramid of deliverables created under the assumption that there should be no gap between the methodologies for current and emerging risks. The process of defining the pyramid has shown that the gap actually appears only at the level of practical applications.

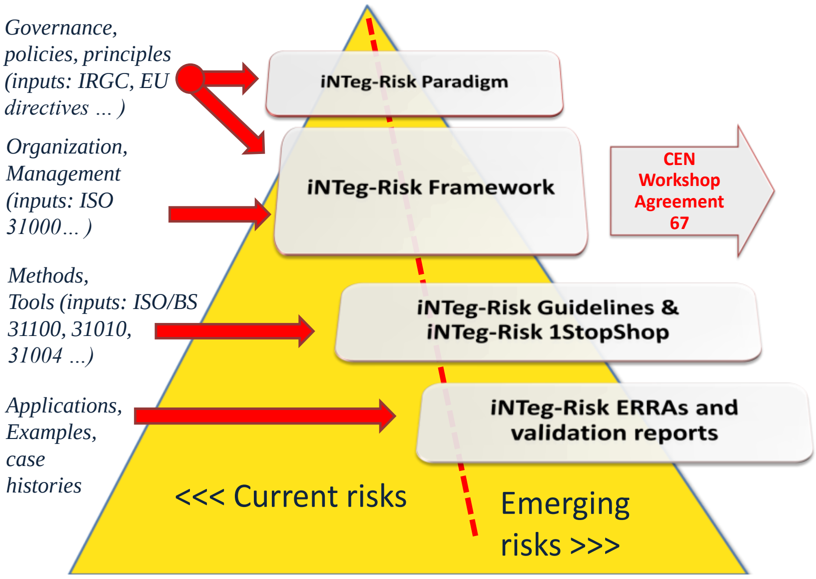

Figure 6 — Organization of iNTeg-Risk deliverables leading to this CEN WS document

7.2 The 10 steps of ERMF

The 10 steps of the ERMF are illustrated in Figure 7 and defined as shown in Table 5, followed by a detailed description in Table 6. Annexes to this document (A, B, C, D, and E) provide use cases of the ERMF in different practical applications; explaining and giving examples to each of the 10 steps.

The process starts with Emerging Risk Horizon Screening provided for in Step 1 Early warnings – notions, followed by Emerging Risk Pre-Assessment (Steps 2 to 4) and Emerging Risk Assessment (Steps 5 to 8). This forms the basis for and includes making management decisions about risk treatment (Step 8) and a follow-up and improvement through Step 10 (of both the risk itself, the implementation and effect of the treatment, and all other steps in the process). Finally, communication and consultation (Step 9) is an overarching activity throughout the entire process (see Figure 7).

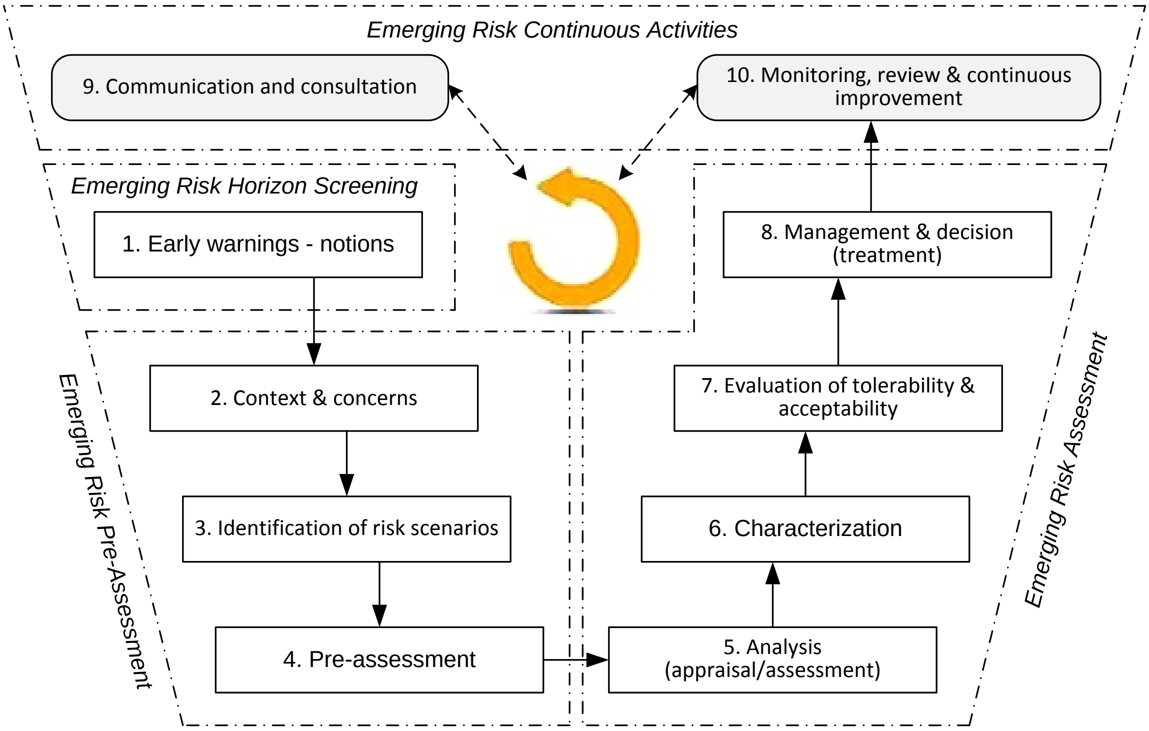

Figure 7 — The 10 steps of the ERMF

Table 5 — Short description of 10 steps of the ERMF

Step	Short description
Horizon screening	
1) Early warnings - NOTIONS (including preliminary hazard identification)	Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic, etc.). The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of risk maturation under control.
Pre-Assessment	
2) CONTEXT establishment and CONCERN assessment	By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process. Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development.
3) IDENTIFICATION of emerging RISK SCENARIOS	The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings.
4) PRE-ASSESSMENT of selected risks scenarios (screening)	Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified.
Appraisal/Assessment	
5) Emerging Risk APPRAISAL/	The analysis of risk governance models revealed the importance of considering the whole life cycle of a product and the need to develop cumulative risk

Step	Short description
ASSESSMENT/ ANALYSIS	assessments; this step should include likelihood analysis and impact analysis for emerging risks.
6) Emerging Risk CHARACTERI-ZATION, Risk categorization/ classification	Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization/classification is an optional part of the process, especially important if large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance).
7) Evaluation of emerging risk TOLERABILITY & ACCEPTABILITY	In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions.
8) Management & DECISION (TREATMENT)	Based on the previous steps results, decisions are made to manage risk in order to keep it at an acceptable or tolerable level. The approaches applied in emerging risk management should: — integrate both qualitative and quantitative data; — combine different type of criteria; — carefully address compensation; — consider variations/alternatives in risk scenarios; — treat uncertainties; — help make robust decisions.
Continuous activities	
9) Emerging risk COMMUNICATION & CONSULTATION	Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles.
10) Emerging risk MONITORING, REVIEW & CONTINUOUS IMPROVEMENT	This requirement means that the procedures to be established have to ensure — continuous improvement, — effectiveness & efficiency, — sustainability & evergreening.

A detailed description of the 10 steps of the ERMF is given below.

Table 6 — Extended description of the 10 steps of the ERMF

(Emerging risk) Horizon screening
Step 1: Early warnings - NOTIONS (including preliminary hazard identification)
In this phase the sub-process of managing notions takes place. The elements of the sub-process are, in general case: a) Identification and monitoring of weak signals (emerging risks need to be detected as early as possible), describing their initial context (technical, social, economic, cultural…), analyzing them, ensuring their monitoring (in order to enable the stakeholders to keep the process of "risk maturation" under control) and their initial aggregation and characterization;

Step 1: Early warnings - NOTIONS (including preliminary hazard identification)

b) Initial scenario development, including analyzing various facets of risk tolerance, preferences of the stakeholders and their possible attitudes along the expected risk maturation;

c) Looking for options, identifying them (creating them if not already available) and analyzing them in terms of their variability, chances of success, potential benefits, etc.

Practically, it means, for instance, that risk horizon must be continuously scanned/screened for emerging threats in an anticipative way because, once when these are clearly identified it may be too late to initiate appropriate actions. With respect to the effects like diffusion of threats to new areas, changes in the natural and/or social environment, changes in vulnerabilities or their risk absorbing capacity, organizational preparedness (contingency plans, resources and skills) and possible changes in the stakeholders' attitudes or behaviors should be anticipated, especially when these influence or may influence the responsiveness of systems, risk perception, etc.

On the scenario development side, the context-related narratives should be prepared (risk stories) in order to support communication and ensure inclusion of all stakeholders. The narratives should include both support communication and ensure inclusion of all stakeholders. Furthermore, they should include both best-and worst-cases and sensitivity analysis, depicting also a desirable line of action and risk management. Finally, a portfolio of scenarios should be updated and checked constantly. Techniques like agent-based simulation could be used in an integrated analytical framework, capable of dealing with dynamics of the context and analyze scenarios in time.

When looking at options, the contributing factors (change context) and their possible, also unexpected, interaction should be analyzed. The analysis should also include possible change of the risk tolerance levels and the role of risk absorbing systems, with emphasis on their robustness and resilience, especially in terms of possible future shocks or unexpected events.

Last but not least, the above needs to be supported by systems (e.g. IT) and also organizational support, more than in the case of conventional risk management systems, including a pro-active and forward-looking communication strategy.

— **Inputs:** early indications, weak signals, indications, opinions

— **Typical actions:** register warnings, indications, and notions coming through multiple channels

— **Outputs:** short information providing basic data and facts, indicating what kind of future action is needed (e.g. exploration of risks, verification of sources, etc.)

— **Possible pitfalls:** false signals, especially negative effects of false positives

Pre-Assessment

Step 2: CONTEXT establishment and CONCERN assessment

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

Concerns refer to perceptions that people associate with risks. These perceptions give rise to expectations, worries or requests for further actions. Concerns can be explored for example by surveys, focus groups, systematic observations, qualitative interviews, and similar methods, aimed at providing sound insights and a comprehensive diagnosis of concerns, expectations and worries that individuals, groups or different cultures may associate with the hazard or the cause of the emerging real or perceived threats/hazard. The evidence coming from all scientific disciplines involved (e.g. engineering, social sciences, etc.); analysis should be submitted to the same kind of methodological critical review.

Although all groups in society have the right to raise concerns, the question of the degree to which these concerns are met or violated by risk-bearing activities or events should primarily be answered by those who have the knowledge, skills and/or the experience to measure or estimate the strength of relationships between cause (or dose) and effect. Intuition or layman's feelings about emerging risks cannot be treated in the same way as the assessment based for example on systematic observations, empirical data collection and rigorous modeling, but it also should not be completely dismissed, as they in themselves can be a source of early

Step 2: CONTEXT establishment and CONCERN assessment

warnings. The inclusiveness (of all stakeholders) is, therefore, an important part of this step providing the decision makers with relevant knowledge regarding stakeholders' expectations and the potential societal risks that might threaten sustainable development.

— **Inputs:** output from Step 1

— **Typical actions:** analyze related context information (e.g. semantic analysis software)

— **Outputs:** report describing the context and containing concerns, expectations and worries of individuals/groups possibly affected by the risk

— **Possible pitfalls:** ignoring some stakeholders; insensitive to strong stakeholder bias

Step 3: IDENTIFICATION of emerging RISK SCENARIOS

The identification step (i.e. establishing cause-effect link) and estimation (determining the strength of the cause-effect link) for emerging risks needs to be performed for hazards and risks separately. The estimation depends on an exposure and/or vulnerability assessment. Exposure refers to the contact of the hazardous agent with the target (individuals, ecosystems, buildings, etc.). Vulnerability describes the various degrees of the target to experience harm or damage as a result of the exposure. In many cases it is suitable to combine hazard and risk estimates in scenarios that allow changing parameters and including different sets of context constraints.

In developing and exploring scenarios for emerging risk, the widening scope of effects for using risk assessment is essential as well as addressing risk at a more aggregated and integrated level. For emerging risks related to new technologies (e.g. integrating risk assessment in a comprehensive technology assessment or option appraisal so that the practical value of its information can be phased into the decision making process at the needed time and that its inherent limitations can be compensated through additional methods of data collection) interpretation is practically unavoidable for a reliable assessment. Only such choice and analysis of scenarios can lead to a realistically assessed and properly managed emerging risk related to new technologies. This is of particular importance for the development of more forgiving technologies that should tolerate errors and provide sufficient time for initiating counteractions. This also enhances the sustainable ERMF and transparency of the risk maturation process supported by the corroborated evidence about both scenarios and early warnings.

— **Inputs:** all significant causes and consequences, short information provided from Step 1

— **Typical actions:** defining an Emerging Risk Issue or a Risk Story

— **Outputs:** comprehensive structured list of risks and possible scenarios based on screened events

— **Possible pitfalls:** wrongly interpreted scenarios of identified risk/hazard due to lack of information or bias

Step 4: PRE-ASSESSMENT of selected risks scenarios (screening)

According to the IRGC, *The purpose of the pre-assessment phase is to capture both the variety of issues that stakeholders and society may associate with a certain risk as well as existing indicators, routines, and conventions that may prematurely narrow down, or act as a filter for, what is going to be addressed as risk. What counts as a risk may be different for different groups of actors. The first step of pre-assessment, risk framing, therefore places particular importance on the need for all interested parties to share a common understanding of the risk issue(s) being addressed or, otherwise, to raise awareness amongst those parties of the differences in what is perceived as a risk*

Pre-assessment clarifies various perspectives on an emerging risk, defines the issue to be looked at and forms the baseline for how the risk is to be assessed and managed. Essentially, it captures and brings to the open both the issues that stakeholders and society may associate with that risk (and the related opportunities), and 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. Pre-assessment needs to

Step 4: PRE-ASSESSMENT of selected risks scenarios (screening)
identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified. Practically, the main issues to look at in the phase of pre-assessment are for example various dimensions of the risk, the limits of its evaluations, real need to act, stakeholders and their framing of the problem, established scientific/analytical tools and methods that can be used to assess the risks, current legal/regulatory requirements, the organizational capabilities of the relevant stakeholders including organizations, businesses and people involved. — **Input(s):** context information and concerns from Step 2 and comprehensive structured list of risks and possible scenarios from Step 3 — **Typical action(s):** issuing a Risk Spark – prioritized and filtered notions/ including scenarios from Step 3 — **Output(s):** pre-assed risk scenario(s) to be further analyzed using appropriate (more specific) methods for identified risk(s) — **Possible pitfalls:** pre-assessment resulting either in false negative or false positive; screening out essential scenarios; keeping inessential scenarios for further analyses
Appraisal/Assessment
Step 5: Emerging Risk APPRAISAL/ASSESSMENT/ANALYSIS
In the risk appraisal phase the knowledge base for the decision on whether or not a risk should be taken and, if so, how the risk can possibly be reduced or contained should be created. The risk appraisal phase comprises, therefore, both the scientific risk assessment – a conventional assessment of the risk's factual, physical and measurable characteristics including the likelihood of it happening, and the perceived risk by all stakeholders, individuals, groups, etc. In the scientific risk assessment the issues like potential damages or adverse effects, ubiquitousness, reversibility or persistence of damage, and cause-effect relationships should be explored and possibly quantified. On the benefit side, the primary and secondary benefits, opportunities and potential related adverse effects should be estimated, too. The perception aspects related to public concerns, social response to the risk, possibilities of political mobilization or potential conflict, role of institutions, governance structures and/or media should be examined. The possibility to face controversial responses arising from differences in stakeholder objectives and values or from inequities in the distribution of benefits and risks should be included as well. The analysis of risk governance models revealed the importance of considering the whole life cycle of a product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks. — **Inputs:** list of all pre-assessed risk scenarios with all available information regarding each respective scenario — **Typical actions:** use of all appropriate risk assessment/analysis tool(s) available — **Outputs:** fully assessed set of risk scenarios with potential damages or adverse effects that are explored and quantified — **Possible pitfalls:** possible scarcity of scientific data; low confidence level in the data, the model or the interpretation of it; lack of attention to interdependencies and interactions between actors and between actors and the risk target; inadequate attention given to the concerns of different stakeholders groups.
Step 6: Emerging Risk CHARACTERIZATION, Risk categorization/classification
Inclusion of this element is intended to ensure that the evidence based on scientific facts is collected and combined with a thorough understanding of values when making the judgment of whether or not a risk is

Step 6: Emerging Risk CHARACTERIZATION, Risk categorization/classification
acceptable (risk reduction is considered unnecessary), tolerable (to be pursued because of its benefits and if subject to appropriate risk reduction measures) or, in extreme cases, intolerable and, if so, to be avoided. Practically, the issues like the societal, economic and environmental benefits, impacts on quality of life, ethical issues to consider, possibilities of substitution, choice of a particular technology impacts, possible options for risk compensation, or reduction, commitments or other reasons for wanting a particular outcome of the overall risk governance process, should be taken into account. Risk characterization, thus, allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization/classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance). Risks may also be characterized as simple, complex, uncertain or ambiguous. — **Inputs:** all relevant information regarding assessed risk scenarios — **Typical actions:** based on scientific facts and values characterize risk as simple, complex, uncertain or ambiguous; assign proposed color codes for scoring emerging risk — **Outputs:** fully characterized risk scenario; thorough understanding of values **Possible pitfalls:** underestimating impact of values; characterization/classification based on too few experts
Step 7: Evaluation of emerging risk TOLERABILITY & ACCEPTABILITY
The most controversial phase of handling emerging risks can be reaching a consensus about its acceptability and/or tolerability. According to IRGC, a risk deemed ‘acceptable’ is usually limited in terms of negative consequences so that it is taken on without risk reduction or mitigation measures being envisaged. A risk deemed ‘tolerable’ requires taking active measures for keeping the risk under control, applying the ALARP principle. Tolerable risks will generally be associated to undertaking an activity – which is considered worthwhile for the value added or benefit it provides. The main effort in this part of the process is usually focused on gathering and compiling the necessary knowledge which, in the case of tolerability, must additionally support an initial understanding of required risk reduction and mitigation measures. These issues usually include questions such as the choice of technology, societal needs requiring a given risk agent to be present and the potential for substitution as well as for compensation. For a systematic analysis of the emerging risks it is advisable to focus on tolerable risks and those where tolerability is disputed; other cases are fairly easy to deal with. In the case of intolerable risks – and often in the case of tolerable but highly disputed risks – risk managers should opt for prevention strategies as a means to replace the hazardous activity with another activity leading to identical and similar benefits. One should first make sure, however, that the replacement does not introduce more risks or more uncertainties than the agent that it replaces. Additional risk reduction or insurance for covering potential but acceptable losses can be an option to consider. If risks are classified as tolerable, or if there is dispute as to whether they are tolerable or acceptable, risk management needs to design and implement actions that make these risks acceptable over time. Should this not be feasible then major effort should be undertaken to bring these risks closer to being acceptable. Risk management aided by communication, needs at least to convey a credible message to make these efforts visible and understood by stakeholders. In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions. Specific or complementary approaches/rules should be regularly considered in this phase. — **Inputs:** level of risk found in risk analysis and context part of the process; legal, regulatory and other requirements — **Typical actions:** decide whether risks are acceptable, tolerable or intolerable; (find and use appropriate KPIs)

Step 7: Evaluation of emerging risk TOLERABILITY & ACCEPTABILITY
— **Outputs:** clear information whether risk is acceptable/tolerable or not; if not what are the proposed measures to be undertaken in order for risk to become acceptable/tolerable — **Possible pitfalls:** not stating clearly acceptance for whom; insufficient search for possible risk reducing measures
Step 8: MANAGEMENT & DECISION (TREATMENT)
All tolerable emerging risks need appropriate and adequate risk management. Risk management involves the design and implementation of the actions and remedies required to avoid, reduce, transfer or retain the risks. Based on the development of a range of options and a consideration of the most appropriate of them, risk management decisions are taken and put into practice. The emerging risk management includes the generation, assessment, evaluation and selection of appropriate risk reduction options as well as implementing the selected measures, monitoring their effectiveness and reviewing the decision if necessary. Questions such as should be adressed: Who is, or who should be, responsible for decisions within the context of the risk and its management?; Have they accepted this responsibility?; What management options could be chosen (technological, regulatory, institutional, educational, compensation, etc.)?; Is there an appropriate level of international cooperation and harmonization for global or transboundary risks?; What are the secondary impacts of particular risk reduction options?; What potential trade-offs between risks, benefits and risk reduction measures may arise?; What measures are needed to ensure effectiveness in the long term?; What compliance, enforcement, monitoring, adaptive management plans, etc. are needed? The approaches applied in emerging risk management should: — integrate both qualitative and quantitative data; — combine different type of criteria; — carefully address compensation; — consider variations/alternatives in risk scenarios; — treat uncertainties; — help make robust decisions. — **Inputs:** evaluation of acceptability and tolerability; options on how to tackle emerging risk issue based on information for assessed risk scenario(s) — **Typical actions:** decisions on risk mitigation measures — **Outputs:** clearly defined actions to be implemented in order to successfully tackle emerging risk issue — **Possible pitfalls:** insufficient search for possible options; delayed or omitted implementation (due to e.g. unclear responsibilities)
Continuous activities
Step 9: Emerging risk COMMUNICATION & CONSULTATION
Successful and effective communication is an increasingly important element of managing emerging risks, comparably even more important than the communication in the process of management of conventional risks. It covers the issues such as e.g. how the expert assessments could be communicated to the public so that the possible gap between public perceptions and expert judgment could be best bridged. Generally, due to increased uncertainty, the emerging risk communication needs even more probabilistic thinking and this aspect can be improved for example by application of risk comparisons. Furthermore, the persuasion and efforts to align stakeholders' stances and understanding better their behavioral patterns are often in the heart of the communication process. The above approaches usually involve one-way communication which often reaches its limits in the area of emerging risks. That's where the modern approaches stress the importance of the two-way communication process in which the main objective of communication effort should be building mutual trust by responding to the concerns of the stakeholders. Finally, the ultimate goal of emerging risk communication must be focused on the stakeholders' understanding

Step 9: Emerging risk COMMUNICATION & CONSULTATION

of the risk management process and its results and help them arrive at a balanced judgment and set of decision that reflects the factual evidence about the matter at hand in relation to their own interests and values. The process itself must be seen as a fair process for all stakeholders, no matter their position. Good practices in risk communication can significantly help stakeholders to make informed choices about matters of concern to them and to create mutual trust. The main particular aspects of emerging risks requiring special attention are those increasing uncertainty, ambiguities and stochastic effects, complex distinction between risk and hazard, often extremely dreadful consequences, very long-term effects, interdependency and synergistic effects with other factors, increased sensitivity to inter-cultural differences.

In practical terms, the emerging risk communication has to be a means to ensure (through transparent risk framing, risk appraisal and risk management) definition and acceptance of the common position towards the emerging risks and trust in policies and measures proposed by the overall risk governance system. Consequently, communication is essential for achieving engagement of the stakeholders, which can be achieved only if these are informed and their interrelationships with all other stakeholders are based on trust.

— **Inputs:** plans for communication, preferably developed in early stage of ERMF; output from all other steps

— **Typical actions:** social dialogue, targeted communication

— **Outputs:** continuous exchange of truthful, relevant, accurate and understandable information with stakeholders, taking into account confidential and personal integrity aspects, to obtain necessary input to all steps of the ERMF

— **Possible pitfalls:** only some groups, not all, represented in the communication process

Step 10: Emerging risk MONITORING, REVIEW & CONTINUOUS IMPROVEMENT

As pointed out by ISO 31000 any risk management continually senses and responds to change. As external and internal events occur, context and knowledge change, monitoring and review of risks take place, new risks emerge, some change, and others disappear. Consequently, monitoring, review and continuous improvement are of increased importance in particular for emerging risks. In this process the effective and continues effort should be devoted to measuring the performance of risk management against indicators (which should be periodically reviewed for appropriateness). In addition, one should periodically review whether the risk management framework, policy and plan are still appropriate, given the possible change of external and internal context. The above also includes reporting and review of the effectiveness of ERMF. Both monitoring and review should be a planned part of ERMF implementation and can be either periodic or ad hoc, with the purpose of obtaining further information to improve emerging risk assessment and management. Monitoring should include provisions for detecting changes in the external and internal context; including changes to risk criteria and the risk itself which can require revision of risk treatments and priorities, and identifying other emerging risks.

Results of the monitoring and reviews are basis for improvement of the emerging risk management framework, policy and implementation. Risk treatment itself can introduce risks. A significant risk can be the failure or ineffectiveness of the risk treatment measures. Monitoring needs to be an integral part of the risk treatment plan to give assurance that the measures are and remain effective.

— **Inputs:** all information available from every step if the ERMF and information on possible proposed changes and improvements that can be a result of communication

— **Typical actions:** continuous surveillance and periodic review

— **Outputs:** control of the risk itself; control of changes to conditions affecting the risk; and control of appropriateness of the ERMF

— **Possible pitfalls:** not being vigilant and sensitive to changes, particularly changes in external and internal context; insufficient monitoring of potential negative effects of risk treatment options implemented

7.3 Comparing the iNTeg-Risk ERMF with general risk management frameworks

The iNTeg-Risk ERMF is heavily influenced by the IRGC risk governance framework and the ISO 31000 risk management process. The main difference is that some issues that are included in other steps in IRGC and/or ISO 31000 have been explicitly addressed as a separate step in the iNTeg-Risk ERMF, and a particular focus on capturing the earliest signs of an emerging risk.

To compare the IRGC risk governance framework and the ISO 31000 risk management process with the iNTeg-Risk ERMF, Figure 9 provides an IRGC and ISO 31000 representation of the ERMF.

Why should the iNTeg-Risk ERMF be preferred to the IRGC risk governance framework, the ISO 31000 risk management process or any other general risk management frameworks or processes? There are two principal reasons for this; first, the iNTeg-Risk ERMF has been established in an eclectic manner, taking the best from existing frameworks and processes, and second, the focus is on the hitherto unknown, i.e. on new and emerging risks. This is illustrated in Figure 8.

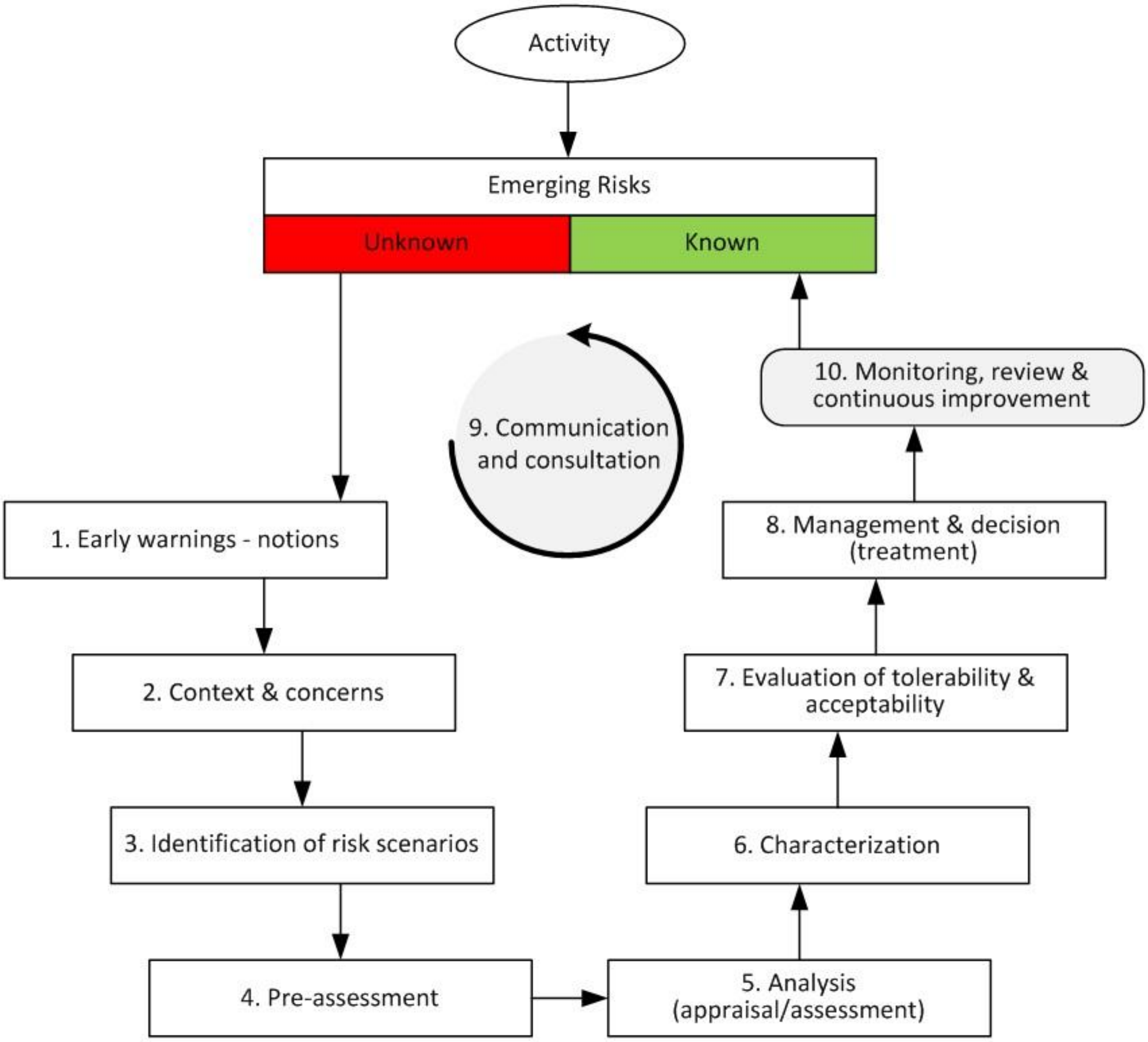

Figure 8 — Main distinctive characteristics of the ERMF process

The most distinctive difference is the active search for an extreme vigilance for any signs of an emerging risk, represented by Step 1 Early warnings – notions.

The 10 step process of ERMF has a particular advantage when dealing with unknown risks, providing the continuous way from Step 1 to Step 10 (Step 1 recognizes emerging risk as early as possible, in a systematic manner, whereas in Step 10 the emerging risks are monitored and followed-up in an optimized manner).

Also for Step 10, as for Step 1, there is an aim to recognize potential dangers as early as possible to avoid accidents. Thus, there are certain similarities between Step 1 and Step 10. Early warning (indicators) is a key issue in both steps.

The other main distinctions from general risk management within industrial safety are related to Steps 2 and 5. In the context description emphasis is put on identifying/knowing the new risk influencing factors (triggers, factors and drivers) and to follow-up these factors in subsequent steps (see Annex F). Concern identification (Step 2) and assessment (Step 5) play a major role due to the potential controversy of emerging risks. This includes a systematic interlinking between the stakeholders and their main concerns (hazards/ vulnerabilities/fears) to ensure that the relevant issues are included in the assessments.

A final characteristic of the ERMF process is related to step 3 where methods for systematic scenario identification have been developed, which also captures unknown-known scenarios (i.e. they have occurred somewhere, but have not been recognized for the specific activity in question). This ensures a better identification of the most critical emerging risks.

The elements of ERMF can be represented both in a way similar to the one in ISO 31000 and in the IRGC-like way, as shown in Figure 9.

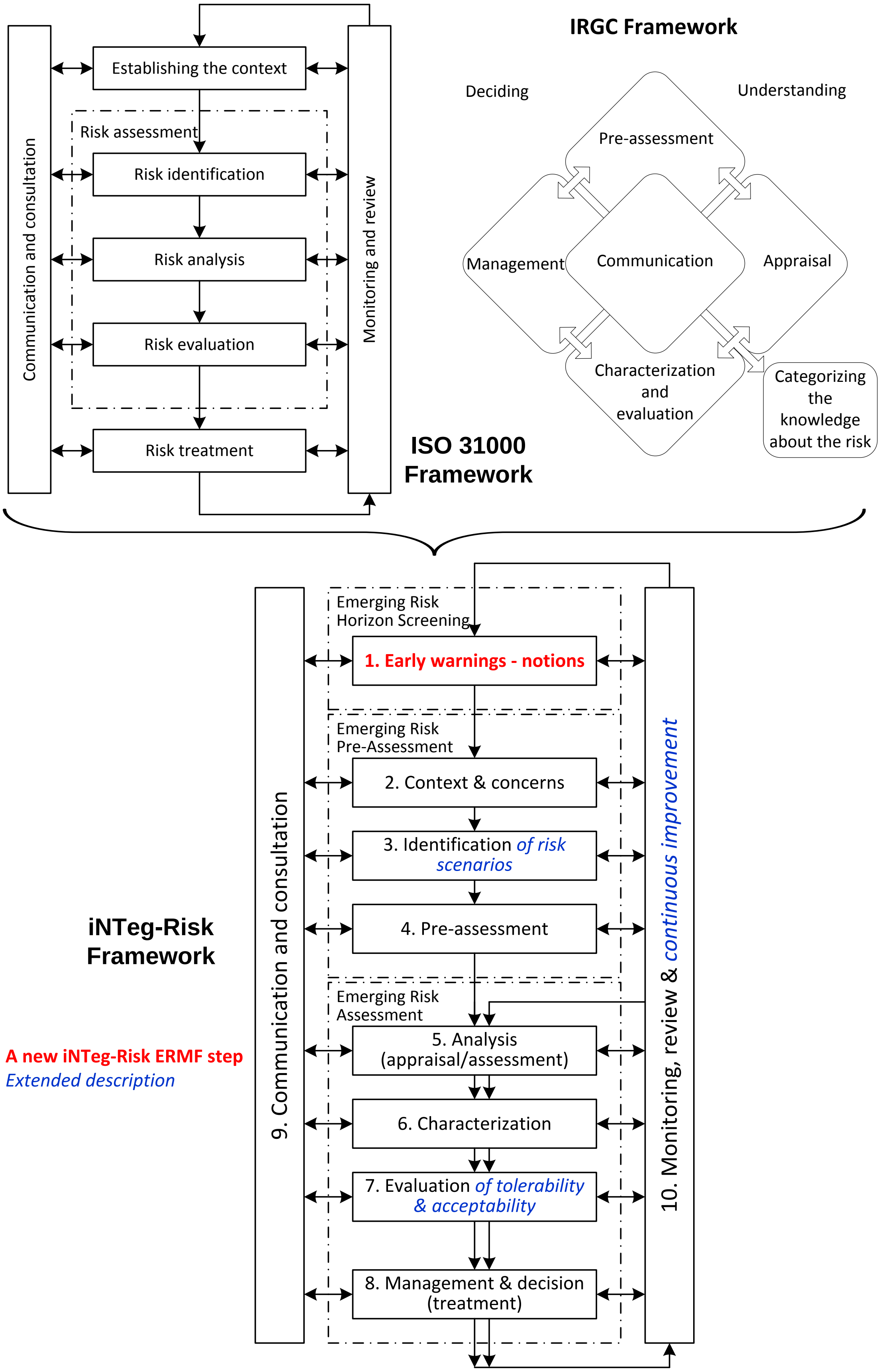

Figure 9 — Using ISO 31000 and IRGC frameworks as a base for creating iNTeg-Risk ERMF

7.4 Details on implementing the ERMF

Details on the implementation of the ERMF that may apply in certain contexts are illustrated in Figure 10. Not all the 10 steps of the ERMF are explicitly shown in this figure, but the steps are indicated in the right part of Figure 11.

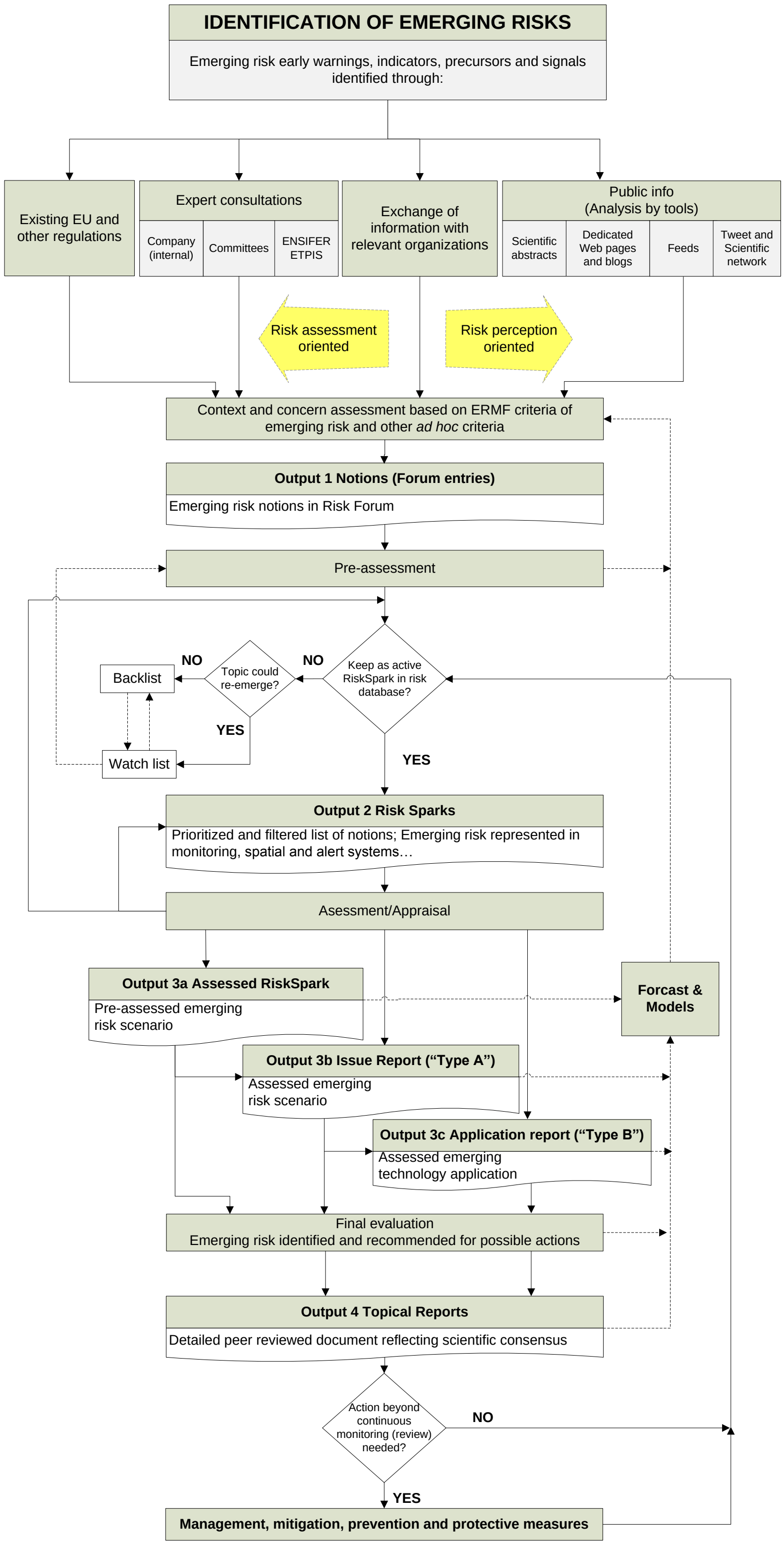

Figure 10 — Details on the implementation of the ERMF applicable in certain contexts

Examples of process for management of emerging risks are illustrated in Figure 11.

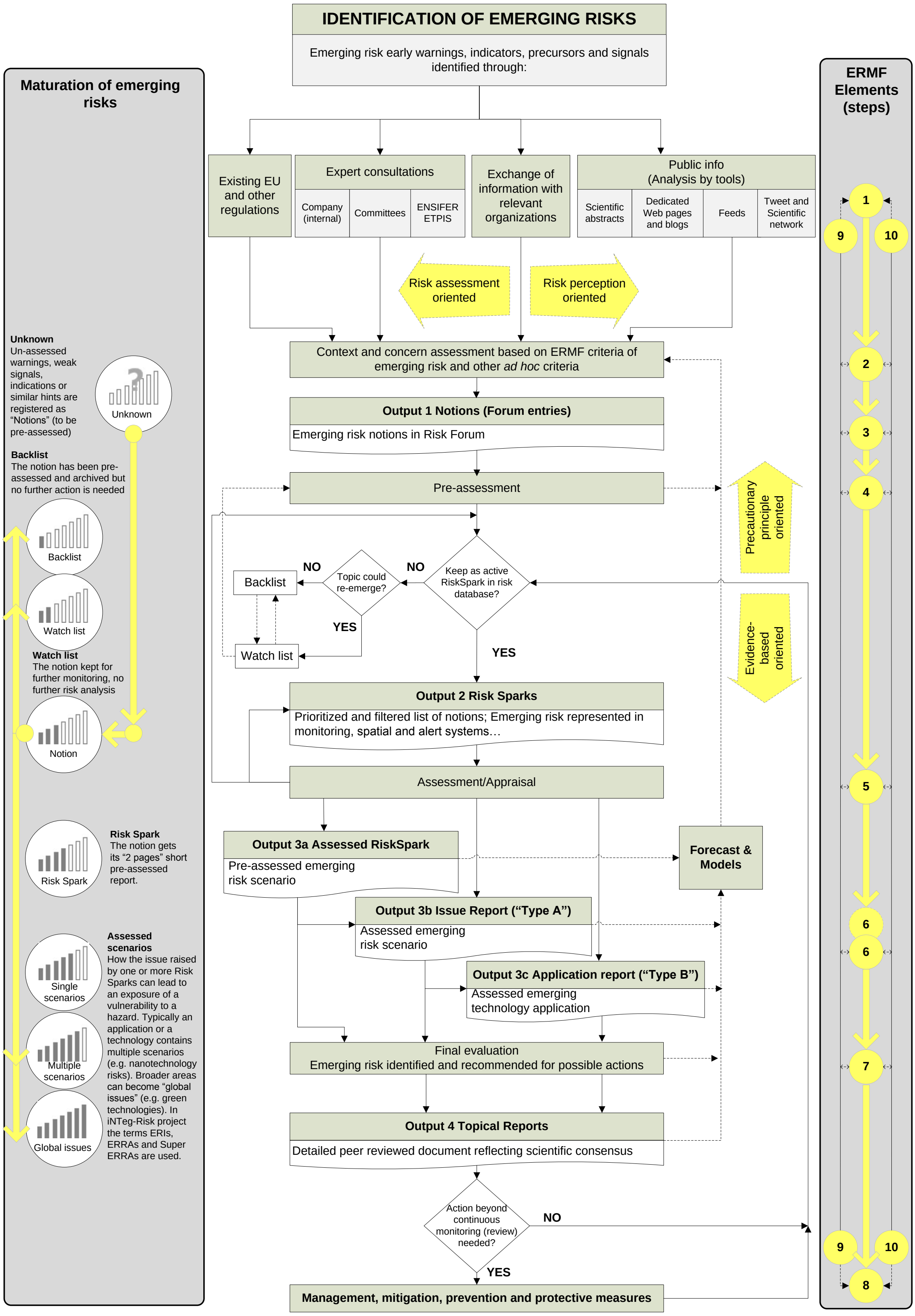

Figure 11 — Example of process for management of emerging risks based on ERMF and illustration of the maturation of emerging risks

8 Concluding remarks

ERMF proposed in this CEN Workshop Agreement allows analyzing aspects of emerging risks in a more consistent way. In particular, ERMF can significantly improve the process of dealing with multiple and interdependent risks by preventing the possible institutional blindness for ancillary risks, having a dedicated concept of dealing with such risks and by having a dedicated infrastructure for better recognition of ancillary risks. ERMF proposes a concept of dealing with the trade-offs of emerging risks both in space and time: mapping risks in geospatial systems and looking at them in time over the lifecycle of the technology, including the aspect of risk maturity, from early notion and indications up to a fully developed system of risk governance covering all technical, human, regulatory and communication aspects. Practical application of ERMF should involve stakeholders from all levels and sectors (see Table 7) and rely on public-private partnership and value chain principles.

Table 7 — Profile of involvement of the stakeholders at different levels of governance for a hypothetical example of an emerging risk (the colors indicate the level of concern; concern primarily at national level)

Actors		Level of concern and/or governance						
		Single site	Multiple sites	Munici-pality	Regional	State/ national	EU or other supra-national	Global
Private Sector	Manufacturers	Low		Medium		High		
	Suppliers		Low		Medium	High		
	Investors, Banks, Insurance			Medium	Low	Low		
	Retailers			Low	Medium	High		
	Work force			Low	High			
	Consumers					High	Low	
	Disposal/ recycling actors				Medium	High	Low	Low
Public sector	Law-makers					High	High	
	Executive authorities, enforcement			High	High	High		
	NGOs				Medium	High	High	
	Other interest groups		High	Medium	Medium			
	Science, R&D, academia					Low	Low	High
	General public	Low	Low	High	Medium			
	Media	Medium	High	Medium				

Legend		
Low Concern	Medium Concern	High Concern

Annex A
(informative)

Application case for new technologies

A.1 Introduction

This part of the CWA deals with the management of emerging risks related to new technologies. It covers the development and the intensified application of new and advanced technologies, all of which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

One example of intensified application of a new technology is unconventional gas (consist of hydraulic fracturing, also known as fracking – mainly linked to exploitation of shale gas) which will be used as an example throughout this Annex. The example is introduced in Section A.2.2 and background information is provided in Section A.5.

Solutions, reference documents, methods and tools specifically applicable to the handling of emerging risks in new technologies are referred to in the relevant process steps of the ERMF in Section A.3.

The process consists of the following 10 steps arranged in 4 groups:

Horizon Screening:

— Step 1: Early warnings – notions.

Pre-Assessment:

— Step 2: Context and concern;

— Step 3: Identification of risk scenarios;

— Step 4: Pre-assessment.

Appraisal/Assessment:

— Step 5: Analysis;

— Step 6: Characterization;

— Step 7: Evaluation of tolerability and acceptability;

— Step 8: Management and decision (treatment).

Continuous Activities:

— Step 9: Communication and consultation;

— Step 10: Monitoring, review and continuous improvement.

The purpose of this process is to improve the ability of the EU industry, society and authorities to identify, monitor and manage emerging risks related to new technologies. By conducting a structured process to deal with potential emerging risks it is possible to limit and manage these risks, and avoid accidents. It will also improve chances of market success of European innovation and new technologies developed in the EU.

The document focuses specifically on new and emerging risks and is limited to industrial safety.

A.2 Specific topic and example case

A.2.1 General remarks/overview related to the specific topic

For new technology related (emerging) risks, where, eager to reduce the main target risks and sell the technology, the decision makers often fail to explore the full set of possible outcomes. In societies as risk-averse as Europe's, lack of confidence in the ability of industry and authorities to identify and manage emerging risks may prolong time to market or prevent success of new technologies. If the technology is concerned by both EU market policy and the national safety policies, possible conflict of policies may arise, and it is often worsened due to the lack of commonly accepted approaches to management of risks (different approaches, fragmentation over countries, branches, sectors, etc.). The EU therefore urgently needs a unified, consensual, validated and operational framework that comprises principles, guidelines and tools for managing multiple risks related to new technologies, readily available to all stakeholders. The framework should help to

— understand well the interdependencies among multiple risks, and

— properly manage these multiple risks, not one-by-one, but simultaneously, in an optimized manner.

An example which will be used throughout this part of the CWA is what in iNTeg-Risk project has been adopted by/named Unconventional Gas.

See more about the technology and public, institutional and scientific interest in these topics under A.5.

A.2.2 Introducing the example case - Unconventional gas

A.2.2.1 Challenges

Issues related to unconventional gas can pose significant risks to environment, facilities (assets), workers and business continuity. On one side there is large economic benefit and opportunity to use less polluting fuels overall and on the other side, possibility of large environmental pollution, mainly considered pollution of water aquifers (drinking water reservoirs).

A.2.2.2 Stakeholders

Main responsible stakeholders in the case of unconventional gas are the authorities providing license e.g. for exploitation of the shale gas reserves, land use for drilling/using wells. These are also the stakeholders responsible for introducing/including an adequate emerging risk management process. Other stakeholders are various branches of government either on central, regional or local level, NGOs, scientific community, public, etc.

A.2.2.3 Concerns

A major concern with respect to unconventional gas is a possible major pollution of ground or underground water supply during the production/extraction process of gas or a situation which is even more difficult to control (release of large amounts of any type of unconventional gas) that has not been experienced or foreseen so far (including all possible/hypothetical consequences).

Background information to the example is provided in A.5.

A.3 Procedure for management of emerging risks

A.3.1 Horizon screening

A.3.1.1 Step1: Early warnings – notions

Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic, etc.).

The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of risk maturation under control (see Table 5).

New or emerging risks related to the introduction of new technologies or use of existing technologies in new contexts, should be actively searched and watched for. The warnings should be properly assessed in order to keep the process of risk maturation under control in a systematic way which can enable stakeholders quick and easy access to the data.

EXAMPLE In addition, if a technology is new and no or just few historical data about potential risks and occurred accidents is available, companies developing and using the technology and authorities providing the permission to do so, have to watch for notions of potential risk scenarios related to the new technology and discuss these with experts on specific platforms dedicated to such activities. iNTeg-Risk RiskEars Forum is offering such a platform with highly sophisticated user management and supported by mapping of relevant experts for different areas. Figure A.1 is giving an example, in this case on potential pollution of underground water due to exploitation of shale gas through fracking processes, of how such a notion is registered (for more information about RiskEars and RiskEars Forum see Annex G).

Figure A.1 — Registration of warning/notion in iNTeg-Risk RiskEars

Apart from the above described approaches towards common solutions for unknown problems and information exchange among experts using forums, a screening of scientific publications, news and social media with respect to the topic is recommended in order to acquire and monitor early warnings not only from scientists, but also from broader public for gathering knowledge about perception and acceptance of a new technology. Negative perception can lead to non-acceptance of the technology and can highly influence its market success. Figure A.2 is showing RiskTweet, being part of the iNTeg-Risk 1StopShop which is monitoring tweets posted in Twitter, as one of the indicators showing how much a topic is up-to-date in community, and provides information about the amount of tweets on the topic for a given day/month as well as geographical and other information about the tweets, including possible links/cross-reference to other media. This enables a decision maker to see if and, possibly, why the topic of fracking was a hot topic for users of this Social Media network. The yellow and the red line are customizable alert and alarm levels that can be introduced for creating automatic notifications (more information can be found in Annex G).

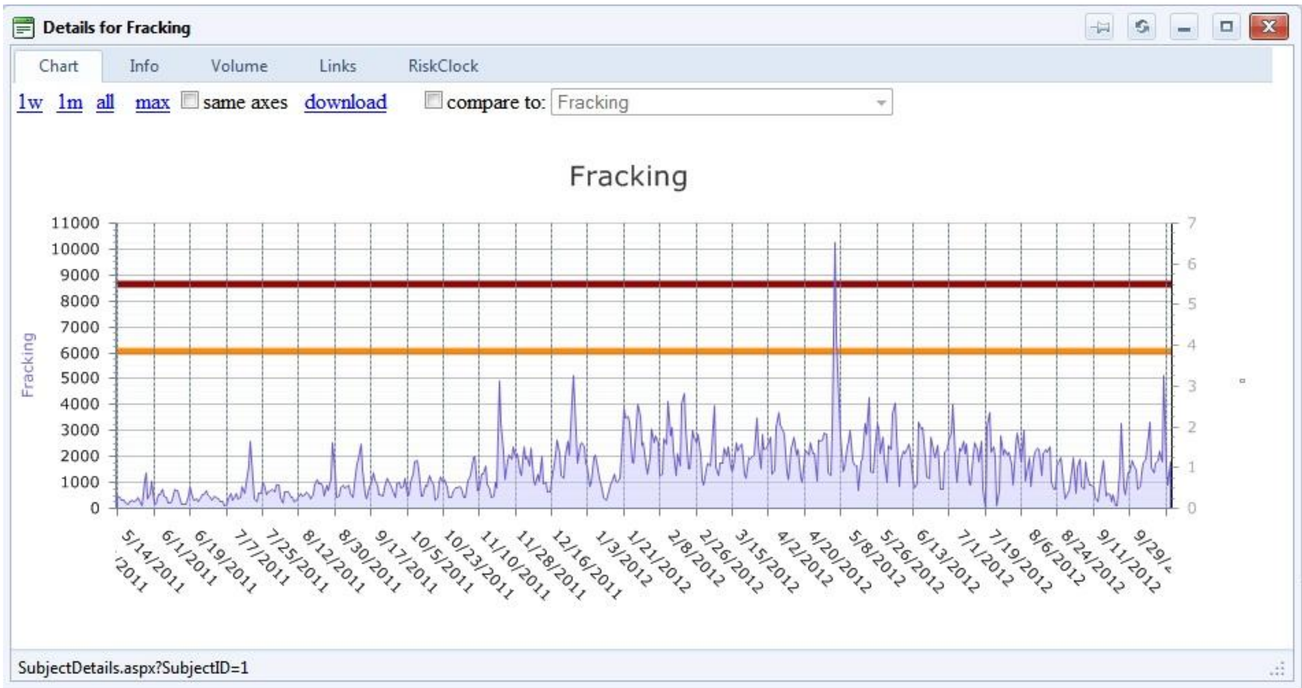

Figure A.2 — RiskTweet, with collected information on tweets related to fracking from Twitter service

A.3.2 Pre-Assessment

A.3.2.1 Step 2: Context and concern

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development. (see Table 5).

In short, this step represents the attempt to map the framing/understanding of different stakeholders regarding new emerging risks related to new technologies. This step is closely related to step 9 (Communication and Consultation). Step 2 results in an effort to resolve all misunderstandings with respect to the emerging risk management process. Stakeholder's engagement in this phase of ERMF process should be focused to actions like clarification of stakeholder's initial framing of the issue; helping to define what conventions and conditions apply for issue at stake, regulative, directives, laws and similar.

Concern assessment can be supported by similar tools as the ones described under Section A.3.1.1, but stakeholder dialogues, interviews and surveys are certainly needed, too.

EXAMPLE As acceptance of the technology by the stakeholders is a crucial point for the introduction of new technologies, modeling of the acceptance with specific agent parameter might be useful in addition. Therefore, a tool for modeling the acceptance of new technologies developed in iNTeg-Risk project is briefly described on the example of fracking as a part of unconventional gas.

Major concern about unconventional gas issue is pollution of surface or underground water during the fracking process, production/distribution/use of gas. However, for the fracking process alone, the public is split among those that support fracking as a new way to satisfy their need for new sources of relatively cheap energy and those strongly opposed due to the possible large scale contamination of environment and health issues.

Reasoning leading to acceptance and non-acceptance of a new technology gathered from e.g. stakeholder dialogues, can be used as an input for modeling of the new technologies acceptance (NTA) for different agents. Especially in development and introduction phase modeling tool can provide decision makers with valuable information about correctives to be implemented in order to reach highest possible level of acceptance.

Figure A 3 shows perception in context to benefits and risk gathered from the RiskTweet tool to be used as an input in NTA model.

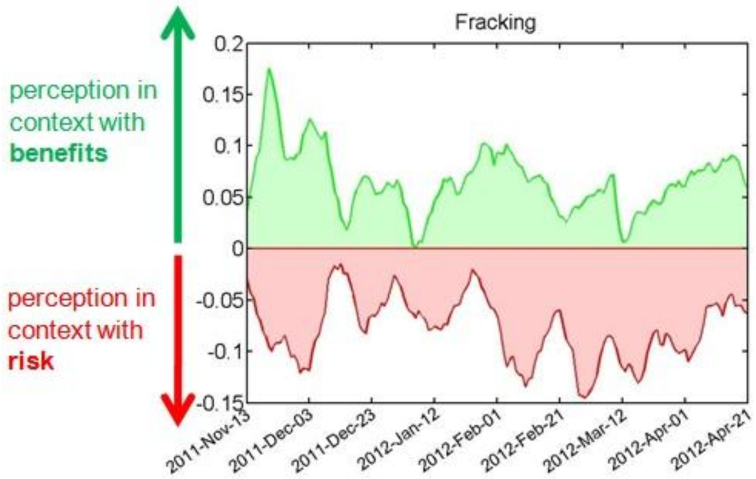

Figure A.3 — Risk/benefit perception for fracking

Figure A.4 is giving an example of the (non-)acceptance modeling for fracking in Germany and Figure A.5 model for Basque country.

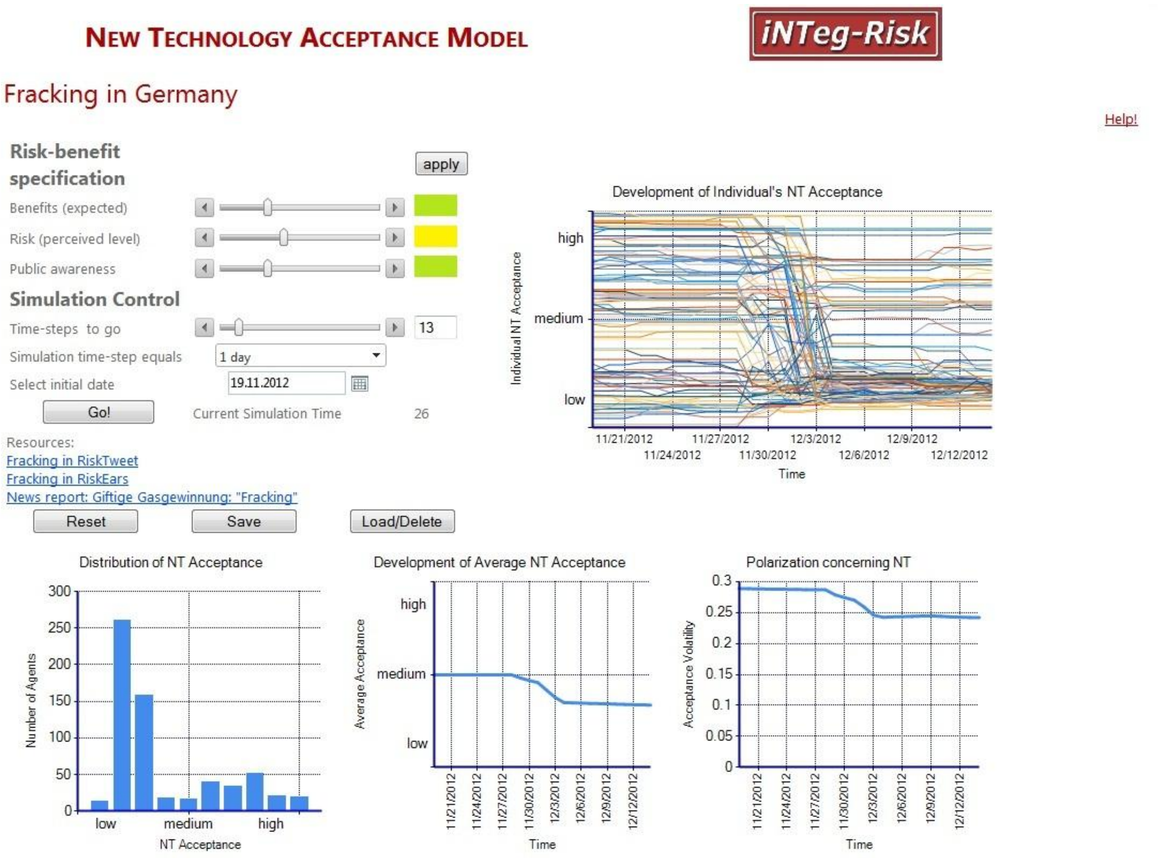

Figure A.4 — Example of Step 3: NTA model for fracking in case of (Lack of acceptance in) Germany (linked to media reports)

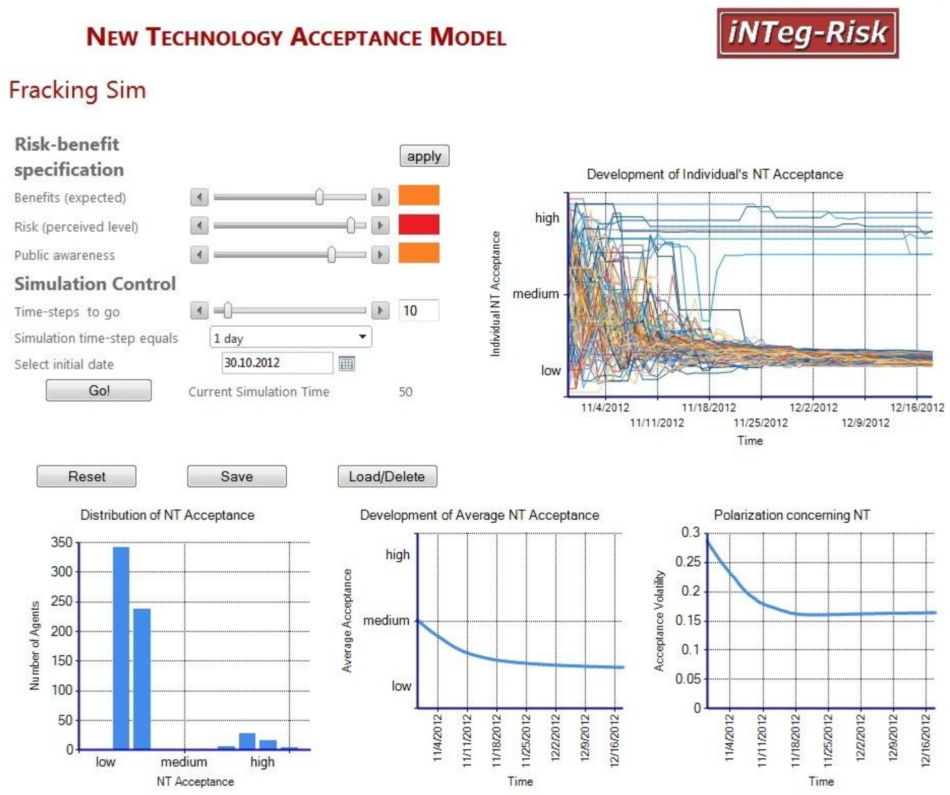

Figure A.5 — Example of Step 3: NTA model for fracking case depicting large public dissatisfaction that can be compared to current problem in Basque Country [21]12)

A.3.2.2 Step 3: Identification of risk scenarios

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings (see Table 5).

All possible emerging risk scenarios, the ones that have already been experienced and possible (plausible worst case) scenarios identified in early warning stage should be listed. Step 3 results in a list of possible scenarios that should be considered through the following ERMF process. This step of ERMF process should be carried out by an expert on the specific issues, e.g. (senior) risk assessors. Inputs/Information from affected stakeholders should also be sought in respect to possible approaches how to tackle the issue.

EXAMPLE A tool supporting this step is RiskEars, more precisely pre-assessment part of Risk Spark(s) and Risk Story, where a scenario is being described and assessed.

Figure A.6 is showing a Risk Story from RiskEars for the case of fracking related to the contamination of underground water.

12) NTA model is ABM application. The greatest expected benefit of fracking (0 to 1 scale) is cheaper gas so it was assigned value of high (0.7/orange). The level of perceived risk was set very high (0.9/red) because the information source was indicating that there were lots of people opposing to this process in Basque Country due to the fear of pollution of water aquifer. The level of public awareness (quite high!) was set to high (0.75/orange). The simulation runs 50 cycles, each representing 1 week. End result/diagram shows that by the May 2013 the most of the agents are going to be strongly opposed to process, which can be correlated, so far, to the real condition.

In case of unconventional gas, there are many newspaper articles already published (Herald Tribune, The Economist, The Financial Times, Der Spiegel etc.) provide a good review of publicly discussed scenarios. These scenarios are the following:

— contamination of (surface and) underground water;

— seismicity: Micro earthquakes caused by the process itself;

— uncontrolled release of gas;

— Air and soil pollution and occupational safety;

— Land use related issues and possible disruptions in community.

Following several studies and publications are providing rational, objective, fact-based assessment of the key environmental concerns. Numerous best practices need to be adopted in order to improve the overall process. Some of these studies are:

— International Gas Union: Shale Gas, the facts about the environmental concerns [42];

— Fact-based regulation for environmental protection in shale gas development, Energy Institute, University of Texas at Austin, February 2012 [41];

— Recommendations from IEA “Golden rules for a Golden Age” [29]

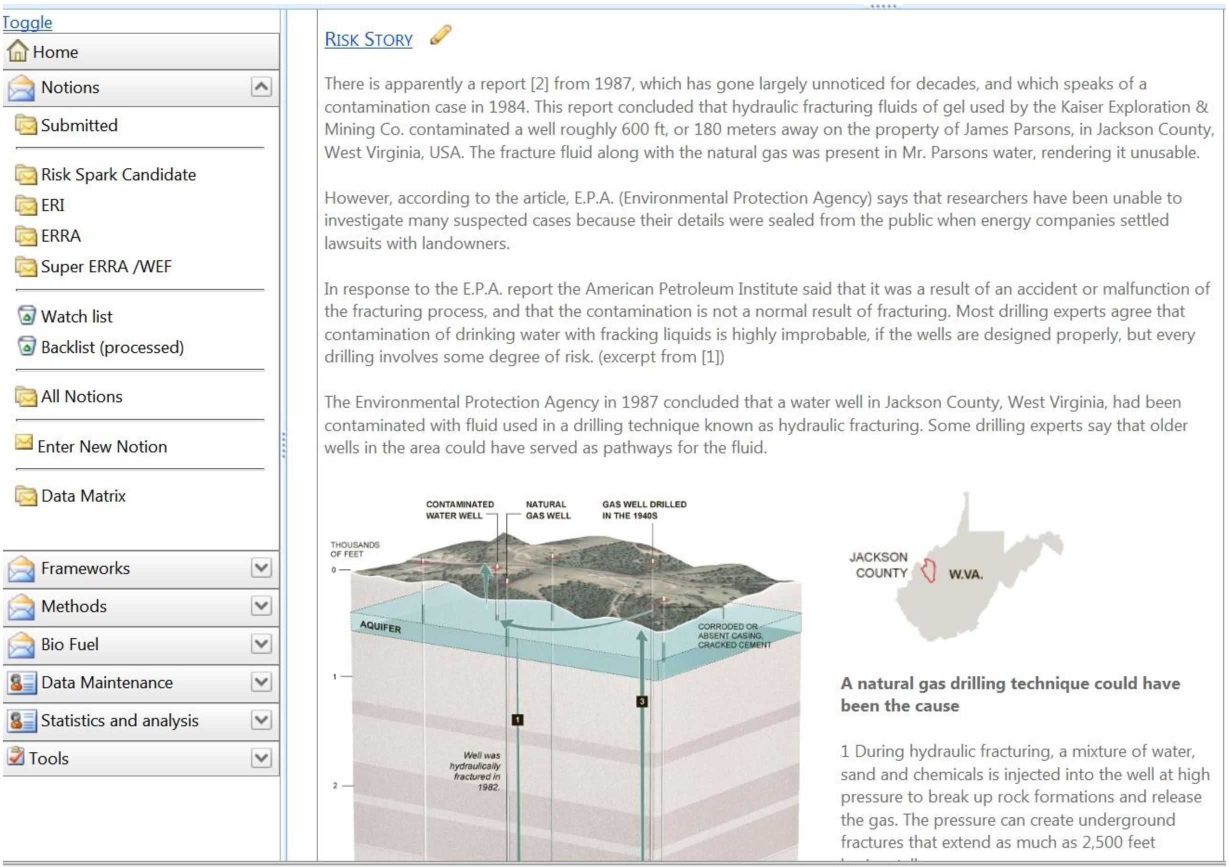

Figure A.6 — Risk Story from RiskEars (describing an emerging risk scenario) about contamination of underground water for fracking topic

A.3.2.3 Step 4: Pre-Assessment

Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified (see Table 5).

Scenarios identified in the previous step should be screened, based on the identified, described and assessed dimensions of risk. Information that is sought for the pre-assessment step should consists of advice from affected stakeholders on what assessors or decision makers are likely to encounter/expect.

EXAMPLE A tool for such pre-assessment for an emerging risk is RiskEars, which is offering the possibility to create a so called Risk Spark, which is a short wrap-up of the emerging risk issue and its consequences done by an expert in the area, serving as input for decision makers on how to deal with the risk. Same Risk Spark can, and it is encouraged to, have multiple (pre-) assessments in order to have the most objective view possible, preferably from experts in multiple scientific fields dealing with the same (type of the) problem (in this case: engineering, environmental protection, social sciences and so on).

For the particular case of unconventional gas, as previously mentioned, five potential scenarios have been identified as most relevant. For all these scenarios a pre-assessment leading to a Risk Spark should be carried out by an experts. Every expert can, and is, encouraged to provide his/her own opinion on the issue thus providing valuable information for further analysis. Figure A.7 is showing an extract from a pre-assessment done in RiskEars application.

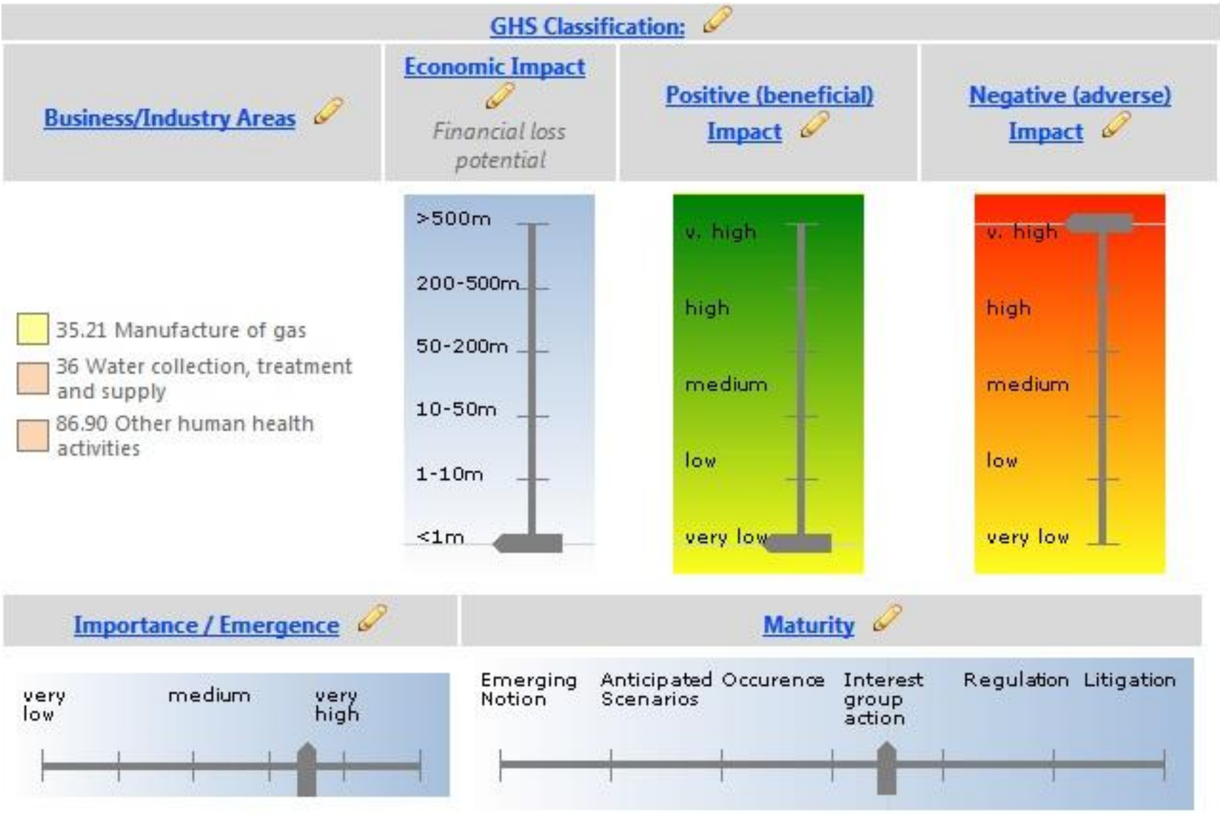

Figure A.7 — Example of Step 4: Extract from the pre-assessment; filled pre-assessment for contamination of (surface and) underground water for unconventional gas example in form of the slider setting from expert considering only environmental risks of technology

NOTE 1 unit for economic impact is monetary type/value (typical currency is € but can also be $, £, as long as it is stated in analysis),

NOTE 2 The “m” in Figure A.7 stands for million (e.g. an economic impact > 500 m means an economic impact bigger than 500 million €)

A.3.3 Appraisal/Assessment

A.3.3.1 Step 5: Analysis

The analysis of risk governance models revealed the importance of considering the whole life cycle of (a) product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks (see Table 5).

In this phase, scenarios identified in step 3 and pre-assessed in step 4 are to be considered as fully emerged issues (risks) and are to be assessed and treated accordingly. Therefore, step 5 results in a detailed assessment of the emerging risk issue, of which it sets as a basis for the following steps. Experts on the specific issue should carry out a detailed analysis, taking into account information provided in step 3 and step 4. At this point, further involvement of stakeholders e.g. government or communities possibly affected by the issue, should be considered.

Usually, most of the encountered scenarios are traditional scenarios, for which classical risk assessment tools could be applied when assessing likelihood and consequence of emerging risks. However, for most new and emerging risks related to new technologies it is very difficult and resource consuming, if not impossible, to carry out a sound and meaningful likelihood/consequence analysis. When missing historical data as input for such analysis is an issue, tools based on Semantic Clustering can be very helpful. Authorities and companies willing to introduce a new technology to the market need to learn about similar technologies, potentially similar risks related to the new technology and the respective ways to deal with them.

EXAMPLE The S-RDI tool (Semantic Distance Risk Index), for more information see Annex G, developed within iNTeg-Risk project provides graphical representations based on similarity score calculated by overlap of properties plus semantic similarity of text in order to identify similarities between well-known and well managed risk scenarios and new, emerging risk scenarios related to the to-be-introduced technology.

Developed scenarios from step 3 for unconventional gas were semantically compared with risk scenarios developed in all 17 Emerging Risk Representative industrial Applications (ERRAs) which were considered in iNTeg-Risk project.

Table A.1 — List of ERRAs considered in iNTeg-Risk project

Number	ERRA or ERRA Group Name
A	**Emerging Risks – New Technologies**
A1	CO_2 capture and sequestration, both technical risks and governance risk
A2	Insurance and re-insurance aspects of emerging risks including the security-related (HSSE) emerging risks of new technologies
A3	Emerging risks related to the industrial use of automated and un-manned surveillance of industrial infrastructure
A4	Liquid Natural Gas (LNG) regasification in sensitive areas on-shore and offshore
A5	Safety and security of underground hubs with interconnected transportation services and shopping centers
B	**Emerging Risks – New Materials And Products**
B1	Public health and medical issues related to monitoring of emerging risks in production, storage and transport of nanomaterials on industrial scale in small and medium enterprises (SMEs)
B2	Emerging risks related to advanced storage technologies for hazardous materials (including H_2)
B3	Emerging risks related to development and use of advanced engineering materials, composite materials

Number	ERRA or ERRA Group Name
C	**Emerging Risks – New Technologies & Production Networks**
C1	Challenges to safety posed by outsourcing of critical tasks – in oil, gas, petrochemical and construction industries
C2	Remote operation in environmentally sensitive areas
C3	On-line risk-monitoring and assessment of emerging risks in conventional industrial plants – monitoring of risks beyond the design/regulatory basis
C4	Atypical, one-of-the-kind major hazards/scenarios (post-Buncefield implications) and their inclusion in the normal HSSE practice
C5	Security of energy supply and related emerging risks
D	**Emerging Risks – Related Policies**
D1	Definition of KPIs for emerging risks for selected industry case studies, including CSR aspects of emerging risks
D2	Integrated approach on emerging risks related to the implementation of European safety legislation on SMEs and its application on companies working in Distributed Energy Resources (DER)
D3	Emerging risks related to interaction between natural hazards and technologies at community level
D4	Emerging risks related to hazardous substances, impact on public health and relations with REACH and GHS

This means that, if needed, tools and methods used for assessing likelihood/consequence analysis in closest technology related emerging risk scenario(s) may be applicable for first assessment for emerging risk scenarios on unconventional gas as well, thus giving decision maker possibility or hint on how to tackle emerged risks. Result of the analysis is shown in Figure A.8. It was requested form the S-RDI tool to make single link clustering and tool calculated only two links with fracking notion: strongest with Storage of materials (B2) and second with CCS (A1).

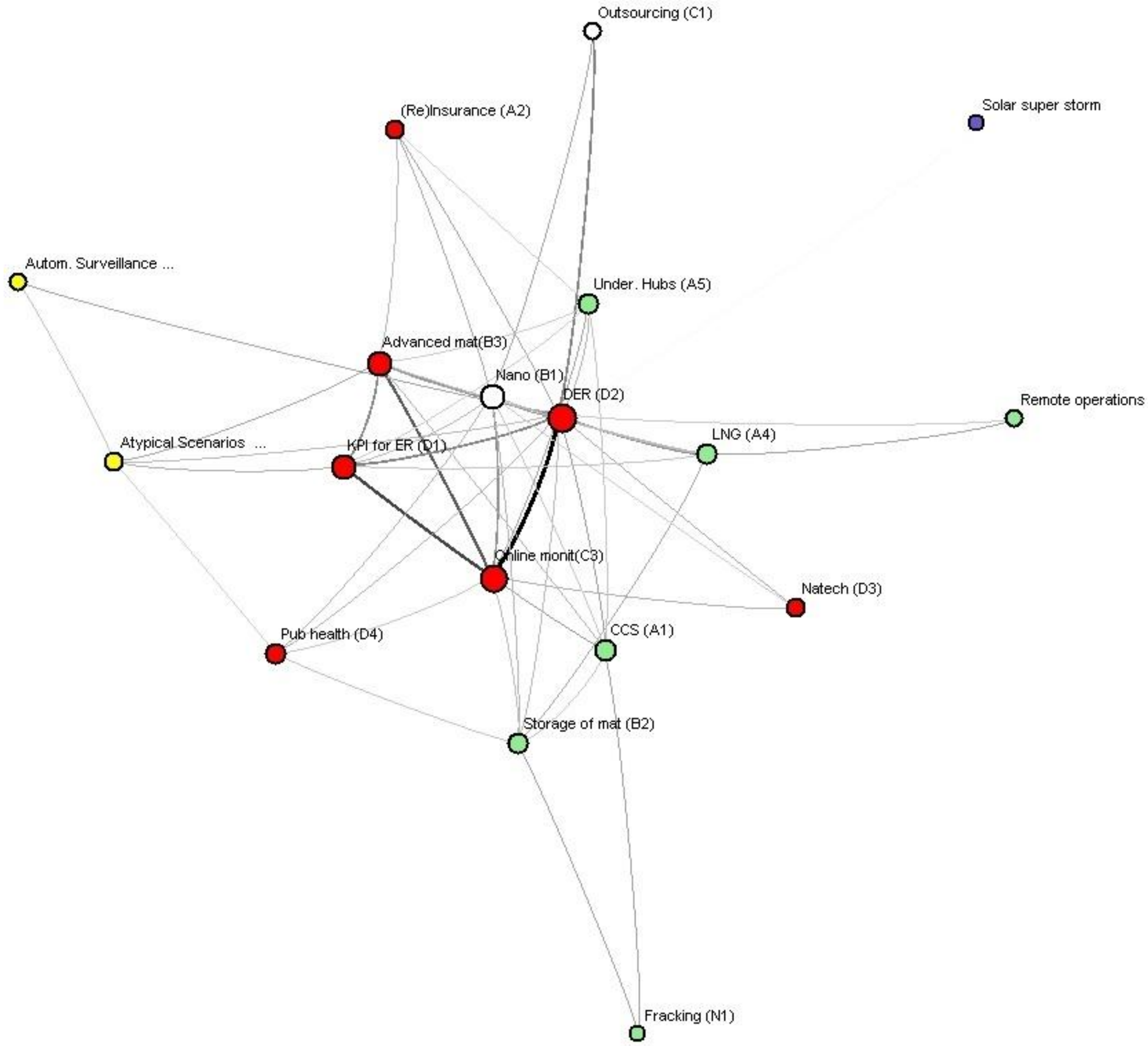

Figure A.8 — Example of Step 5: S-RDI analysis for unconventional gas topic when comparing it with other ERRAs (using single link clustering option)

NOTE Strongest link with storage of materials (B2), second with CCS (A1).

Similar analysis can be made using the C-RDI method. C-RDI (Cluster risk distance index) is based on the distance defined by data mining clustering methods (e.g. fuzzy C-mean) between a new notion and a center of a cluster of notions. Result of this analysis is shown in Figure A.9 C-RDI helps recognize criticality of a new emerging risk based on its similarity (risk vicinity) to another (better) known emerging risk; if the solutions for risks B are known, this can help tackling the new risk better (e.g. the solutions from LNG and CO_2 risks can help when dealing with hydraulic fracturing risks).

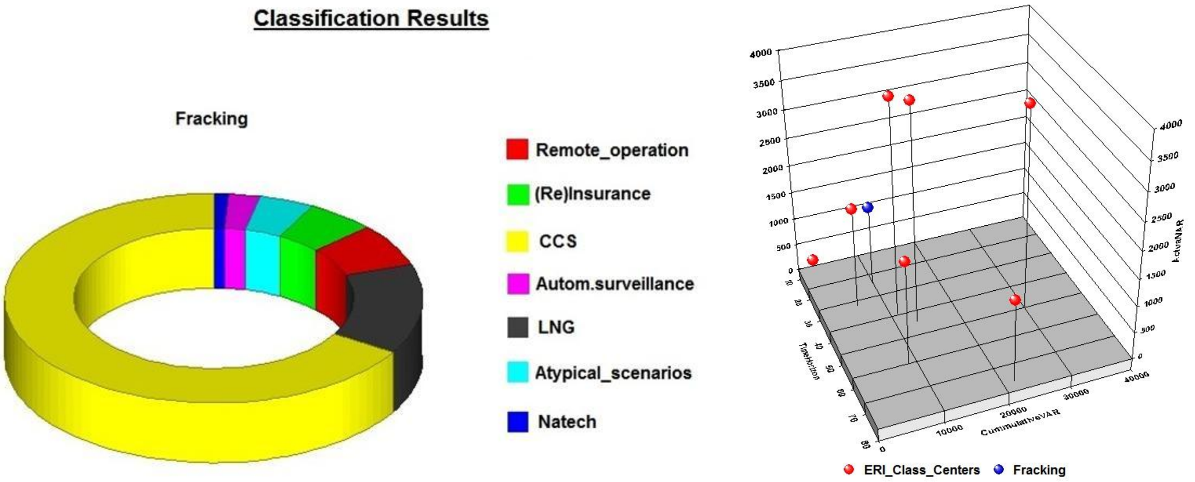

Figure A.9 — Example of Step 5: C-RDI analysis from DataEngine software of contamination of (surface and) underground water for unconventional gas

A.3.3.2 Step 6: Characterization

Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization/classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance) (see Table 5).

Risk characterization, in short, can be viewed as collecting and summarizing all relevant evidence necessary for making an informed choice on tolerability or acceptability of the risk in question and suggesting potential options for dealing with the risk from a scientific perspective [22].

EXAMPLE iNTeg-Risk project [21] is offering a tool for this step as well: Assigning color codes for different parameters to risk scenarios in RiskEars, rechecking the slider position and other information from step 4 if there is a need, thus fulfilling basic risk profile and judgment of the seriousness of the risk partly mentioned in [22]. The tool provides an option to grade the risk scenario, show its geographical applicability on a map, link it to the appropriate industry/area, select which part of life cycle is particularly affected with issue which part of the process is of importance to assessor and so on.

Figure A.10 is showing an extract of the characterization of an emerging risk scenario related to the case of unconventional gas.

MCDM (Multi Criteria Decision Making) tool can be also very helpful during the characterization step. Grading each of the defined scenarios by criteria proposed can offer a possibility to determine which of the alternatives are more important for each step. Overview of all criteria available for use in MCDM matrix, also mentioned in [2], is presented in quick view in Table A.2 more information regarding criteria can be found in Annex F.

In the first MCDM analysis only 12 IRGC criteria, were used and results are shown in Figure A.11. Measurements in MCDM analysis are derived or interpreted subjectively as indicators of the strength of various preferences. In the present case factors have six different expressions, defined as Linguistic fuzzy type with following gradation:

— not applicable;

— very low;

— low;

— medium;

— high;

— very high.

Figure A.10 — Example of Step 6: Characterization of contamination of (surface and) underground water scenario of unconventional gas

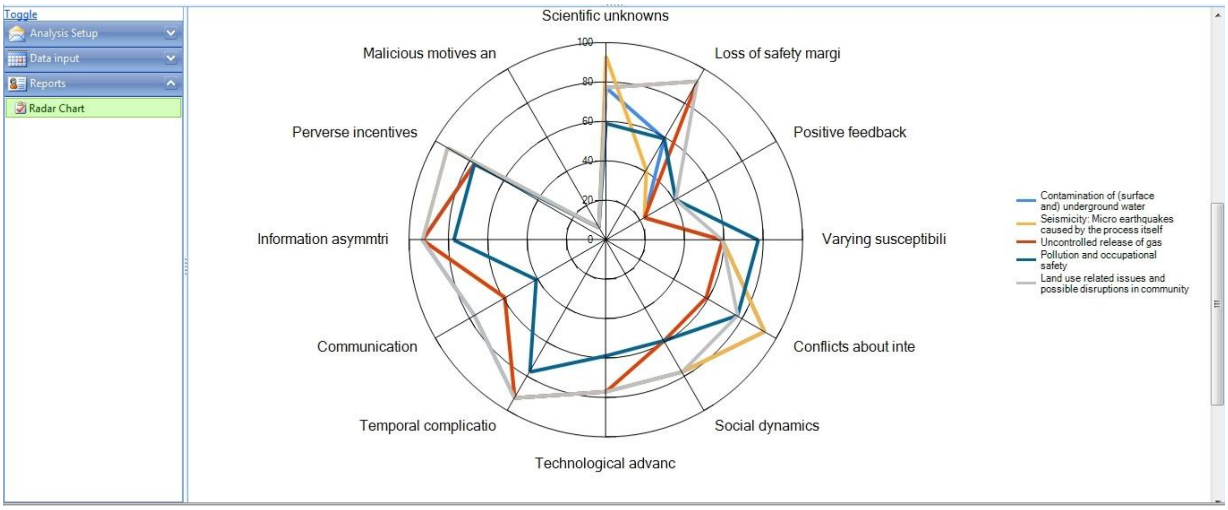

Figure A.11 — Example for five unconventional gas scenarios MCDM analysis based on 12 IRGC factors

Table A.2 — List of 50 iNTeg-Risk factors

	50 iNTeg-Risk ERMF Factors		**50 iNTeg-Risk ERMF Factors**
General perception & communication	Misperception	Governance of emerging risks	Frameworks exist
	False positives		Authorization
	False negatives		Mapping
	(Global) Catastrophic potential		Management
	Sensitivity		Protection / precaution
	Communication		Ingérence
	DIF-Perception		Social unrest
	Misinterpretation	Global management of ER	Lack of possibility to observe/monitor
Single person level perception	Incertitude		Lack of possibility for mitigation
	Lack of familiarity		Susceptibility to global ignorance
	Lack of understanding		IRGC-12 factors
	Lack of personal control	Risk characteristics	Contradiction
	Lack of voluntariness		Incoherence
	Involvement of children		Persistence
	Involvement of / risk for future		Ambiguities
	Victim identity		Lack-Proportionality
	Dread		Sudden change in perception
	Lack of trust		Increasing
	Accident history		Origin of risk
	Lack of equity	Time	Novelty
	Lack of clear benefits		Time to impact
	Lack of reversibility		Duration
	Personal risk		Latency

	50 iNTeg-Risk ERMF Factors			50 iNTeg-Risk ERMF Factors
				Evolution in time
			Risk Assess-ment	Propagation
				X-uncertainties
				Known-to-science

A.3.3.3 Step 7: Evaluation of tolerability and acceptability

In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions.

Specific or complementary approaches/rules should be considered in this phase (see Table 5).

[24] states the following: “The purpose of stakeholder engagement here is to assure that, [...], the values and preferences of those who will be affected are made clear to those ultimately responsible for deciding the tolerability or acceptability of risk and how it might be managed.”

EXAMPLE For this step, the New Technology Acceptance Model described under section A.3.2.1 is applicable, too. Respective parameters of the agent have to be defined and provided as preparatory step.

The text below is giving the current situation regarding tolerability and acceptability of Fracking in different countries.

Hydraulic fracturing, during the writing of this Annex, has not been regulated in two different countries in the same way. The best known case(s) where fracking is in dispute is the USA, where there are several well-known/popular documentaries depicting this process, both in favor and against represented in a large amount of published articles. China, according to [25], has 36.1 trillion cubic meters of technically recoverable shale gas reserves, but has a problem of water shortage that is essential to the fracking process. Depending on the depth of the gas reserves and the source of information, the amount of water needed for drilling horizontal shale well ranges from 7 to 20 million of liter. According to [26], there is a recent, still ongoing, long-term study that shows that Germany has up to 22 trillion cubic meters of shale gas that can be safely exploited if right rules and laws are in place. Germany’s government has won a parliamentary vote that will permit hydraulic fracturing to continue in the country, Figure A.12, after arguing that the controversial technique could help boost energy supply security [43]. Another European country, Poland, which is heavily depending on coal and gas from Russia, is allowing exploitation of shale gas reserves and has already granted more than 100 licenses. [27] surveyed Poland’s prospects for tapping its reserves of unconventional gas and also discussed the relevant technical, economic, environmental and legal issues relating to the fledgling Polish shale gas industry. In contrast to these countries that are currently exploiting shale gas reserves or have ongoing studies on how to safely exploit them, France banned fracking altogether in the middle of 2011, thus being the first country to pass a law that bans this gas exploration & production technique, Bulgaria following shortly after in January 2012. With declaring moratorium on hydraulic fracturing in duration of two years.

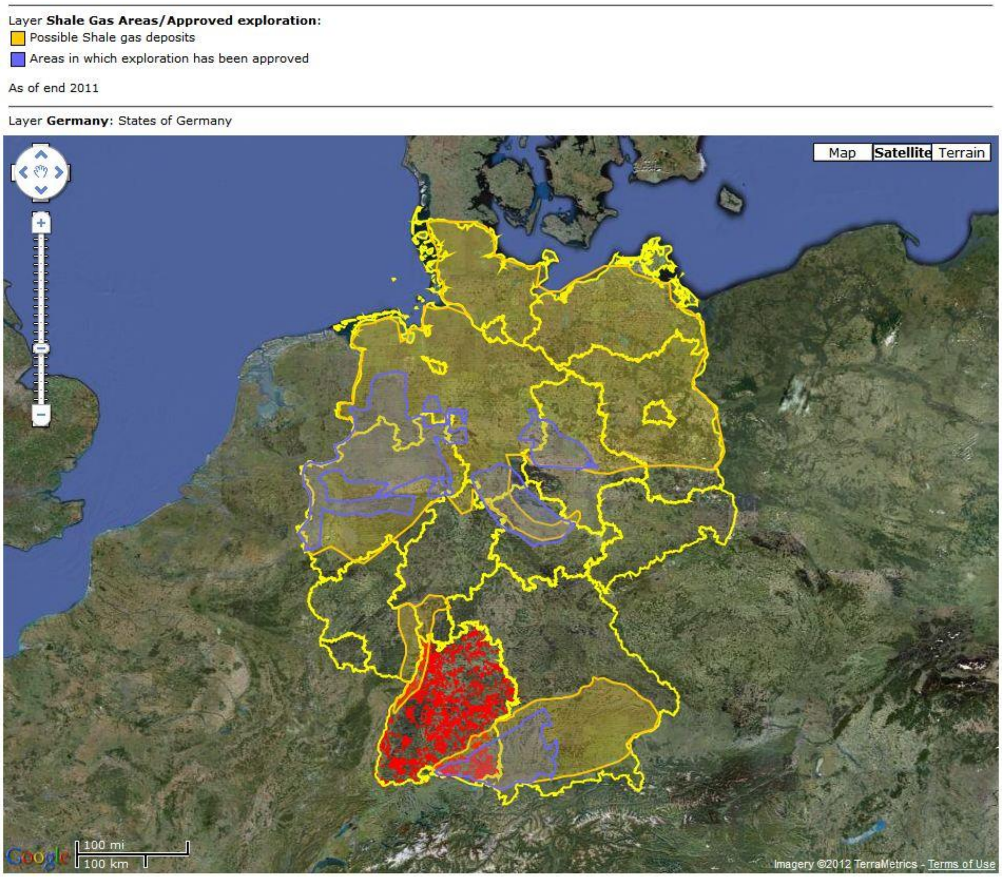

Figure A.12 — Graphical representation of shale gas resources in Germany overlapping with natural protected areas in Baden-Württemberg (shown red) from iNTeg-Risk RiskAtlas

Some examples of the protective and preventive measures that can be (or are already) applied in case of unconventional gas, specifically concerning fracking fluids are now evolving towards decreasing the amount of additives, as well as towards using components used in the food industry as additives, as they are known to be innocuous.

A.3.3.4 Step 8: Management and decision (treatment)

Based on the previous steps results, decisions are made to manage the risk in order to keep it at an acceptable or tolerable level.

The approaches applied in emerging risk management should:

— integrate both qualitative and quantitative data

— combine different type of criteria

— carefully address compensation

— consider variations/alternatives in risk scenarios

— treat uncertainties

— help make robust decisions (see Table 5)

Assuring relevant expertise and knowledge that is crucial for successful completion of decision making process is one of the main purposes of this step.

EXAMPLE The text below is giving the current situation regarding management and decision processes for unconventional gas as understood in iNTeg-Risk project.

Regarding the stance that countries took towards the process itself, management and decision making is going in very different directions. Management of emerging risk like the ones related to fracking can depend on not just the feasibility studies regarding the prospects of shale gas exploitation but from various, on first place, environmental studies and legal basis for this process. USA is allowing exploitation on most of its territory but some, both non-governmental and governmental, organizations are trying to prevent drilling on the area that is known to contain both shale gas reserves and substantial reserves of drinking water (please see A.5 for more information). Mechanisms like Adaptive Risk Management, that allow updating prevention and protection measures based on progress in scientific knowledge and improved practices. The dynamic nature of industry response to public concerns shows that tools to share knowledge also need to be adapted for quick updating. Especially Neutral Exchange Platforms should reflect such evolutions and stay up to date.

A.3.4 Continuous activities

A.3.4.1 Step 9: Communication and consultation

Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles (see Table 5).

Communication and consultation is proving to be an increasingly important element when dealing with emerging risks. It is taking place during all phases of the ERMF process, among all stakeholders, and can be considered as the core element for successful completion of an emerging risk management process.

When dealing with an emerging risk situation, it is in general recommended to:

— Arrange a formal hearing process (whether or not this is a mandatory requirement);

— In parallel; plan, prepare and perform an informal communication process;

— Communicate the process itself, e.g., by the use of progress reports/videos on the web;

— Consider how to deal with specific well-known risk communication challenges.

EXAMPLE An external evaluation of the risk communication process should also be considered. One example of such an external evaluation, including the methodology chosen, can be found in [28].

The Risk Forum, as part of the iNTeg-Risk 1StopShop and mentioned here earlier, was developed also for serving (parts of) this above described step and is enabling different stakeholders to exchange their ideas and views concerning emerging risk notions among each other in a structured and monitored way.

A.3.4.2 Step 10: Monitoring, review and continuous improvement

This requirement means that the procedures to be established have to ensure

— continuous improvement,

— effectiveness & efficiency,

— sustainability & evergreening (see Table 5).

The whole emerging risk management process (step 1-10) should be monitored, regularly reviewed and continuously improved. As a distinction from the use of early warnings in the horizon screening to identify emerging risks for the first time (step 1), this monitoring covers known risks, with known factors/issues for which it is easier to establish indicators.

EXAMPLE In case of unconventional gas it is of utmost importance to develop a gradual approach to tapping-in shale gas reserves. Possible action that can improve efficiency is that companies involved in process should disclose information regarding chemicals they are using which can in turn help scientific community in finding possible prevention measures/supplements to the currently used, etc. Some progress in finding possible solution(s) to this problem has been noted, but still most of the chemicals are consider as a trade secret in the US and are, by law, protected from being transparent to public view. Continuous improvement should be mandatory process with a shared responsibility between all involved stakeholders.

A.4 Conclusions/Summary

In this Annex, ten steps of the ERMF process have been applied for the case of unconventional gas with emphasis on fracking. Authors' intention was not to point out possible flaws or downsides of technology but to be as objective as possible considering data/sources available. The document provides suggestions how to apply the ERMF steps practically for the case of emerging risks in unconventional gas as one of examples of New Technologies. Although, all steps of the ERMF are of great importance and should be followed per suggestions provided in Chapter 7, some of steps are found to be of the outmost importance for unconventional gas example:

— Proper identification of emerging risk scenarios is crucial for successful completion of the process for managing of emerging risk;

— Having good pre-assessments from multiple experts from different fields of expertise that are later used in Analysis step, can also contribute to successful completion of the process for managing of emerging risk, giving broader view of the tackled issue;

— Communication and consultation can be, and is, considered as one of the important steps since it is taking place during all phases of the ERMF process;

— Continuous improvement as one of the steps with its envisioned role to monitor, review and improve data/results/conclusions from all ten steps, in combination with communication is giving an overall picture of the issue, thus helping to better understand critical points in emerging risk management process.

A.5 Example – Use of new technologies for unconventional gas

A.5.1 Hydraulic fracturing

A.5.1.1 Introduction

Fracking is a process in which a mixture of chemicals, sand type particles and water are injected, at high pressure, 1500 m to 6000 m deep into the ground to break rock layers, usually limestone or sandstone but now more and more common, shale rock, in order to release gas stored there. Many of previously mentioned chemicals are present in common household and commercial applications; some, used in low concentrations, are toxic (the situation has improved recently as a reaction to public concern, as toxic additives were used more frequently in the past). In the process of reaching the gas, pipes must also pass water aquifers (see Figure A.13), and after the well has been fracked, fracture fluids must be pumped out in order for the gas to be released. During the production process, there is a very small risk that formation water, fracture fluids or gas might migrate to higher aquifers. While natural gas is not toxic, formation water may carry along salts and other dissolved material that can be contaminant. Well design and completion are aimed at preventing such migration along the wells. However, fracking as a process (or as a new technology) is considered as one of the answers to the challenge of keeping up with increasing demand for supply of natural gas.

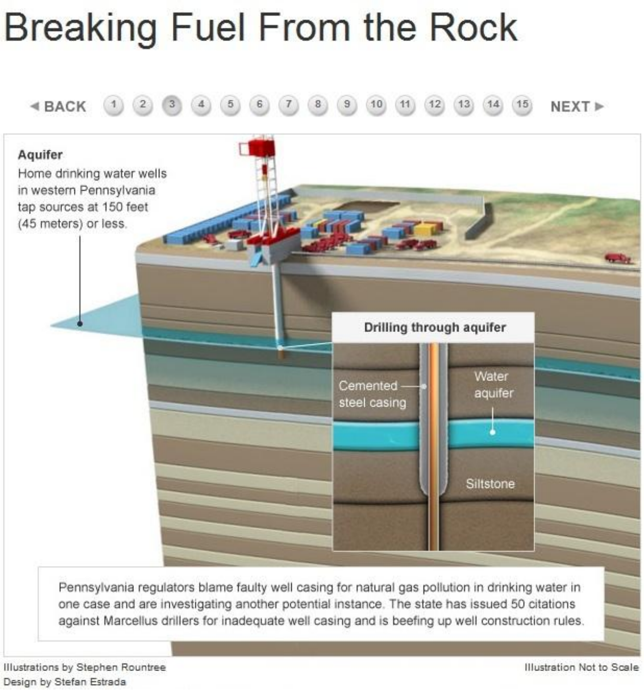

Figure A.13 — Process of fracking [30]

A.5.1.2 Public, institutional and scientific interest in fracking and their possible questions

Currently there is wide spread discussion if and how much exploitation of unconventional gas will add to the existing CO_2 emissions. Report [29] is mainly oriented to giving instructions on how to, if the world enters into something what IEA called “Golden Age of Gas”, implement rules to maintain this Golden Age. However, in one of the sections where comparison is made between few scenarios, issue of carbon footprint has been addressed. Before stating the findings of report short introduction is needed regarding IPCC’s (Intergovernmental Panel on Climate Change) goal in respect to emissions of Greenhouse gases (GHG).

In order to have a 50 % chance of keeping the global mean temperature rise below 2 °C relative to pre-industrial levels, atmospheric GHG concentrations must stabilize below 450 ppm (parts per million) CO_2 equivalence. Stabilization below 400 ppm will increase the probability to roughly 66 % to 90 % [31] (see Figure 1.14).

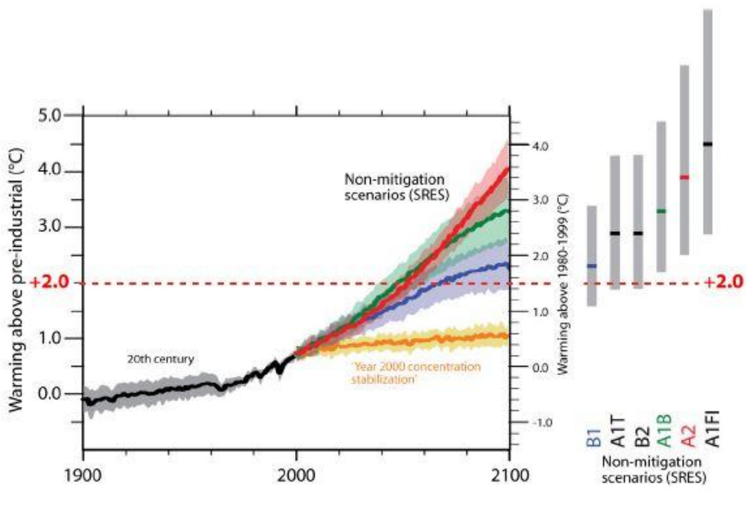

Figure A.14 — Projections of global mean surface temperatures for three SRES non-mitigation scenarios as presented by IPCC AR4 and the year 2000 constant concentration experiment [14]

Having the previous paragraph in mind, it states the following: The Golden Rules Case puts CO_2 emissions on a long-term trajectory consistent with stabilizing the atmospheric concentration of greenhouse-gas emissions at around 650 parts per million, a trajectory consistent with a probable temperature rise of more than 3.5 degrees Celsius in the long term, well above the widely accepted 2 °C target.

Report written by an Independent Expert Forum [29] as one of the means to introduce fracking to German community states the following: Our simulations revealed that the greenhouse-gas footprint of shale gas is anywhere from 30 to 183 percent greater than that of classic natural gas. This performance could potentially be improved by using renewable electricity rather than diesel to run hydrofracking pumps. If this were done, the carbon footprint of shale gas would be only 43 percent greater. If realistic data concerning the methane emissions from the shale stratum were available, it would be possible to measure the greenhouse-gas footprint of hydrofracking related methane emissions.

From previously mentioned reports/brochure it is safe to conclude that exploitation of unconventional gas resources will not reduce carbon footprint but, quite opposite, it will increase it. On the other hand, using unconventional gas would reduce emission from facilities/plants that are using dirtier types of energy sources (such as lignite or heavy crude oil).

In the US, the largest shale gas fields are the Barnett, Haynesville, Marcellus and Eagle Ford formations. Production has now reached critical mass to affect the US gas market. Supply from shale gas has outstripped demand growth, and net imports have been declining, while prices for natural gas are at historical lows [21]. Another very important fact is that price of natural gas is, since roughly 2009, formed regardless of oil price and it is at record low [33] all due to the tapping-in in unconventional gas reserves, mostly shale gas.

Despite this, there is a large public dissatisfaction regarding hydraulic fracturing on a large scale due to contamination of drinking water reserves. There is a report, [34], from 1987, which has gone largely unnoticed for two decades, and which speaks of a contamination case in 1984. This report concluded that hydraulic fracturing fluids of gel used by the Kaiser Exploration & Mining Co. contaminated a well roughly 180 meters away on the property of James Parsons, in Jackson County, West Virginia, USA. The fracture fluid along with the natural gas was present in Mr. Parsons' water, rendering it unusable (summary from [35]). However, according to the article [35], EPA (Environmental Protection Agency) says that researchers have been unable to investigate many suspected cases because their details were sealed from the public when energy companies settled lawsuits with landowners. Despite that this report has been written more than 20 years ago and the fact that technology has been significantly improved, contamination of water aquifers remains one of the most problematic issues when dealing with Hydraulic fracturing.

Figure A.15 — River system in US (left), locations of major drilling campaigns in US (right) [36]

One of the largest unfiltered water reserves in the world is based in the north-east part of the US, supplying more than 15 million people with drinking water, 6.8 million people in New York City alone. The same reservoir is located on the northern outskirts of what is known as Marcellus shale (see Figure A.15) and thus is being endangered by possible contamination by fracture fluids, which is a mixture of almost 900 known and mostly unknown (some of those that are used in low concentrations are highly toxic and possibly cancerogenous) chemicals, sand type particles and water. For now, there is no drilling in New York City Watershed area due to the fact that the region is protected area [37], and that moratorium has been put on hydraulic drilling over the shale, but considering current gas boom in US and constant hunger for more domestic energy resources, that might change soon [38], Figure A.16.

Poland is the first European country that is going to use its unconventional gas reserves and is today seen, by some media, as a savior from the dependence on import gas from Russia, (see Figure A.17). Overall representation of major shale basins in world is presented on Figure A.18.

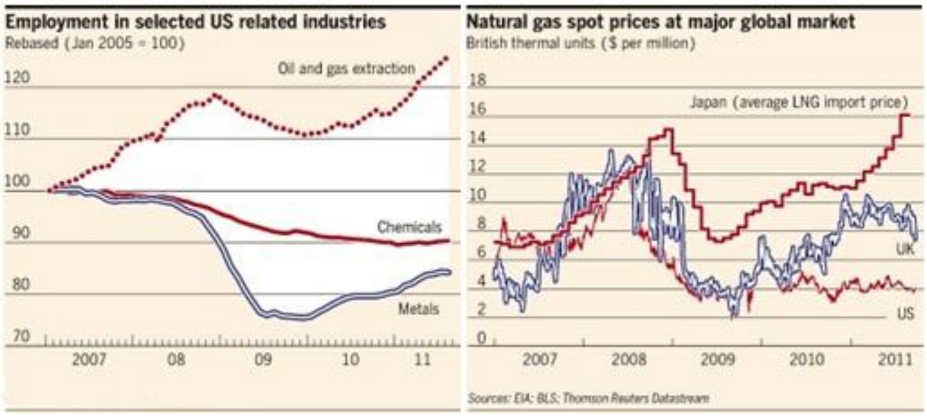

Figure A.16 — Employment in various US industries and natural gas prices at major global market [38]

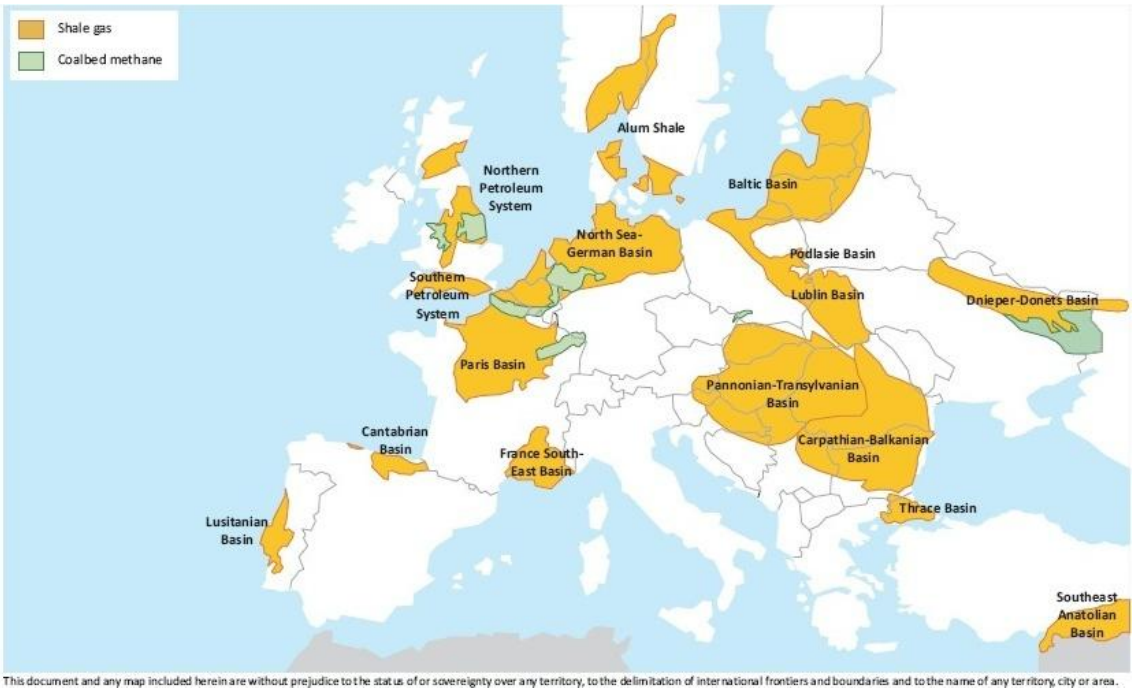

Figure A.17 — Major unconventional natural gas resources in Europe [29]

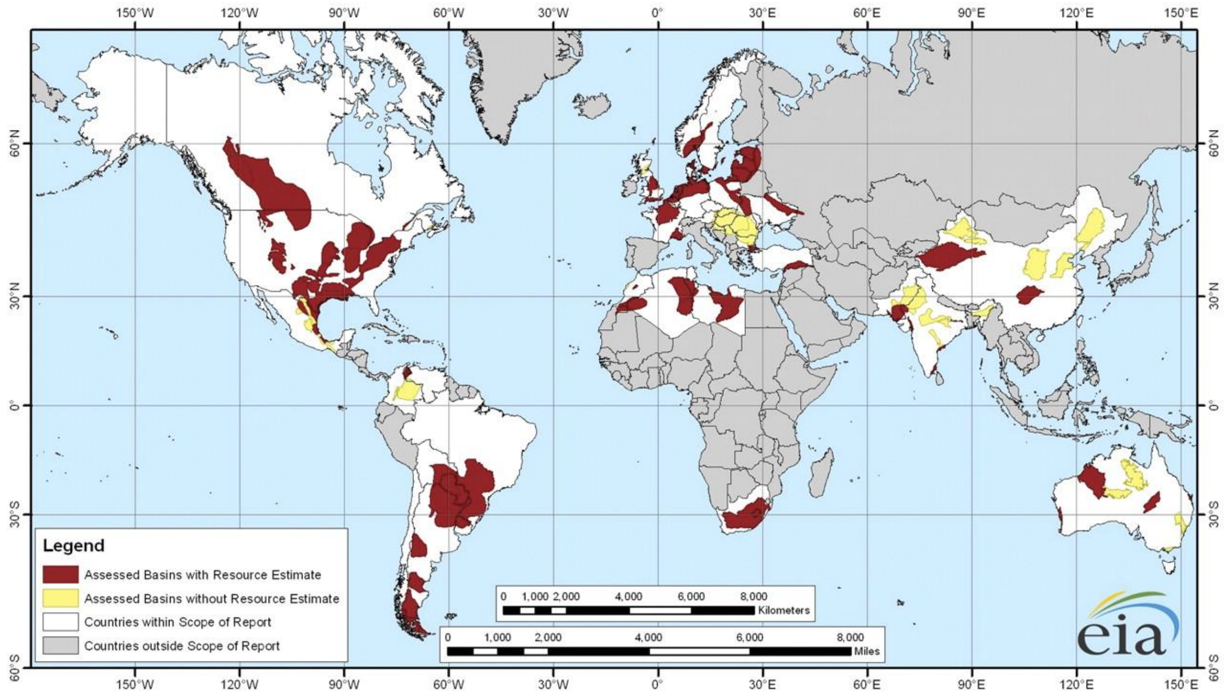

Figure A.18 — Map of 48 major shale gas basins in 32 countries [25]

Regarding the OSHA definition of emerging risk, fracking is a prototype example addressing all parts of the definition:

— the risk did not previously exist because the technology of horizontal drilling, which is main part of fracking, is fairly recently enhanced;

— social or public perceptions regarding the process is changed, despite the economical benefit there is an issue of environmental protection;

— new scientific knowledge allows to correlate some of the health issues that are thought to be triggered with the use of frack fluids;

— number of hazards have risen, beside environmental risks there are now issues with micro-earthquakes and growing concerns with health issues;

— long exposure of people to contaminated water leads to number of health problems that were now linked to process itself;

  - It is relatively well-known that anthropogenic activity can result in manmade or induced earthquakes. Although such events are generally small in comparison to natural earthquakes, they are often perceptible at the surface and some have been quite large. Underground mining, deep artificial water reservoirs, oil and gas extraction, geothermal power generation and waste disposal have all resulted in cased of induced seismicity).

— long exposure of people to contaminated water leads to number of health problems that were now linked to process itself [44][45].

Annex B
(informative)

Emerging risks in new materials and products

B.1 Introduction

This annex suggests common/agreed solutions for dealing with emerging risks in the area of new products and materials. It includes methods for integrated analysis of the problems and reference solutions for Emerging Risks in New Materials and Products and provides a set of specific model tools and solutions for integrated risk management.

The examples of existing new materials and products in new context are advanced composites or materials and products containing Carbon Nanotubes (CNTs). The example of emerging risk management of CNTs is introduced in B.2.1 and background information is provided in B.5.

This annex is first of all intended for managers and their staff within authorities and companies responsible for managing risks related to new production and production networks where there is an aspect of novelty in the activity/project/process in question, which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

Solutions, reference documents, methods and tools specifically applicable to the handling of emerging risks in new production and production networks are referred to in the relevant process steps of the ERMF in B.3.

The process consists of the following 10 steps arranged in 4 groups:

Horizon Screening:

— Step 1: Early warnings – notions

Pre-Assessment:

— Step 2: Context and concern;

— Step 3: Identification of risk scenarios;

— Step 4: Pre-assessment.

Appraisal/Assessment:

— Step 5: Analysis;

— Step 6: Characterization;

— Step 7: Evaluation of tolerability and acceptability;

— Step 8: Management and decision (treatment).

Continuous Activities:

— Step 9: Communication and consultation;

— Step 10: Monitoring, review and continuous improvement.

B.2 Specific topic and example case

B.2.1 General remarks/overview related to the specific topic

The development of new materials and products is always accompanied by new desired and non-desired mechanical and chemical behavior.

The behavior cannot be predicted ahead. In principle, only the global chemistry and the desired composition are known, while side reactions and mechanical and structural properties of these materials are unknown.

In the last years the structural properties of the advanced materials have gained more attention because the structural dimensions were shifted to the nanometer scale. This obviously introduces a second parameter to the more general questions of direct toxicity and side products that needs to be considered.

The side products can either be fixed on the surface or be free particles in powdered form or fume. It is clear, that physical and chemical properties of advanced materials have significant implications for emerging risks.

The following questions of emerging risk rise:

— How does new material distribute itself between air, water, soil etc.?

— What are the design and failure criteria for these materials including: joining, durability, life assessment, lack of standards and data bases to ensure adequate safety factors are employed in the design phase?

— What is the environmental and human health risks involved in the disposal or recycling of new materials and products, especially, the potential for small-particles of material to escape from 'contained' waste disposal sites as well as their impact on sewage treatment plants;

— What is the risk during the phases of production and use of new materials?

Examples of emerging risks during these phrases are:

EXAMPLE 1 difficulties to characterize mechanical/material properties of the new materials;

EXAMPLE 2 stability risk – ability of a material to remain unchanged during conditions of anticipated use;

EXAMPLE 3 incompatibility risk – material may create hazardous reaction when in direct contact with another material;

EXAMPLE 4 reactivity risk – material undergoes a chemical reaction with release energy;

EXAMPLE 5 corrosivity risk – material causes visible destruction or irreversible damage at site of contact;

EXAMPLE 6 decomposition risk – material disassociates or breaks down into parts or simpler compounds.

B.3 Procedure for management of emerging risks

B.3.1 Horizon screening

B.3.1.1 Step1: Early warnings – notions

Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic, etc.). The warnings should be properly aggregated, classified and monitored in order to enable to the stakeholders to keep the process of risk maturation under control (see Table 5).

Current knowledge in new materials and products comes from developments in chemistry, physics, life sciences, medicine, and engineering. Advanced materials technology is under active development or already in practical use in several areas: material science, biology and medicine, consumer products, electronic, engineering, optical devices, and many more.

Emerging risks related to new materials and products need to be detected as early as possible and their evolution needs to be constantly monitored. New or emerging risks should be actively searched and watched for. Even the underlying processes related to the ability to foresee the unforeseen and to cope with the unexpected need to be monitored.

The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of risk maturation under control. It is necessary to keep track of all warnings, indications, etc. and to monitor any trends. This includes learning from others (industry wide). For SMEs, for which this is a challenging task, their branch organizations should play a key role in providing this kind of learning/warning.

Examples of monitoring of possible early warnings for CNTs:

EXAMPLE New scientific evidence has been published that multi-walled carbon nanotubes – the so-called 'wonder material' of nanotechnology induce asbestos-like pathogenicity in mice. Carbon nanotubes are now used commercially in: sports equipment; fuel lines, pumps, filters and coatings for premium cars; specialty boating, building and aerospace equipment; electronics equipment; and as additives in a wide range of high performance plastics and polymers. They are touted for wide use in manufacturing, electronics, packaging and even food packaging.

Industry analysts estimate the value of products containing carbon nanotubes to be up to US $1.9 billion by 2010. But despite the mounting evidence that multi-walled carbon nanotubes produce mesothelioma in test mice, and the rapid growth in their commercial use, there are still no new laws and no nanotechnology-specific workplace exposure standards anywhere in the world to ensure that we do not repeat mistakes of asbestos.

There are still no nanotechnology-specific controls to protect workers, the public and the environment from risks associated with multi-walled carbon nanotubes and other nanomaterials.

B.3.2 Pre-Assessment

B.3.2.1 Step 2: Context and concern

> By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.
>
> Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development. (see Table 5).

This step includes the way stakeholders understand (frame) the emerging risk situation at hand (related to new production processes and new production networks), and what their main concerns are.

Currently the public only has a limited awareness of the science, uses, impacts and implications of new material technology. Not all stakeholder groups that might be interested in or affected by new materials and products applications have the same level of awareness about these issues, nor do they share identical interests in participating in the decision making. The potential benefits and risks must be examined together in order for a realistic discussion about trade-offs to occur, and much more must be done to raise the knowledge level of all parties to prepare for meaningful participation in decision-making about the current and future role of new materials technology.

Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations to the emerging risk issue itself (i.e. expectations to the progress/pace of new production processes or production networks) and to the caution/control thereof (i.e. expectations to the process of emerging risk management) in order to avoid potential societal risks that might threaten sustainable development.

The context should be described including all new influencing factors. It is essential to focus on, analyse and follow-up on any new influencing factors.

An overview of all relevant stakeholders should be prepared including information about their expectations and concerns.

Information and communication about framing and concern is obtained through the continuous activity of emerging risks communication and consultation (step 9). It is essential that both understanding and misunderstanding with respect to the risk situation are captured in dialogue with the stakeholders, so that any misunderstandings can be attempted resolved.

It is also important to inform the stakeholders about the emerging risk management process, so that the stakeholders have trust in the process, even if they might not agree with the final outcome.

The framing and concern assessment should be carried out at an early stage in order to direct the allocation of resources and topics included in the analysis phase (step 5). Big concerns should be accompanied with a fair share of resources in the analysis phase. The dialogue with stakeholders should start as early as possible after a decision has been made to investigate the development of a new production process or production network.

EXAMPLE Generally, the public is less concerned about a particular application or risk, and more worried about the capacity for human misuse, unexpected technological breakouts, or new material's potential to exacerbate existing social inequalities and conflicts. These concerns may grow if new materials technology becomes associated with specific dangerous incidents that occur in a context of deep suspicion of industry motives and doubts regarding government's ability or desire to act if required. Some concerns raised include: - further enhancements to genetic modification; - devices to control the human brain and body; - changes to the environment, human safety and quality of life.

The public's concerns will be included by minimization of technical risk related to the use of new materials.

For example, we don't know enough about CNTs effects on the environment and human health. The regulatory groups need more studies like to provide information on the safety of CNTs. The researchers found that CNTs, along with any impurities could reduce growth rates and even kill some species of aquatic organisms. Good waste management and handling procedures can minimize this risk. Also, to control long-term risks, we need to understand what happens when these materials break down. The researchers cautioned that care should be taken to prevent the release of CNTs into the environment as the materials enter mass production.

B.3.2.2 Step 3: Identification of risk scenarios

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings(see Table 5).

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more (merged) early warnings.

The scenarios may have been experienced (fully matured) or potential based on the information provided by the early warnings (i.e. warning before or after the full scenario has occurred).

All plausible worst case scenarios should be included at this stage, and all the scenarios should be listed.

EXAMPLE Complexity and toxicity of advanced materials – composite materials. Technically composite materials are considered complex and could be toxic - they can be non-linear, are anisotropic, their properties are dependent on time and environmental conditions and joining them to other components is a non-trivial task. Therefore, the consequence of making something from composite materials may be seen as more complex still.

EXAMPLE Advanced materials - physical and chemical properties. Engineered new materials and products raise particular concerns because of the unknown characteristics of their new properties and their potential use in concentrated amounts. For example, some CNTs may have similar characteristics to known high-risk materials at the microscale.

EXAMPLE Effect of size, shape and surface area of nanomaterials on human health. The sub -100 nm size of CNTs is one of the primary features that provide them with unique properties as compared with bulk materials of the same composition. However, their size can also represent a health hazard as they may be more likely to cross biological barriers, gaining entry to the body and subsequently size governs their kinetics including absorption, distribution, metabolism and excretion.

EXAMPLE Lack of relevant composite materials performance information. There is a significant lack of relevant performance information, especially in hostile offshore environments (including erosion, fatigue, wear and impact abuse, as well as fluid environments), which hinders the specification of composite materials.

EXAMPLE The lack of sufficient database of mechanical/material behavior of advanced materials during exploitation phase. In principle, only the global chemistry and the desired composition are known, while side reactions and mechanical and structural properties of these materials are unknown or difficult to characterize.

EXAMPLE Lack of data for LCAs. Existing standards for carrying out Life Cycle Assessments are fully suitable for use on CNTs and nanoproducts. Nevertheless, one of the identified serious problems is a lack of data on environmental impacts of new materials and products containing CNTs.

EXAMPLE Lack in current legal/regulatory systems. Since the market of new materials developed very rapidly the needed regulations and laws are not very well developed. Need for further regulation towards safe and permitted use of nanomaterials. Current legal regulatory systems do not take into account the risks in a sufficient way. The gaps in legal/regulatory systems may hamper preventing of emerging environmental, social and technological risks.

EXAMPLE Environmental Risks of using composites - recycling consideration. Greater use of composite materials will have an environmental impact which may be mitigated by recycling. However, it is generally more difficult to recycle materials with glass- and carbon fibre at high fibre fractions, since wear increases in the machining equipment used for grinding the material. Controlled combustion at high temperatures (1000 °C) works generally well and is best suited for fully combustible materials, which excludes products made of glass fibre and non-combustible fillers.

EXAMPLE The data-base or reference values for the basic design composites properties. There is no recognized data-base or reference values for the basic design properties required such as modulus and strength for oil and gas grade composite materials. The fact that composites can be tailored to the properties desired is termed an advantage, but it requires analysis and testing to understand the global material properties of the tailored design. Compared with steel, there is a wider variety of composite materials available which can be tailored to specific applications. This presents variety to the engineer but introduces complexity.

EXAMPLE Standards for composite products. Some standards exist for many composite products, but new standards will be required for new applications and harsh service conditions. Standards can be slow to create/harmonize and update and consensus can lead to the lowest common denominator. In addition, more appropriate test methods are required to ensure that the product performance meets required specifications.

EXAMPLE Unification of measurements techniques and identification standards. To characterize new materials mechanical properties common measurement techniques and identification standards should be agreed on and issued among all material engineering scientific laboratories. Lack of such unification can lead to different material properties description/values.

B.3.2.3 Step 4: Pre-Assessment

Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified (see Table 5).

Pre-assessment needs to identify all relevant dimensions of risk, or at least all the dimensions of interest for the various stakeholders identified.

Following the ERMF framework the four dimensions in question are technology/technical (T), human/ management (H), governance/communication (C) and policies regulation/standardization (R). All the dimensions are in general applicable for new production and production networks.

The list of scenarios from the previous step (step 3) is screened based on the identified, described and assessed dimensions of risk. The criteria for the screening should be clearly described and the process of screening needs to be transparent.

EXAMPLE High exposure potential related to manufacture and production:

- Number of workers handling novel materials or general population living around e.g. nanomanufacturing facilities;
- Magnitude of environmental release during production;
- High potential for chronic human or environmental exposure related to use, disposal, or recycling;
- Uses resulting in repeated or continuous release;
- Detection in environment or biota (e.g. based on monitoring);
- Diversity of uses (i.e. multiple applications may provide cumulative exposure to a given advanced materials);
- Broad scale of uses (e.g. based on market penetration, commonness of use);
- Directness of contact or proximity to exposure sources.

B.3.3 Appraisal/Assessment

B.3.3.1 Step 5: Analysis

The analysis of risk governance models revealed the importance of considering the whole life cycle of (a) product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks (see Table 5).

The appraisal involves assessing risks related to new materials hazard, exposure, risk management and societal concerns including also how new materials risk is perceived and what stakeholders are concerned about. For new materials and products it requires the selection of strategies designed to reduce or transfer risks that have been judged to be tolerable and to decide how to prevent the occurrence of risks that have been deemed intolerable. Individual countries will probably want to conduct their own new materials risk appraisals, not least because much of the knowledge generated will be context-specific, particularly regarding societal concerns.

EXAMPLE The risk appraisal should take into account:

- Review hazard and exposure profiles;
- Match exposure situations with hazards and compare potential exposure levels to published or derived effect levels, where available;
- Evaluate uncertainty in the risk assessment;
- Identify knowledge gaps;
- Develop a plan to fill data needs or identify reasonable worst-case values, assumptions, and scenarios for use as benchmarks in risk management.

B.3.3.2 Step 6: Characterization

Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization/classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance) (see Table 5).

Characterization of the knowledge about cause-effect relationships can assist in designing both risk management strategies and in planning for the participation of stakeholders in the risk handling process. A distinction is made between simple, complex, uncertain and ambiguous risks [86].

The risk characterization involves identifying the scientific- and value-based evidence about a risk, and evaluating it by balancing the levels of tolerability or acceptability (see next point) within societal norms. This process guides risk managers towards risk governance decisions that are practicable and account for the views and needs of different stakeholders. Risks can be categorized in terms of what is known about them, how well the cause and effect relationship is understood, and how controversial and ethically challenging the risk is perceived to be by stakeholders.

Applying this approach allows the initial categorization of any risk into four groups: very low importance, low importance, medium importance, high importance, very high importance

EXAMPLE Generally, at present, data on the effect of CNTs on human health is relatively limited. The experiments performed up to date indicate that they may have significant genotoxic potential. However, there are also clear inconsistencies in the literature that make it very difficult to come to firm conclusions. Additionally, limited physicochemical characterization in most reports means that the true nature of the nanomaterials being investigated is unknown.

B.3.3.3 Step 7: Evaluation of tolerability and acceptability

In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions.

Specific or complementary approaches/rules should be considered in this phase (see Table 5).

The policy makers need to determine which new materials applications would be considered acceptable or tolerable by society. These judgments will, most probably, not be uniform throughout society and are also likely to be different for specific new materials applications. One approach is to match the probability of an adverse event against the extent of the consequences of such an event. Risky activities deemed acceptable would include those with a low probability of occurrence and limited consequences.

As both occurrence probability and the scope of consequences increase, risk enters into the ranges of

— tolerable, with the need for management to reduce it to the as low as reasonably possible level. This may include some engineered nanostructures,

— intolerable, as in the case for example of several nanomaterials designed to be used for other purposes,

— undefined, as in the case of nanomaterials provided brain modification.

EXAMPLE Making these distinctions, especially in the context of insufficient scientific evidence of CNTs, is one of the most difficult tasks of risk governance, although collaborative processes for making these kinds of choices have been used to tackle other contentious issues for which there is incomplete information and high uncertainty. To be ultimately successful, a combination of technical data and multi-stakeholder (especially public) inputs should be part of the process.

The total absence of technical data concerning some potential applications which are still some years from being developed into final products makes these judgments very difficult.

B.3.3.4 Step 8: Management and decision (treatment)

Based on the previous steps results, decisions are made to manage the risk in order to keep it at an acceptable or tolerable level.

The approaches applied in emerging risk management should

- integrate both qualitative and quantitative data,
- combine different type of criteria,
- carefully address compensation,
- consider variations/alternatives in risk scenarios,
- treat uncertainties,
- help make robust decisions (see Table 5).

Risk management comprises actions to reduce the potential risk for humans and the environment from new materials and products. A risk management assessment should provide information sufficient for determining how to pursue practices, conduct processes, and safely produce, use, and ultimately dispose of or recycle the product best. In other words, the assessment should endeavor to eliminate or minimize any potential adverse impacts throughout the product's full lifecycle.

Depending on the stage of development and availability of relevant hazard and exposure data, this step's analysis will result in qualitative, semi-quantitative, or fully quantitative estimates of the nature, likelihood, and magnitude of adverse effects on human health and the environment.

Ideally, the early recognition of potential risks, at all stages of the product lifecycle, will provide better options for risk mitigation and management.

EXAMPLES

- Discuss and consider business, legal, and stakeholder issues.
- Determine who is responsible for implementing recommended actions. Preferably, assign a responsible product steward.
- Based on these inputs, decide whether to proceed; and if so, how to proceed.
- Determine additional data needs and initiate data collection, as necessary.
- Establish and implement appropriate risk management, monitoring, compliance, and reporting processes.
- Determine the appropriate product-review cycle.
- Document and report decisions and actions.

B.3.4 Continuous activities

B.3.4.1 Step 9: Communication and consultation

Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles (see Table 5).

Currently the public has only a limited awareness of the science, uses, impacts and implications of new material technology. Not all stakeholder groups that might be interested in or affected by new materials and products applications have the same level of awareness about these issues, nor do they share identical interests in participating in the decision making. The potential benefits and risks must be examined together in order for a realistic discussion about tradeoffs to occur, and much more must be done to raise the knowledge level of all parties to prepare for meaningful participation in decision-making about the current and future role of new materials technology.

Communication and consultation are key elements when dealing with emerging risks. This step/activity/issue takes place in all phases of the overall process and among all the stakeholders, although in a way and scope adapted to the respective stakeholders' roles.

EXAMPLE Examples of advanced materials Risk Communication issues:

— Lack of communication and understanding about advanced materials science among all stakeholders has negative risk perception outcomes;

— Gap in communication within scientific disciplines (social sciences and natural sciences);

— Gap in communication between various regions of the world when it comes to the different regulatory systems in existence;

— Lack of judgment among stakeholders.

EXAMPLE Examples of recommendations to reduce the Risk Communication issues:

— Common set of methods to assess and monitor technologies of advanced materials production;

— Risk communication training courses and exercises for material engineering scientists (e.g. on health and environment impact);

— Information about the benefits of using advanced materials in open communication;

— Integrated risk communication programs for scientists, regulators, industrial developers, media and interested parties;

— International disclosure of risk information;

— Public information on the principles and procedures used to test new materials products.

B.3.4.2 Step 10: Monitoring, review and continuous improvement

This requirement means that the procedures to be established have to ensure — continuous improvement, — effectiveness & efficiency, — sustainability & evergreening (see Table 5).

Monitoring, including the use of early warnings, should be conducted continuously or on a regular basis. As a distinction from the use of early warnings in the horizon screening to identify emerging risks for the first time (step 1), this monitoring covers known risks, with known factors/issues for which it is easier to establish indicators.

The following practices should be taken into account:

— **As-Needed Reviews.** A change in production, processing, or use patterns for the material or application that would alter the lifecycle exposure profile. The acquisition of new data relevant to the risk evaluation for the material or application, such as results from testing initiated by the review team.

— **Regular Reviews.** Analyze any new data on properties, hazards, exposure, or risk management. Decide on any additional data needs and how they are to be met. Determine whether previous decisions on development or deployment of the advanced material application remain valid. Determine any needed changes in the risk evaluation or the associated risk management practices.

— **Adapting Risk Management and Collecting Additional**

Information, as appropriate

— Confirm and continue on-going actions, including the production, use, and marketing of the material or application as well as the current risk management practices,

— Provisionally continue on-going actions, with additional information required,

— Put a provisional hold on current actions, pending generation and review of new information,

— Revise current actions in any part of product development — including the design, production, use, and marketing of the material or application — or revise current risk management practices,

— Terminate current actions (e.g., stop the development, production, or use of a material or application, initiate recall, or pursue other remediation activities).

B.4 Conclusions/Summary

New materials can have a range of new properties and hazards associated with them. Only a comprehensive collection of safety data on a new material can give a better picture. But it is inherit with new materials that a lot is not known in the early stages. It is a real frontier scenario. Many MSDSs (Material Safety Data Sheets) documents are written in a generic form to “cover all bases” because the hazards are not fully realized at first. Some effects are determined put front and quickly such as acute effect such as toxicity or flammability. They can be determined quickly. But some effects can be more chronic and slower to materialize. These can take a time to determine, e.g. organ toxicity or reproductive hazard etc.

For example, at present, data on the effect of nanomaterials on human health is relatively limited. The experiments performed up to date indicate that they may have significant genotoxic potential. However, there are also clear inconsistencies in the literature that make it very difficult to come to firm conclusions. Additionally, limited physicochemical characterization in most reports means that the true nature of the nanomaterials being investigated is unknown. Confusion arises frequently from the selection of test systems.

In the reports [46][47], the consistent approach to management of the emerging risks connected with the introduction of new materials into new generation of products and technologies has been proposed.

B.5 Example - Carbon nanotubes

B.5.1 Introduction

CNTs are one of the fibrous nanomaterials and they are molecular scale manufactured three dimensional forms of carbon, falling into two general groups:

— single walled (SWCNTs) and

— multiwalled (MWCNTs).

CNTs may be present as long, straight fibres or tangled bundles. CNTs can differ in terms of chemical composition; they may be pure carbon or contain metals or other materials, by design, through contamination or as a result of residual catalyst. They can be sixty times stronger than steel, yet six times lighter. CNTs have chemical, physical and bioactive characteristics of considerable research and commercial interest.

Occupational exposure to CNTs can occur:

— during manufacture;

— through incorporation in other materials, e.g. polymer composites, medical applications and electronics

and

— generating nanoparticles in non-enclosed systems;

— during research into their properties and uses;

— cleaning of dust collection systems used to capture nanoparticles;

— as a result of incorrect disposal;

— as a result of accidental spillage.

Emerging data indicates that when CNTs are breathed in they can cause lung inflammation and fibrosis. The type of CNT, its physical form and presence of impurities and surface modifications may influence the severity of the response but at present there is not enough information to identify which factors are of greatest concern. It is also not clear if inhaled CNT have a role in the development of adverse health effects at other sites in the body. There is an increasing body of evidence to suggest that CNTs and other nanomaterials with a long, thin and straight shape (referred to as high aspect ratio nanomaterials or HARN) may be particularly hazardous. However, there are insufficient data to confirm the health consequences of long-term repeated exposure.

There is some evidence to suggest that CNTs may be able to provoke inflammatory reactions in the skin but more information is required to properly understand the conditions of exposure that are required to produce such effects.

In view of the evidence for lung damage and lack of information on the effects of long-term repeated exposure a high level of control is warranted for CNTs.

B.5.2 Lack of standardized physical and chemical information

Many of the chemical and physical properties, along with the health and environmental fate and effects data, are unavailable or unknown for the CNTs. To the extent that such data exist, it usually resides with the CNT suppliers who are unwilling to divulge what they consider proprietary information. Some CNT suppliers will not allow analysis of their material, since it may reveal proprietary information about coatings, surface treatments, impurities, etc.

Today, CNTs are available from a wide variety of sources, and are made using a range of manufacturing methods, that generate materials with widely varying compositions, structures and properties. CNTs are generally supplied as a black powder in the form of two highly agglomerated visible fibrils with less dusting potential than carbon black, or as pellets, which are CNT concentrates encapsulated in a polymer. Presently CNTs in powder form are of a concentration approaching 100 %, typically with 0 % to 4 % impurities. Masterbatch concentrations may range from 5 – 50 wt. %, with 10 – 25 % being typical. Nanocomposite products may contain 0.1 – 10 wt. % CNTs, with 1 – 5 % being typical. Nanotube diameters range from ~ 0.4 to > 3 nm for single-walled nanotubes (SWCNT) and from ~ 1.4 to at least 100 nm for multi walled nanotubes (MWCNT). Nanotube lengths vary from 100 nm to several millimeters, depending on type and supplier.

B.5.3 Fibrous nanomaterials emerging risk

Fibrous nanomaterials such a carbon nanotubes are a promising breakthrough in the field of material science for consumer, industrial and medical purposes. The rise in the current and the expected near-future interest in their use mean that the extent of exposure to these materials is likely to increase. However, due to the fibrous structure of these nanomaterials, parallels have been drawn with asbestos (see Figure B.1) and consequently it is possible that they might fit the fibre toxicological paradigm leading to prolonged inflammatory responses.

Under a microscope (see Figure B.1), some CNTs look identical to asbestos fibres, leading to concerns that they could cause similar health problems. Occupational exposure to asbestos led to widespread lung disease, and cancers known as mesothelioma, in the 20th century.

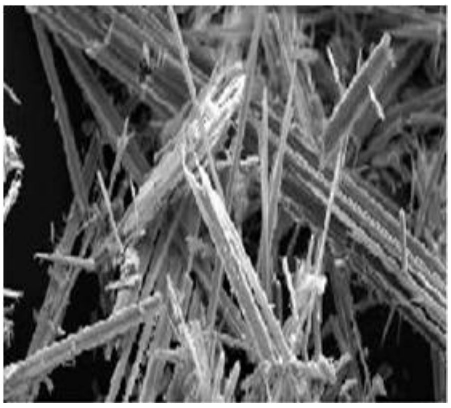

Figure B.1 — Image of asbestos fibres similar to fibrous nanomaterials.

CNTs can be produced using a variety of methods, including arc discharge, laser ablation, high pressure carbon monoxide (HiPco), and chemical vapor deposition (CVD). Each method uses different starting materials and conditions, thus producing different CNT samples that vary with respect to their electro-chemical and physico-chemical properties. Because of this variation, it is logical to hypothesize that the toxicity of each CNT sample could also be different. Therefore, the toxicological assessment of CNT systems is a complicated issue. Toxicity is expected to be CNT specific and generalizations likely cannot be made.

Therefore, the toxicity of CNTs has not yet been fully investigated.

However it is clear that Safety Data Sheets for CNTs that are based on conventional graphite or graphene will not provide suitable adequate information to assess the risk from CNTs.

It is important that everyone potentially exposed to CNTs receives a high standard of information, instruction and training, particularly on controlling exposure and maintaining that control.

To date, there are very few studies in the literature that have focused on the cellular impact of other fibrous nanomaterials as nanofibres, nanorods or nanowires. A number of reports demonstrate that nanorods such as fluorescent lanthanide ortho phosphate and ZnO nanowires demonstrate no significant toxicity based largely on cell proliferation and apoptosis assays [48][49][50]. However, these studies in some aspects are very limited and the data is often inconclusive due to study design. For example, a recent publication reports that ZnO nanowires were not toxic as they broke down into zinc ions in the presence of horse serum, but no cellular-based toxicity studies were performed [50].

In fact a study on mice demonstrated that lung cell injury and inflammation have been attributed to a soluble component, possibly zinc metal ions in atmospheric dust [51][52][53].

The safety evaluation of nanofibres, nanowires and nanorods of differing compositions requires considerably more attention to fill in the current knowledge gaps. In contrast, carbon nanotubes (CNT) have attracted considerably more attention, but despite this, the literature is still conflicting with some investigations reporting cytotoxic effects following the exposure of several cell types to both single walled carbon nanotubes (SWCNT) and multi walled carbon nanotubes (MWCNT) [54][55][56][57][58][59]; whilst others demonstrate very low or insignificant cellular responses [60][61][62][63].

Additionally, few have considered the genotoxic potential of CNT, which is of importance given that asbestos fibers are considered genotoxic as they promote chromosomal and mutations damage.

Given SWCNT have been found to not only penetrate cells, but can also become localized in the nucleus, assessment of their genotoxic potential is of key concern [64]. Furthermore, recent publications have demonstrated that MWCNT not only induce an asbestos-like inflammatory response [51], but also promote the development diseases in more long-term studies [65][66].

The research on CNT toxicity indicates that their physico-chemical characteristics are likely to be central in governing the resultant biological response following exposure. Additional factors such as rigidity are an important characteristic that will influence the final form that the CNT will take under experimental conditions and thus their cellular impact .It should be reminded, that asbestos is a natural fibrous mineral product with high tensile strength, heat and corrosion resistance. For these reasons, asbestos was used in many home products, such as ceiling tiles, floor tiles, insulation, and roof shingles. In the heating and air conditioning trade, asbestos was widely used in underground duct systems, and as a duct joint sealer and a heat shield, by both heating equipment manufacturers and by field technicians during system installation. Although the numbers are dwindling, we still find many homes which have asbestos attached to their duct systems. The inhalation of asbestos fibres usually cause serious illnesses, including malignant lung cancer, mesothelioma (a formerly rare cancer strongly associated with exposure to amphibole asbestos.), and asbestosis (a type of pneumoconiosis).

Long term exposure to asbestos is more likely to cause health problems, as asbestos exists in the ambient air at low levels, which itself does not cause health problems.

Annex C
(informative)

Emerging risks in new production and production networks

C.1 Introduction

This annex deals with the management of emerging risks in new production and production networks. It covers new or changed production technology (i.e. the way products are produced), new or changed production networks (i.e. the external organization of the production – the way external/outside companies are taking part in the production) and changes in the context of the production, all of which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

One example of existing production in new context is drilling in Arctic, which will be used as an example throughout this annex. The example is introduced in C 2.2 and background information is provided in C 5.

This annex is first of all intended for managers and their staff within authorities and companies responsible for managing risks related to new production and production networks where there is an aspect of novelty in the activity/project/process in question, which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

Solutions, reference documents, methods and tools specifically applicable to the handling of emerging risks in new production and production networks are referred to in the relevant process steps of the iNTeg-Risk ERMF in C.3.

The process consists of the following 10 steps arranged in 4 groups:

Horizon Screening:

Step 1: Early warnings – notions.

Pre-Assessment

Step 2: Context and concern;

Step 3: Identification of risk scenarios;

Step 4: Pre-assessment.

Appraisal/Assessment:

Step 5: Analysis;

Step 6: Characterization;

Step 7: Evaluation of tolerability and acceptability;

Step 8: Management and decision (treatment).

Continuous Activities:

Step 9: Communication and consultation;

Step 10: Monitoring, review and continuous improvement.

C.2 Specific topic and example case

C.2.1 General remarks/overview related to the specific topic

For new production and production networks we may distinguish between new production processes and new production networks, as illustrated in Figure 1.

For new production processes the main focus is on how to cope with the potential inherent danger of new production processes or existing production processes used in a new context (e.g. pushing the limits for the production process). An example which will be used throughout this annex is drilling in Arctic, which is really about pushing the limits.

For new production networks the main focus is on the potential danger of outsourcing/subcontracting, which is highly relevant in the offshore petroleum industry in general, including the case of drilling in Arctic, but also in other industries.

Both production processes and production networks can become rather complex and whether or not the risks are emerging or emerged, unexpected scenarios may occur. Thus, it is also necessary to cope with the unexpected, i.e. to be resilient. Therefore, this process for management of emerging risks related to new production and production networks includes considerations of resilience as well as the strengths of the classical risk based approach. One general token of this is the focus on success (contributing success factors – CSFs) as well as focus on risk (risk influencing factors – RIFs) when monitoring the activity.

C.2.2 Introducing the example case - Drilling in Arctic

C.2.2.1 Challenges

The arctic and sub-arctic areas including the Barents Sea pose risks to personnel, the environment and assets. Some of the specific factors or challenges that influence the risks related to petroleum activity in these areas are:

— The harsh and extreme weather conditions such as icing, low temperature, darkness, polar lows;

— The extra remoteness and long distance from shore;

— Lack of infrastructure.

The first challenge may also be part of the contributing causes to accidents, whereas all the challenges make the emergency response in these areas particularly difficult.

C.2.2.2 Accidents

Five accidents have been identified over the last twenty years in the arctic areas, of which two are onshore (pipeline) accidents. The accidents are:

1) Qugruk two well blowout accident, in USA/Alaska in 2012 [67] [68];

2) Kolskaya rig capsize accident, in Russia in 2011 [69];

3) Alaska pipeline oil spill accident, in USA/Alaska in 2006 [70];

4) Nefterudovoz-57 ship collision accident, in Russia in 2003 [71];

5) Usinsk pipeline oil spill accident, in Russia in 1994 [70].

C.2.2.3 Stakeholders

The main responsible stakeholders are the authorities providing license announcements and awards, and the oil companies applying for the licenses for exploration and production of petroleum resources in the arctic areas. These are also the stakeholders responsible for introducing/including an adequate emerging risk management process.

There is a range of other stakeholders at central, regional and local level. These include politicians and public administration, private enterprises and associations, and academia, NGOs, media, etc.

C.2.2.4 Concerns

A major concern with respect to drilling in Arctic is a large oil spill of the type of Exxon Valdez or Deepwater Horizon, or perhaps a situation which is even more difficult to control that has not been experienced or foreseen so far, due to the particular challenges in the arctic and sub-arctic areas.

Background information to the example is provided in C.5.

C.3 Procedure for management of emerging risks

C.3.1 Horizon Screening

C.3.1.1 Step1: Early warnings – notions

Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic, etc.).

The warnings should be properly aggregated, classified and monitored in order to enable to the stakeholders to keep the process of risk maturation under control (see Table 5).

Any changes in production processes or networks should call for suspicion and a state of alertness. New or emerging risks should be actively searched and watched for. Even the underlying processes related to the ability to foresee the unforeseen and to cope with the unexpected need to be monitored. This can be facilitated using the resilience based early warning indicator (REWI) method [72][73][74].

The REWI method is a set of self-assessment measures that provide information to senior managers and safety professionals within an organization about fundamental attributes of organizational resilience. The goals of the method are to provide early warnings to prevent major accidents, and to improve organizational safety and performance in the long run.

The fundamental attributes of resilience covered by the REWI method are called contributing success factors (CSFs) and are: risk understanding, anticipation, attention, response, robustness, resourcefulness/rapidity, decision support and redundancy. For each CSF the REWI method defines a set of general issues contributing to the fulfillment of the goals of the CSF. Measurable indicators are developed for the issues.

The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of "risk maturation" under control. It is necessary to keep track of all warnings, indications, etc. and to monitor any trends. This includes learning from others (industry wide). For SMEs, for which this is a challenging task, their branch organizations should play a key role in providing this kind of learning/warning.

EXAMPLE In the case of drilling in Arctic the authorities and the oil companies need to learn about the accidents that have occurred in the arctic area world-wide. These accidents (see C.2.2) are not particularly novel when it comes to how they occurred, i.e. they could have occurred elsewhere as well; however, there are lessons to be learned about the challenges related to the emergency response, which are particular for the arctic area.

A recommended strategy would be to gradually increase the activity, force the responsible stakeholders to participate about lessons learned and coping with the challenges, and continuously develop best practices for the whole industry on a world-wide basis. This will also include the sharing of new technology between competing companies, both operating companies and contractors.

For other industries the strategy could be to gradually take a new process through different stages, e.g. piloting of the process, including range finding studies to cover what may happen if something goes wrong, and how to react.

C.3.2 Pre-Assessment

C.3.2.1 Step 2: Context and concern

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development (see Table 5).

This step also includes the way stakeholders understand (frame) the emerging risk situation at hand (related to new production processes and new production networks), in addition to what their main concerns are.

Concern assessment relates to the stakeholders' expectations to the emerging risk issue itself (i.e. expectations to the progress/pace of new production processes or production networks) and to the caution/control thereof (i.e. expectations to the process of emerging risk management).

The context should be described including all new influencing factors. It is essential to focus on, analyze and follow-up on any new influencing factors.

An overview of all relevant stakeholders should be prepared including information about their expectations and concerns.

Information and communication about framing and concern is obtained through the continuous activity of emerging risks communication and consultation (step 9). It is essential that both understanding and misunderstanding with respect to the risk situation are captured in dialogue with the stakeholders, so that any misunderstandings can be attempted resolved.

It is also important to inform the stakeholders about the emerging risk management process, so that the stakeholders have trust in the process, even if they might not agree with the final outcome.

The framing and concern assessment should be carried out at an early stage in order to direct the allocation of resources and topics included in the analysis phase (step 5). Big concerns should be accompanied with a fair share of resources in the analysis phase. The dialogue with stakeholders should start as early as possible after a decision has been made to investigate the development of a new production process or production network.

EXAMPLE A major concern with respect to drilling in Arctic is a large oil spill of the type of Exxon Valdez or Deepwater Horizon, or perhaps a situation which is even more difficult to control that has not been experienced or foreseen so far, due to the particular challenges in the arctic and sub-arctic areas. These challenges include new influencing factors such as drifting ice, darkness, polar lows, lack of infrastructure, remoteness, etc. All such new influencing factors that may be of concern need to be identified and included in the subsequent analyses.

The main responsible stakeholders in the case of drilling in Arctic are the authorities providing license announcements and awards, and the oil companies applying for the licenses for exploration and production of petroleum resources in the arctic areas. These are also the stakeholders responsible for introducing/including an adequate emerging risk management process.

There is a range of other stakeholders at central, regional and local level. These include politicians and public administration, private enterprises and associations, and academia, NGOs, media, etc.

The specific concerns depend on the specific stakeholder. In case of the authorities there is a dual interest which is also reflected in the concerns. The authorities responsible for resource management will in many cases promote the opening of new prospective areas in order to be attractive for the oil companies and keep up the activity level in the oil industry, whereas the authorities responsible for health, safety and environment (HSE) need to be cautious with respect to the maturity of the technology for exploration and production in new challenging areas.

For the oil companies it will be a balance between having the opportunity to discover new and potentially large oil or gas reservoirs, and to have necessary mature technology in place to ensure sufficiently safe exploration and production so that major accidents can be avoided. Both being too impatient and too aggressive can prove to be wrong strategies.

The concerns of the public stakeholders are often quite dispersed, and in some cases the concerns are even more related to risk-benefit trade-offs than just the risk itself **Error! Reference source not found.**.

In any case, it will be important to unveil and understand the concerns of all relevant stakeholders, and a key issue here is communication and consultation (step 9). Examples and recommendations for addressing and managing a fair communication process, both seen from the responsible oil company's point of view and the other stakeholders' view are discussed in [76]**Error! Reference source not found.**. Keywords are honesty/trust, fairness and transparency of the risk (risk-benefit) communication process.

C.3.2.2 Step 3: Identification of risk scenarios

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings (see Table 5).

The scenarios may have been experienced (fully matured) or potential based on the information provided by the early warnings (i.e. warning before or after the full scenario has occurred).

In addition to the use of early warnings to identify risk scenarios, a systematic search using the DyPASI method [77] should be conducted if applicable. In particular for existing production processes used in new contexts this should be pursued. The existing risk scenarios can be described/illustrated in bow-ties, e.g. by the use of the MIMAH method [77], and any new/additional scenarios can be added by the use of DyPASI.

All plausible worst case scenarios should be included at this stage, and all the scenarios should be listed.

EXAMPLE In the case of drilling in Arctic blowouts, capsize, ship collision and pipeline accidents have been experienced (see C.2.2). However, there is nothing new about these accident scenarios at the causal side, except that ice and waves contributed to the Kolskaya rig capsize [78]. With respect to the consequences, on the other hand, the accidents show particular challenges when occurring in the remote and harsh environment of the arctic area, e.g. emergency response is more challenging and has led to more severe consequences. The same is the case for highly environmentally sensitive areas with respect to environmental consequences.

It should be possible to build further on the existing knowledge represented by the experienced accidents, by systematic identification of potential scenarios using e.g. the DyPASI method.

C.3.2.3 Step 4: Pre-Assessment

Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified (see Table 5).

Following the ERMF framework the four dimensions in question are technology/technical (T), human/management (H), governance/communication (C) and policies regulation/standardization (R). All the dimensions are in general applicable for new production and production networks.

The list of scenarios from the previous step (step 3) is screened based on the identified, described and assessed dimensions of risk. The criteria for the screening should be clearly described and the process of screening needs to be transparent.

EXAMPLE 1 In the case of drilling in Arctic a hypothetical scenario may be related to specific challenges in communication when drilling far north. In fact, the Electronic Navigation Charts for the Arctic Sea are not very accurate due to ice covering the sea and land. This makes the navigation of ships very difficult thereby making Escape, Evacuation and Rescue (EER) operations challenging [79]. It may postpone the rescue operation dramatically, thereby increasing the consequences.

The scenario may be challenging with respect to all dimensions; however, during the screening process it may turn out that all relevant locations in question for drilling is further south in the arctic area, where the problem of inaccurate electronic navigation may not be an issue. Thus, this particular scenario may be screened out.

EXAMPLE 2 Another example or scenario, which is related to both the human and the technical dimensions, is the risk for personnel whom during evacuation or otherwise have ended in the sea. In such situations the quality of the survival suits (personal protective clothing) is essential. The commonly used requirement, at least in some countries, of a maximum of two hours rescue time (i.e. a maximum stay in the sea for two hours) is based on the capability of the survival suits to prevent the personnel from hypothermia in water temperatures down to 4 °C.

As the water is even colder further north, and the locations are more remote (also for rescue operations) this may require survival suits of better quality, or other solutions that ensure that the risk of survival from the sea is not increased when exploration and production activities are moved towards the Arctic. This is something that is already being considered by some oil companies, and if – as an example – the survival suits during testing can prove to prevent hypothermia for four hours instead of two hours, this particular scenario may be screened out for further consideration, depending on the particular location and infrastructure in the nearby area.

C.3.3 Appraisal/Assessment

C.3.3.1 Step 5: Analysis

The analysis of risk governance models revealed the importance of considering the whole life cycle of (a) product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks (see Table 5).

In this step the considered risks are assessed before being compared to criteria (acceptability, tolerability) in the evaluation phase. Afterward they will be treated.

The starting point is the scenarios from step 4. Most of the scenarios are traditional scenarios for which classical risk assessment tools are applied for likelihood assessment and consequence assessment.

The analysis should focus on the new and unfamiliar scenarios, which include the effect of new risk influencing factors and how these are influencing the likelihood and consequences. Also for these scenarios classical risk assessment tools are applied; however, lack of data will require more extensive use of expert judgments [80].

The analysis may require integrated methods covering technical aspects but also human/organizational and contextual ones (i.e. environment and regulation); however, the integrated methods are not mature in most areas, but a suggested approach for integrated (emerging) risk assessment (IRA) is as follows [81]:

1) Understanding and formalizing the functioning and dys-functioning of the studied system. This step is based on a Functional Analysis (definition of sub-systems, identification of interactions and definition of its principal functions) followed by a Failure Modes and Effects Analysis (FMEA). The stakes involved in IRA could be unavailability, safety or sustainability.

2) Modeling of the system. This step leads to build a model which is used for the subsequent quantification. It represents functional groups, integrates the different failure modes, the events (environmental, regulatory, etc.) and the different impacts on the stakes. As these elements are correlated, the use of Bayesian networks is advised.

3) Quantification of the model. The following data have to be collected: environmental data (for instance, meteorological and hydrological), data characterizing the most critical human actions (human actions description in terms of indicators of their efficiencies – quality of delegation (outsourcing if any), quality of procedures, guides, tools, level of experience, etc. as described in D.2.3.3.1 [81] and organizational analysis to detect for example production pressures or lack of feedback experience). Intrinsic failure probabilities of the components (or sub-systems, depending on the level of details retained for the study), physical phenomena that could impact their functioning. The principal result of this step is a quantified representation of the model which is shared by the actors of the study. When data are lacking, we rely on expert judgment and results of interviews.

4) Use of the model and validation of the results. This step aims at ranking the most critical elements and the risks of the studied system. A set of options could be introduced here and ranked as well. It will lead to a set of recommendations for an improvement of the supervision and/or the reliability of specific material, and identification of the main influencing physical phenomena.

If pertinent, also a thorough assessment of the main concerns identified in step 2 should be conducted. Awareness and proper consideration of stakeholders' perception of risk should be included as an integral part of the concern assessment [82][83].

When subcontracting is an issue, it should be made sure that this is carried out without negative effects on safety. Checklists for safe subcontracting may be used for this purpose [84][85]. The implementation of the previously defined four steps of integrated risk assessment is also described on a chemical field in which outsourcing is involved in D.3.1.5.1 [85].

EXAMPLE In the case of drilling in Arctic the scenarios are related to the traditional accident types such as blowout, capsize, ship collision, pipeline accident, fire and explosion. Causes may be novel, as well as the consequences (including the effect of emergency response), due to new influencing factors – specific challenges in the arctic area such as drifting ice, darkness, polar lows, lack of infrastructure, remoteness, etc.

Those new influencing factors that are of major concern to the stakeholders should be thoroughly assessed, e.g. polar lows which are difficult to forecast. Also, concerns such as a large oil spill of the type of Exxon Valdez or Deepwater Horizon should be thoroughly assessed (e.g. to what extent it is possible to experience and/or control an accident such as Deepwater Horizon if occurring in the arctic area).

Subcontracting is used to an extreme degree in drilling operations. The drilling rig owner provides most of the crew, whereas the operating oil company only have one or two persons (company men) on-board. Risks associated with subcontracting should be assessed.

C.3.3.2 Step 6: Characterization

Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization / classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance) (see Table 5).

Characterization of the knowledge about cause-effect relationships can assist in designing both risk management strategies and in planning for the participation of stakeholders in the risk handling process. A distinction can be made between simple, complex, uncertain and ambiguous risks, as suggested in the IRGC risk governance framework [86].

EXAMPLE Drilling in Arctic may be considered an uncertain risk due to lack of clarity of several issues, such as harsh and extreme weather conditions (icing, low temperatures, darkness, polar lows, etc.), extra remoteness and long distance from shore, lack of infrastructure, knowledge related to oil in/under/on ice, etc.

This implies, according to IRGC [86], that the risk management strategy should be precaution-based and resilience-focused, with the intension being to apply a precautionary approach to ensure reversibility of critical decisions and to increase a system's coping capacity to the point where it can withstand surprises.

The precautionary approach in the case of drilling in Arctic could be, as some oil companies have decided, to only drill for gas and not for oil, due to the much larger uncertainties and challenges with oil leak on ice compared to gas leak.

C.3.3.3 Step 7: Evaluation of tolerability and acceptability

In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions.

Specific or complementary approaches/rules should be considered in this phase (see Table 5).

The most controversial part of handling risks refers to the process of delineating and justifying a judgment about the tolerability or acceptability of a given risk [87]. The term **'**tolerable' refers to an activity that is seen as worth pursuing yet it requires additional efforts for risk reduction within reasonable limits. The term 'acceptable' refers to an activity where the remaining risks are so low that additional efforts for risk reduction are not seen as necessary **Error! Reference source not found.**.

Different principles for acceptability should be considered, e.g. ALARP, MEM, GAMAB [88], or a combination of these. A combination of an absolute criterion and a relative criterion may be relevant in some cases. Lack of data should be anticipated and taken into account when deciding on the acceptability principles.

The purpose of risk evaluation is to assist in making decisions, based on the outcomes of the risk analysis. Decisions should take account of the wider context of the risk and include consideration of the tolerance of the risks borne by parties other than the organization that benefit from the risk. Decisions should be made in accordance with legal, regulatory and other requirements [3].

EXAMPLE In the case of drilling in Arctic the wider context of the risk is extremely important. It is not sufficient that an oil company only considers its own well or project in isolation and it is not even sufficient that the responsible authorities in one of the countries bordering the arctic region consider their own development plans in isolation. It needs to be a consolidated effort for the whole region. One mistake by one country or one oil company may hamper further development for the whole region.

The evaluation of tolerability and acceptability should not simply be a game of numbers, i.e. demonstrating that a certain risk metric from the risk analysis meets the predetermined risk acceptance criteria. Additional considerations, e.g. evaluation of the relative change to previous projects, should be taken into account, only allowing for a stepwise or gradual development.

C.3.3.4 Step 8: Management and decision (treatment)

Based on the previous steps results, decisions are made to manage the risk in order to keep it at an acceptable or tolerable level.

The approaches applied in emerging risk management should

— integrate both qualitative and quantitative data,

— combine different type of criteria,

— carefully address compensation,

— consider variations/alternatives in risk scenarios,

— treat uncertainties,

— help make robust decisions (see Table 5).

Risk management involves the design and implementation of the actions and remedies required to avoid, reduce, transfer or retain the risks. It includes the generation, assessment, evaluation and selection of appropriate risk reduction options as well as implementing the selected measures, monitoring their effectiveness and reviewing the decision if necessary.

EXAMPLE In the case of drilling in Arctic the risk is not necessarily acceptable unconditionally, meaning that in certain circumstances (due to weather, icing, etc.) drilling (or the subsequent production process) may need to be stopped. The criteria for this should be predefined to the extent possible, and the threshold for a halt should possibly be lowered for emerging risks compared to conventional risks due to larger uncertainties.

C.3.4 Continuous activities

C.3.4.1 Step 9: Communication and consultation

Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles (see Table 5).

Communication and consultation are key elements when dealing with emerging risks and it may in general be recommended to:

— Arrange a formal hearing process (whether or not this is a mandatory requirement);

— In parallel; plan, prepare and perform an informal communication process;

— Communicate the process itself, e.g., by the use of progress reports/videos on the web;

— Consider how to deal with specific well-known risk communication challenges.

Well-known risk communication challenges (last general recommendation above) should be assessed prior to, during and after a project or activity involving emerging risks. One such assessment method is the risk communication assessment framework – RICAF [76].

The use of the RICAF method is beneficial for the responsible entity in order to document how challenging issues were satisfactorily dealt with, or suggestions for improvements in those cases where risk communication issues were not satisfactorily dealt with.

An external evaluation of the risk communication process should also be considered. One example of such an external evaluation, including the methodology chosen, can be found in Renn et al. **Error! Reference source not found.**.

EXAMPLE In the case of drilling in Arctic a formal hearing process is useful for two reasons. First, most of the relevant stakeholders are identified by showing an interest to participate in the hearing process. Second, the stakeholders can provide input to the necessary studies to conduct, thereby also capturing their main concerns.

As the activity moves further north, far from shore, it is not obvious who the local stakeholders are, and it may be necessary to perform some kind of outreach activity and carry out informal communication processes, since all stakeholders may not be well organized.

C.3.4.2 Step 10: Monitoring, review and continuous improvement

This requirement means that the procedures to be established have to ensure — continuous improvement, — effectiveness & efficiency, — sustainability & evergreening (see Table 5).

Monitoring, including the use of early warnings, should be conducted continuously or on a regular basis. As a distinction from the use of early warnings in the horizon screening to identify emerging risks for the first time (step 1), this monitoring covers known risks, with known factors/issues for which it is easier to establish indicators.

Also in this step the resilience based early warning indicator (REWI) method [72][73][74] referred to in step 1 is relevant. However, additional risk indicator methods can be considered for the purpose of monitoring [73][89][90].

The whole emerging risk management process (steps 1-10) should be regularly reviewed and continuously improved.

EXAMPLE In the case of drilling in Arctic it is particularly important to apply a gradual/stepwise approach to the exploitation of the arctic area, with a maximum of learning and improvement from the previous/last development project, irrespective of company or country. The continuous improvement needs to be an industry wide process with a shared responsibility between all the involved oil companies and countries/ authorities. It could be an idea to monitor the degree to which the involved companies and authorities know and have learned from incidents occurring in other companies/other continental shelves as they move north.

C.4 Conclusions/Summary

A process consisting of ten steps for management of emerging risks in new production and production networks has been presented. It covers new or changed production technology (i.e. the way products are produced), new or changed production networks (i.e. the external organization of the production – the way external/outside companies are taking part in the production) and changes in the context of the production, all of which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

C.5 Example – Drilling in Arctic

C.5.1 Introduction

This description covers needs and opportunities, and status of offshore petroleum activity in the arctic. It is to a large extent based on Basharat [91].

The Arctic Sea (also known as the Arctic Ocean) located in the Northern Hemisphere (75° 00° N latitude and 00° 00° longitude) of the globe and partly covered by sea ice throughout the year, is the smallest and shallowest ocean as compared to the world's five major oceans. The sea ice, formed when the sea water freezes, of the Arctic sea varies in thickness depending on the wind and ocean currents which can also compress the ice to form pack ice. The size of the sea is almost equal to the size of Russia having roughly a circular basin. The Arctic Sea is surrounded by the lands of North America, Greenland, and Eurasia and by a number of islands. The Arctic Sea includes the seas of Barents, Beaufort, Chukchi, East Siberian, Greenland, Kara, Laptev, White and Bays of Hudson and Baffin [92]. The geographical location of the Arctic Ocean and its seas is shown in Figure C.1.

Figure C.1 — Geographical location of the Arctic Sea [92]

The general climatic condition of the Arctic Sea is characterized by dark nights, cold and stable weather conditions during winter time, and foggy weather and weak snow with cyclones in summer time. Maximum snow is normally encountered during the months of March or April making snow cover (20 cm to 50 cm) over the frozen ocean. Petroleum and gas are a few resources out of many which are abundant in this region [92].

The sub-arctic area is a geographical area just south of the Arctic Circle. It covers most of Canada, Alaska, Siberia, northern Mongolia and Scandinavia (includes kingdom of Denmark, Norway and Sweden). The sub-arctic region (50° N and 70° N latitude) is characterized by very cold winters (below - 30 °C) and short and warm summers (30 °C) [93].

C.5.2 Needs and opportunities

In the middle of the 21st century, the world will face doubling of energy use [94]. The overall utilization of natural gas and oil will increase by 25 % and 20 % respectively in the next 25 years [95].

There is a dire need for the exploration of hydrocarbons due to the rising energy demands, high oil prices and concerns over energy security. In order to meet these demands successfully, the offshore petroleum industry is moving further north to the Arctic area.

The Arctic Sea has enormous petroleum reserves amounting to almost 10 % of the world's known conventional petroleum resources. Onshore oil production in the Arctic Sea began in the 1940s while offshore production started in the 1960s, but still, most of the Arctic area including the Barents Sea is unexplored. Russia, Norway, USA, Canada and Greenland are the main oil producing countries in the Arctic area [94].

C.5.3 Status of offshore petroleum activity in the Arctic

C.5.3.1 Russia

According to Koivurova and Hossain [96], abundant oil and gas reserves (equivalent to 100 billion tons of oil) for Russia are located in the Arctic Sea. About 70 trillion cubic feet of gas is estimated to be buried under the soils of the Barents, Pechora and Kara Seas. The Barents Sea alone accounts for 22.7 billion tons of oil and gas. The oil and gas activities in Russia may start in the Prirazlomnoe oil field, the Medynsko-Varandey area, and the Kolokolmor and Pomor area. Prirazlomnoe oil field, located in the Russian Arctic Continental shelf, is the pilot oil field and is a source of attraction for oil and gas companies who intend to operate in the Arctic Sea. The Medynsko-Varandey area is located in the south-eastern part of the Barents Sea while the Kolokolmor and Pomor area are located in the southern part of the Pechora Sea. An estimate of 300 million tons of oil is made which can be extracted from the Kolokolmor and Pomor area [96].

C.5.3.2 Norway

Norway has abundant reserves of oil (10.2 billion barrels) and gas while on average approximately 3 million barrels of oil are produced every day and are exported to the markets of UK, France, Germany, the Netherlands and the US. When it comes to the Norwegian Arctic Sea, oil and gas activities are only limited to the Barents Sea [96]. It is estimated that 7 billion barrels of oil equivalents are present in the Norwegian part of the Barents Sea which is almost equal to the sale value of NOK 3000 billion [97]. The Barents Sea has 90 exploration and appraisal wells so far and most of them are in the Hammerfest Basin [98]. 39 production licenses and 61 exploration wells have been awarded in the Norwegian Arctic sector since 1980. The first gas field of Snøhvit (by Statoil) was discovered in 1984 while in 2000 the oil field of Goliat (by Eni Norge) was discovered. It is said that the Goliat field has reserves of 240 million barrels in oil equivalent [99]. Reserves of oil have also been found in the Havis prospect with an estimate of 200 to 300 million of oil equivalents as well as in the Skrugard prospect of the Barents Sea with an estimate of 250 million recoverable oil equivalents in this field [100]. The reserves of oil and gas in the Obesum area of the Norwegian Barents Sea were also discovered in 2008 and 2009 [101][102].

C.5.3.3 USA

Most of the hydrocarbon production in Alaska (US) is in the Prudhoe Bay area. Three major oil fields in this area are Endicott, Point McIntyre and Northstar oil fields. The Endicott oil field is connected to onshore Prudhoe Bay oil field while the Point Macintyre oil field produces oil from the East Dock off the Prudhoe Bay oil field. The Endicott oil field contained 582 million barrels which is greater than the containment of oil (400 million barrels) in the Point McIntyre oil field. The Northstar oil field started production in 2001 and presently producing 65,000 barrels a day. The oil from this field is transported through pipelines which are buried very deep to minimize the effects of ice [96].

C.5.3.4 Canada

According to the estimates made in January 2008 by Oil and Gas Journal (OGJ), 179 billion barrels of oil reserves are present in Canada. The first Arctic well in Canada was drilled in 1961/1962 and the oil exploration and production continued till date. Currently, three oil fields namely Terra Nova (300 to 400 million barrels oil), White Rose (250 million barrels oil) and Hibernia (615 million barrels oil) are in operation in the part of the Arctic belonging to Canada [96].

C.5.3.5 Greenland

Some of the Greenland Basins and provinces have more than 50 trillion cubic feet of natural gas [95]. The exploration of hydrocarbons in Greenland started in the beginning of the 1970s in Greenland. Different areas were drilled in the following years but oil was found only in the well of Kangâmiut-1 and on the peninsula of

Nuuussuaq by a Canadian company. The offshore petroleum activity in Greenland is moving forward gradually and it is hoped that hydrocarbons will be found in the area [96].

Annex D
(informative)

Emerging risk policies

D.1 Introduction

This part of the CWA deals with emerging risks within the area of policies and regulation. It covers the issue of lack of regulation, the issue of adjustment to new regulations as well as proper understanding of complex regulations related to emerging risks.

One example in the area of emerging risk policies is the regulation on European level for nanotechnology-based products, nanoparticles and nanotechnology-related production processes, which will be used as an example throughout this part of the CWA. The example applied will cover all regulatory fields relevant for nano-regulation, which are workplace safety, chemicals and various products and industrial and environmental law [103]. The example is presented in D 2.2.

The main goal of the iNTeg-Risk project [1] is to improve the ability of the EU industry, society and authorities to identify, monitor and manage emerging risks. The project should improve chances of market success of European innovation and new technologies developed in the EU, which has to be supported by specific emerging risk related policies. Its particular concern is the issue of public trust and confidence in the research efforts promoted by the EU, e.g. in the technologies and solutions/innovations developed within European projects. These technologies and solutions should be well accepted by the European society and should be accepted and perceived as a good and just investment of the EU taxpayers' money. On the other hand, mistrust, or lack of confidence, lack of fairness and/or transparency of innovation can damage or even stop the innovation in a particular field. A common EU-regulation on nanotechnology may contribute to maintaining a level playing field across member states, reduce cost for evaluation of new nanomaterials and enhance the response to incidents.

This document is first of all intended for managers and their staff within authorities and companies responsible for managing risks when e.g. it is in question if related emerging policies are existing, are applicable or if and how processes can be adjusted to these new regulations. These uncertainties and the way decision-makers on company level are dealing with them may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

Especially SMEs have fewer capabilities and resources to manage safety issues and usually require additional support. Large companies, subcontracting SMEs and having high capabilities for risk management, can therefore provide a clear motivation for the implementation of an emerging risks safety culture and required adjustment to regulations in these companies. The absence or poor communication of risks and safety measures especially to SMEs as well as the ignorance or poor understanding of safety regulation requirements by SMEs can cause a growth of emerging risks and the probability of accidents in these companies [104].

Solutions, reference documents, methods and tools specifically applicable to the handling of emerging risks when lacking regulation or the challenges in implementation of policies and regulations are referred to in the relevant process steps of the ERMF in Section D.3.

The process consists of the following 10 steps arranged in 4 groups:

Horizon Screening:

Step 1: Early warnings – notions.

Pre-Assessment

Step 2: Context and concern;

Step 3: Identification of risk scenarios;

Step 4: Pre-assessment.

Appraisal/Assessment:

Step 5: Analysis;

Step 6: Characterization;

Step 7: Evaluation of tolerability and acceptability;

Step 8: Management and decision (treatment).

Continuous Activities:

Step 9: Communication and consultation;

Step 10: Monitoring, review and continuous improvement.

D.2 Specific topic and example case

D.2.1 General remarks/overview related to the specific topic

For new emerging risks related to policies and regulations, mainly the following issues can be identified.

1) There might be a lack of (specific) regulation, which puts decision-makers in a situation with a high level of uncertainty on how to manage the risks they are facing.

2) There might be a lack of resources and capabilities by decision-makers (especially for SMEs) in understanding complex regulative environments, even hampered by different non-harmonized regulations on national level.

3) There might be a lack of understanding by decision-makers (especially for SMEs) on how to implement new regulations they have to adjust their processes to.

Another aspect to be considered is the conflict of market and safety policies: In societies as risk-averse as Europe’s, lack of confidence in the ability of industry and authorities to identify and manage emerging risks may prolong time to market or prevent success of new technologies. If the technology is concerned by both EU market policy and the national safety policies, possible conflict of policies may arise, and it is often worsened due to the lack of commonly accepted approaches to management of risks (different approaches, fragmentation over countries, branches, sectors, etc.). The EU therefore urgently needs a unified, consensual, validated and operational framework that comprises principles, guidelines and tools for managing multiple risks related to policies and regulations, readily available to all stakeholders. The framework should help to

— understand the interdependencies among multiple risks and

— properly manage these multiple risks, not one-by-one, but simultaneously, in an optimized manner.

An example which will be used throughout this part of the CWA is the regulation on European level for Nanotechnology-based products, nano particles and nanotechnology-related production processes.

D.2.2 Introducing the example case - Nano-regulation

Nanotechnology-based products, nano particles or nano production processes are in general subject to existing law, especially regarding protection of workers, the registration of chemicals, product safety, the licensing of operational plants and the protection of the environment. However, for this new technology it is questionable whether the existing legislative frameworks are adequate or whether regulatory gaps are arising from new products, materials or process characteristics. In the context of nanotechnology the particular question is, to what extent the mainly substance-related regulations can meet the size-specific properties of nanomaterials.

Most important regulatory fields also relevant for nano-regulation are:

— Workplace safety;

— Chemicals and various products;

— Industrial and environmental law.

In its communication published in 2004 [105] the European Commission first time defined the goals of the European policy on nanotechnology, trying to establish an environment, which would be conducive to innovation as well as guarantee a safe and responsible development of this new technology. In this communication the Commission stressed the importance of appropriate and timely regulation, which is one of the main issues also addressed in this CWA.

However, after having reviewed existing legislative frameworks (as planned in the action plan from 2005 [106] the Commission stated in 2007 that a lack of data on health and environmental risks would be the crucial problem, but that the legislative frameworks in place were, in principle, suitable and adequate, although weaknesses in implementation measures and with regard to the implementation process of existing regulatory mechanisms have been identified [107].

In 2009 the European Parliament contested this view and asked the Commission to deal with a number of measures, including the drafting of new regulations [108]. Concerning the above mentioned regulatory fields, the following was demanded by authorities (mainly European Parliament), supported by some scientists.

— **Workplace safety**: It was requested that the existing health and safety regulations had to be amended and accordingly, they should be oriented towards the risk exposure of employees [109].

— **Chemicals and various products**:

  - **Chemicals, biocidal products and plant protection products**: It was requested that a substance which has been registered in its macroscopic (bulk) form and which is going to be manufactured in nano form, must be updated regarding its relevant information [110]. For CLP regulation separate labeling and classification of nanomaterials was requested [111]. However, for plant protection products neither the currently applicable plant protection directive contains any nano-specific provisions [112] and there are no plans for any separate labeling of nanomaterials. In addition, the established risk assessment for biocidal products was considered as not adequate for provision of nano-specific hazards [113].

  - **Cosmetics, medical devices and foodstuffs:** Specific regulation efforts designed to explicitly incorporate nano-specific regulations do exist for products in cosmetics, medical devices and foodstuffs [103]. An additional aspect in nanomedicine concerns products which cross the boundaries of different regulatory schemes, which is a particular problem for cross-cutting technologies as nanotechnology [114][115].

— **Industrial and environmental law:** For this regulatory field, the European Parliament mainly emphasized on the need to adapt EU waste legislation [108].

As a conclusion, what could be observed throughout the last years for nano-regulation was that the European Commission considered the legal frameworks for nanotechnologies as being suitable and adequate, whereas the European Parliament, as a primary driving force, was requesting further regulatory changes leading to amendments e.g. for chemicals, cosmetics and foodstuffs [103]. Still there seems to be a long road to go as not only activists were asking for a better EU nano regulation when researchers were publishing their results related to specific issues, e.g. findings from Swedish researchers that the amount of silver in sewage works sludge is rising [116].

As the Observatory NANO confirms in its 3rd report on developments in nanotechnologies regulation and standards, “the demand for nano-regulation remains high on the agenda, as the responsible development of nanotechnologies is considered instrumental to their success and the activity in this area is rather intense. So far regulation is still based essentially on existing provisions, albeit under revision to comply with the specificity of nanotechnologies”. Furthermore it is stated that considering “the existing gaps in scientific knowledge, the progress of research and the increasing number of applications, the different positions and stances of regulatory agencies around the world, the settlement of this matter cannot be expected in the short term and in any case it will remain a dynamic process. An appropriate balance between hard and soft regulation still seems the most viable short-term option [117]. Observatory NANO mentioned the following factors making the implementation of effective regulatory schemes for nanotechnologies “complex and cumbersome” [117]:

— The wide variety of materials and applications;

— The limited knowledge on the toxicity of nanomaterials;

— The proprietary nature of information on novel nanomaterials;

— The lack of harmonized standards or guidance;

— The issues related to classification of nanomaterials.

The fact that many European countries, in particular those more active in nanotechnologies, have started their own activities on nano-regulation, especially France [118][119][120][121], Germany [122][123][124], Switzerland [125][126], the Netherlands [127][128] and the UK [129][130][131][132][133][134] is not contributing to the goal of a harmonized EU approach towards nano-regulation in the first place.

However, apart from the probing of extendibility of existing regulatory schemes on European level, voluntary measures have been endorsed by public bodies and industry to build confidence and trust, promote safety or gather data. This approach can be seen as a result of the challenges the regulatory environment is imposing for authorities as well as for the industry and that there is the strong need to reach highest possible acceptance of nanotechnologies by broader public in order to introduce nano-enhanced products successfully to the market.

Therefore, regulation in the area of nanotechnology remains an important issue which is far from being settled. As observatory NANO states: “The evolution of nano-regulation can influence the path of the development of nanotechnology-related product and processes” [117], but certainly has to do that in a way, which enables innovation and on the same go protects society and the environment.

D.3 Process for management of emerging risks

D.3.1 Horizon screening

D.3.1.1 Step1: Early warnings – notions

Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic, etc.). The warnings should be properly aggregated, classified and monitored in order to enable to the stakeholders to keep the process of risk maturation under control (see Table 5).

Emerging risks related to policies and regulations need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic). New or emerging risks should be actively searched and watched for. The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of risk maturation under control.

EXAMPLE In the case of nano-regulation the early warnings need to be collected by monitoring the developments in industry and the discussions among scientists. It has to be identified regulatory problems developers, producers and users of nano-enhanced products are facing in order to adequately react on that with legislative measures. For this purpose active monitoring of scientific publications and on-going discussions in industry needs to be done by an independent and reliable public institution, initiating legislative processes that address the difficulties in existing (or non-existing) policies and regulations related to nano.

D.3.2 Pre-Assessment

D.3.2.1 Step 2: Context and concern

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development. (see Table 5).

This step includes the way stakeholders understand (frame) the emerging risk situation at hand (related to new technologies), and what their main concerns are. This step is closely related to step 9 (Communication and Consultation). Step 2 results in an effort to resolve all misunderstandings with respect to the emerging risk management process.

The expectations mentioned above should be aimed towards the introduction of a new technology and to the caution/control thereof (i.e. expectations to the process of emerging risk management) in order to avoid potential societal risks.

An overview of all relevant stakeholders should be prepared including information about their expectations and concerns.

EXAMPLE Concern assessment can be supported by stakeholder dialogues, interviews and surveys. However, in the case of nano-regulation an institutionalized context and concern assessment is usually being carried out during public consultation phase, way before a new regulation or new laws are coming into force. European institutions are providing this kind of stakeholder involvement quite frequently, but it is obvious that not all concerned stakeholders are participating in such consultation phases, due to lack of resources or ignorance about the procedures and the possibility to get involved. Therefore, means for stakeholder involvement should be improved and the currently running institutionalized consultation phases should be considered as one instrument to gather concerns from different stakeholders, but should be supported by dedicated stakeholder dialogues, interviews and surveys.

D.3.2.2 Step 3: Identification of risk scenarios

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings(see Table 5).

All possible emerging risk scenarios, the ones that have already been experienced and possible (plausible worst case) scenarios identified in early warning stage should be listed. Step 3 results in a list of possible scenarios that should be considered through the following ERMF process. This step of ERMF process should be carried out by an expert on the specific issues, e.g. (senior) risk assessors. Inputs/Information from affected stakeholders should also be sought in respect to possible approaches how to tackle the issue.

EXAMPLE In case of nano-regulation, the main emerging risk scenarios are related to the above mentioned emerging risk issues identified.

1) Lack of (specific) regulation, which puts decision-makers in a situation with a high level of uncertainty on how to manage the risks they are facing.

2) Lack of resources and capabilities by decision-makers (especially for SMEs) in understanding complex regulative environments, even hampered by different non-harmonized regulations on national level.

Lack of understanding by decision-makers (especially for SMEs) on how to implement new regulations they have to adjust their processes to.

D.3.2.3 Step 4: Pre-Assessment

Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified (see Table 5).

Scenarios identified in the previous step should be screened, based on the identified, described and assessed dimensions of risk. Information that is sought for the pre-assessment step should consist of advice from affected stakeholders on what assessors or decision makers are likely to encounter/expect.

EXAMPLE A tool for such a pre-assessment for an emerging risk is RiskEars offering the possibility to create a so called RiskSpark, which is a short wrap-up of the emerging risk issue and its consequences done by an expert in the area, serving as input for decision makers on how to deal with the risk.

Bearing in mind the risk issues identified in step 3, in the case of nano-regulation as well as in any case of emerging risks related to new policies and regulations, the pre-assessment step has to be done by an expert having a high level of understanding about the regulatory environment and the legislative frameworks existing, as well as on operational aspects regarding production processes etc., which decision-makers on company level (especially SMEs) are dealing with. The expert carrying out the pre-assessment for emerging risks related to nano-regulation has to put emphasis on various aspects. One of the most important is the issue of uniformed decision being taken, when existing regulation is applied for nanotechnology, without having carefully assessed their applicability.

D.3.3 Appraisal/Assessment

D.3.3.1 Step 5: Analysis

The analysis of risk governance models revealed the importance of considering the whole life cycle of a product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks (see Table 5).

In this phase, scenarios identified in step 3 and pre-assessed in step 4 are to be considered as fully emerged issues (risks) and are to be assessed and treated accordingly. Therefore, step 5 results in a detailed assessment of the emerging risk issue, of which it sets as a basis for the following steps. Expert on the specific issue should carry out a detailed analysis, taking into account information provided in step 3 and step 4. At this point, further involvement of stakeholders e.g. government or communities possibly affected by the issue, should be considered.

EXAMPLE For the case of nano-regulation, in step 5, the relevant identified risk issues from step 3.

1) Lack of (specific) regulation, which puts decision-makers in a situation with a high level of uncertainty on how to manage the risks they are facing.

2) Lack of resources and capabilities by decision-makers (especially for SMEs) in understanding complex regulative environments, even hampered by different non-harmonized regulations on national level.

3) Lack of understanding by decision-makers (especially for SMEs) on how to implement new regulations they have to adjust their processes to.

After passing through a first pre-assessment in step 4 it has to be analyzed in detail. The expert needs to address the respective risk issue, which is relevant for the specific case he is carrying out his analysis for. He may have to deal with example number 1), 2) or 3) of the above mentioned risk issues at a time.

D.3.3.2 Step 6: Characterization

Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Thus better decisions can be taken. Risk categorization/classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance) (see Table 5).

Risk characterization, in short, can be viewed as collecting and summarizing all relevant evidence necessary for making an informed choice on tolerability or acceptability of the risk in question and suggesting potential options for dealing with the risk from a scientific perspective [2]. Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization/classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance).

EXAMPLE The challenging aspect for the case of nano-regulation was already briefly mentioned above: The issue of uninformed decisions, possibly leading application of existing non-nano-specific regulations, without having carefully assessed their applicability. As the description of step 7 states, distinguishing between scientific facts and policy orientations is the key to make appropriate decisions in further steps. This applies even more for the case of nano-regulation.

D.3.3.3 Step 7: Evaluation of tolerability and acceptability

In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions. Specific or complementary approaches/rules should be considered in this phase (see Table 5).

Especially for emerging risks related to policies the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions. Specific or complementary approaches/rules should be considered in this phase.

Following what was already mentioned for step 2, a dedicated consultation with concerned stakeholders should be carried out in order to assess tolerability and acceptability of risk mitigation measures to be taken. For regulations and policies there are institutional procedures to be followed for this step. However, facing the issue of emerging and possibly not very well understood risks, additional stakeholder involvement should be considered.

EXAMPLE For the case of nano-regulation, the above mentioned stakeholder involvement is particularly challenging as regulation in the area of nanotechnology affects various sectors. So the tolerability and acceptability assessment has to take into account many different views and interest. One of the biggest concerns with respect to new nano-regulations is the successful introduction of innovations by the European nanotechnology related industry, which has to be enabled to rapidly operate according to the state of the art of nano-regulation and thus increase its competitiveness.

D.3.3.4 Step 8: Management and decision (treatment)

Based on the previous steps results, decisions are made to manage the risk in order to keep it at an acceptable or tolerable level.

The approaches applied in emerging risk management should

— integrate both qualitative and quantitative data,

— combine different type of criteria,

— carefully address compensation,

— consider variations/alternatives in risk scenarios,

— treat uncertainties,

— help make robust decisions (see Table 5).

Assuring relevant expertise and knowledge that is crucial for successful completion of decision making process is one of the main purposes of this step.

EXAMPLE For the management and decision making step different decision makers are to be considered in case of nano-regulation. First, it is the authorities introducing regulations and taking decisions on adapting existing regulations, e.g. in order to harmonize different existing regulation, or to introduce new ones. Second, the decision makers on company and industry level have to deal with the lack of regulations or new regulations being introduced. The steps above should help both types of decision-makers to take appropriate and informed decisions.

D.3.4 Continuous activities

D.3.4.1 Step 9: Communication and consultation

Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles (see Table 5).

Communication and consultation are increasingly important elements of dealing with emerging risks and are taking place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles.

For new policies and regulations, as mentioned several times already, institutionalized communication and consultation processed have been established. However, as mentioned earlier, too, these institutionalized consultations should possibly be extended and enriched with other instruments for stakeholder involvement and means for communication when the topic is related to an emerging risk, for which some stakeholders may not even be aware of that it is of their concern.

EXAMPLE Having learned from the introduction of the example in section D2.2 nano-regulation in Europe is to be considered as a very dynamic process. This puts high relevance on step 9, dealing with communication and consultation as a continuous activity. The assessments made and the decisions taken with respect to existing or new policies and regulations for production and handling of nanotechnology have to be continuously checked as (1) existing gaps in scientific knowledge, (2) the progress of research and (3) the increasing number of applications as well as (4) the different positions of regulatory agencies around the world are under on-going change and will continue to be so for the next years.

D.3.4.2 Step 10: Monitoring, review and continuous improvement

This requirement means that the procedures to be established have to ensure

— continuous improvement,

— effectiveness & efficiency,

— sustainability & evergreening (see Table 5).

The whole emerging risk management process (step 1-10) should be monitored, regularly reviewed and continuously improved. As a distinction from the use of early warnings in the horizon screening to identify emerging risks for the first time (step 1), this monitoring covers known risks, with known factors/issues for which it is easier to establish indicators.

EXAMPLE For the specific case of nanotechnology, iNTeg-Risk project [1]-developed a self-assessment tool, which contributes to this step of the ERMF. The self-assessment is designed for companies producing or working with nanomaterials and is covering the following knowledge-related aspects, which have to be regularly checked in order to understand if a company and its employees have the required level of knowledge to handle nanomaterials as foreseen by the regulatory bodies and the respective legislative frameworks:

— General Requirements, Scope, Procedure, Documentation;

— Staff-Related Requirements;

— Organizational Requirements;

— Risk Assessment and Monitoring Requirements;

— Requirements Related to Risk Treatment and Risk Communication.

This approach can of course also be applied to previous steps of the ERMF process, e.g. on early warnings or concern and context assessment.

D.4 Conclusions/Summary

The ten steps of the ERMF procedure have been applied for the general case of nano-regulation in Europe. Although a more specific example as being used in the other informative Annexes of this document can provide more details about how to apply the ERMF steps practically. Annex D has underlined the importance of the ERMF procedure as a general concept, applicable for various cases, even for the difficult case of emerging risks related to policies and regulations. The practical application cannot be described in such detail, as the risk issues that have been identified in step 3.

1) Lack of (specific) regulation, which puts decision-makers in a situation with a high level of uncertainty on how to manage the risks they are facing.

2) Lack of resources and capabilities by decision-makers (especially for SMEs) in understanding complex regulative environments, even hampered by different non-harmonized regulations on national level.

3) Lack of understanding by decision-makers (especially for SMEs) on how to implement new regulations they have to adjust their processes to.

Although all ten steps are important and also for this example of nano-regulation none of them can be skipped or neglected, most relevant steps for this case as considered by the authors are step 1 (Early warnings – notions), addressing the rapid progress of research and the increasing number of applications (also step 9 and 10 on continuous improvement are contributing to this aspect), and step 8 (Management and decision (treatment) addressing the broad impact especially for decisions taken by regulators, affecting business and innovation processes for numerous stakeholders.

Annex E
(informative)

Emerging risks due to uncertainties in measurement and characterization

E.1 Introduction

This annex deals with the management of emerging risks due to the uncertainties of measurements and characterization. It covers new or changed uncertainties in measurement and characterization (i.e. the way new materials, technologies and processes are tested and characterized), all of which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large.

One example of emerging risks due to the uncertainties of measurements and characterization is "Extreme Storage of Hazardous Materials", which will be used as an example throughout this annex [135]. The example is introduced in E.2.2 and background information is provided in E.5.

This annex is first of all intended for managers and their staff within authorities and companies responsible for managing risks related to testing procedures, which may impose foreseen or unforeseen new or emerging risks to the responsible company, to the partner companies or to the society at large. Solutions, reference documents, methods and tools specifically applicable to the handling of emerging risks due to uncertainties of measurements and characterization are referred to in the relevant process steps of the iNTeg-Risk ERMF in E.3.

The process consists of the following 10 steps arranged in 4 groups:

Horizon Screening:

— Step 1: Early warnings – notions.

Pre-Assessment:

— Step 2: Context and concern;

— Step 3: Identification of risk scenarios;

— Step 4: Pre-assessment.

Appraisal/Assessment:

— Step 5: Analysis;

— Step 6: Characterization;

— Step 7: Evaluation of tolerability and acceptability;

— Step 8: Management and decision (treatment).

Continuous Activities:

— Step 9: Communication and consultation;

— Step 10: Monitoring, review and continuous improvement.

E.2 Specific topic and example case

E.2.1 General remarks/overview related to the specific topic

Measurement is more valuable today than ever [136]. The world depends on measurement for almost everything from time keeping to heavy-duty manufacturing, industrial research and medical science. Since measurement plays such an important part in our lives, it is important that the accuracy of the measurement is fit for purpose.

The measurements of all physical quantities are subject to uncertainties in the measurements. Variability in the results of repeated measurements arises because local variables that can affect the measurement result are impossible to hold constant. Even under the strictest controlled conditions, the result would still have an error associated with it. Steps can be taken to limit the amount of uncertainty but it can never be eliminated [137][138][139]. In order to interpret data correctly and draw valid conclusions the uncertainty must be indicated and dealt with appropriately. The result of any physical measurement has two essential components: A numerical value of the measure and the degree of uncertainty associated with this estimated value. The consideration of uncertainty provides a range of values within which the value of the measure and can be said to lie within a quoted level of confidence.

The main variability in requirements and practices for uncertainties regarding testing laboratories involves the amount of measurement accuracy that each test type provides. Estimating uncertainties allows for meaningful comparison of equivalent results from different laboratories or within the same laboratory. An estimation of the components contributing to the overall uncertainty of a measurement or test result provides a means of establishing that the measurement made and results are valid. When developing a new test method a thorough assessment of the components contributing to the uncertainty in the measurement may also provide an indication which components of the test method require reassessment in order to improve procedures and accuracy of the measurement. In some cases it is important to confirm that tolerances included within a performance specification have been met or that the item under test is fit for the intended purpose, which is important for industrial safety. In other situations it is important to estimate the uncertainty when there is a need to compare the result with a reference value given in specifications or standards.

There is the issue of systematic errors that has an effect on a measurement result of a quantity that may not have been included in the original protocol, but nevertheless affects the result. Repeating the measurement does not affect the result, under the same conditions and their effect is to introduce a bias or offset between the true value of the measure and the experimentally determined mean value. The systematic errors can be corrected, but in some cases there is still remaining uncertainty in the value. Another source of error comes from random variations of observation (random effects). Random effects from various sources influence the measured value, under nominally the same conditions. They cannot be eliminated by the application of corrective factors, but the uncertainty in the mean value may be reduced by increasing the number of observations. General requirement for the estimation and reporting of uncertainty of measurement by all accredited laboratories is covered by the implementation of International Standard ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories [140].

The emerging new technologies, production and materials all require extensive research and development to allow for the smooth transfer to market. A key part of this work requires a range of measurements and characterizations to gain a deeper understanding of the new technology or materials. Defining properties of new materials is very important, a range of different parameters need to be established. Risks may emerge from new materials as the hazard profile of the material has not been fully established. Some properties such as flammability can be defined quickly, other occupational health issues may be more difficult to establish. Chronic effects can be very difficult to assess rapidly, and may take some time to fully evaluate. For some measurements required, the range could be very narrow. Any uncertainty in the measurement could have an important effect on decisions made, exposing people to risks handling these new materials.

Any scale-up of new production processes requires a varied range of decisions made, based on established data collected in the development phase, benchmarked against the processes run on the smaller scale. Any analytical tests made, rely on the accuracy of the data to make valid decisions. This may range from purity of the starting materials, completion of the reaction, levels of impurities, solvent compositions, and assay on desired product. If specifications were defined for parameters in a new process, e.g. solvent composition or key water content for a production stream, if the uncertainty in the measurement was not well defined, the could be a risk the true value is out of range and in turn has a profound effect on the new production process. Key effective analytical support would minimize the risks.

Any new technology that defines a new frontier will have a number of risks associated with them, some are well known from former technology, emerged risks. However, there is the potential that new emerging risks may be discovered. In a similar way to new materials and production, new technology is heavily reliant on the acquisition of the research data. The new technology may use radiation, if there is any significant uncertainty in the radiation measurements, this may put operators and patients as risk. New technology is used in the medical sector heavily and key decisions and treatment are based data measurements.

E.2.2 Introducing the example case extreme storage of hazardous materials

E.2.2.1 Challenges

The use of hydrogen storage technology has the potential to provide an environmentally-friendly prospective substitute for fossil fuels [141]. Unlike petroleum, hydrogen can be easily generated from renewable energy sources. It is non-polluting, and forms water as a harmless by-product during use. However there are challenges associated with its use, these include:

— Hydrogen gas is a very flammable gas and readily forms explosive mixtures with air;

— It has very low ignition energy in air;

— In liquid form, hydrogen can only be stored under high pressures and cryogenic temperatures;

— The long transfer time for fuelling hydrogen gas into the storage facility;

— Condensation of oxygen-rich liquid air on and around the cold surfaces; explosion potential;

— Concerned businesses and residents with the operations of the facility locally.

E.2.2.2 Stakeholders

The stakeholders are the local authorities (both environmental and health and safety), and the businesses running the hydrogen storage facilities. Stakeholders could also be local residents and businesses.

E.2.2.3 Concerns

A major concern with respect to hydrogen storage is the potential for hydrogen gas leaks and the potential for an explosion to occur. In the summer of 1985, there was a severe hydrogen-air explosion which occurred in an ammonia plant in Norway [142]. The accident resulted in two fatalities and the destruction of the building where the explosion took place. Hydrogen burns with an intense flame. The pressurized nature of the technology also means there is a stored energy issue with facilities. Also the cryogenic nature of the storage requires consideration for low temperature burns and possible condensation of oxygen-rich liquid air.

Background information to the example is provided in E.5.

E.3 Procedure for management of emerging risks

E.3.1 Horizon screening

E.3.1.1 Step1: Early warnings – notions

Emerging risks need to be detected as early as possible and their evolution needs to be constantly monitored, also with respect to different spheres (technical, social, economic…). The warnings should be properly aggregated, classified and monitored in order to enable to the stakeholders to keep the process of "risk maturation" under control (see Table 5).

In ideal risk management, a prioritization process is followed whereby the most significant risks with the greatest impact have the highest priority to be addressed first, risks with lower probability of occurrence and lower risks are handled in descending order [143]. Emerging risks due to uncertainties in measurements and characterization need to be detected as early as possible and should be monitored constantly to check conformity. Measurement uncertainties can come from instruments, from the item being measured, from the environment, for the operator, and from other sources. The uncertainties can be estimated using statistical analysis of a set of measurements, and using other kinds of information about the measurement process. Rules have been established on how to calculate an overall estimate of uncertainty from these individual pieces of formation. By providing traceable calibrations, careful calculation, good record keeping, and routine checks all can help reduce measurement uncertainties. By reducing down the uncertainties in a measure and the risks can be reduced as the same time. By having more accurate data from measurements taken, more valid assessments of new or emerging risks may be made. Most risks can be foreseen, but the unexpected hazards must be considered.

Stakeholders, who are reliant of the measurement data, must assess if there is an issue with the measurement or characterization data used. Does the measurement or characterization have a significant uncertainty estimated? Is the uncertainty too large and can it be reduced? Does the uncertainty mask any new or emerging risks? The warnings should be properly aggregated, classified and monitored in order to enable the stakeholders to keep the process of risk maturation under control.

EXAMPLE For the use of extreme storage of hydrogen, all authorities and research and development companies need to learn about this new technology. The hazards associated with the use of hydrogen need to be fully assessed. The handling of hydrogen safely under extreme pressures and temperatures are the challenges for hydrogen storage techniques. For this technology 5,000 psi and 10,000 psi (350 bar and 700 bar) compressed tanks, and cryogenic liquid hydrogen tanks are typically deployed. Any uncertainty in key measurements under such extreme conditions could have a big safety impact.

E.3.2 Pre-Assessment

E.3.2.1 Step 2: Context and concern

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

Concern assessment will provide decision makers with relevant knowledge regarding stakeholders' expectations and the potential risks they perceive that might threaten sustainable development. (see Table 5).

If a key parameter is monitored regularly by the undertaking of a measurement, uncertainty in the measurement may mask the developing emerging risk. This would raise concerns for the stakeholder on key knowledge gaps and potential societal risks, which could impact on development of the technology, process, material or policies. To understand the emerging risks due to uncertainties in measurements and characterization, stakeholders should understand the sources of uncertainties and their potential importance.

One of the most important aspects of uncertainty evaluation is the need for a detailed understanding of the measurement process and all potential sources of measurement uncertainty. This would involve a detailed study of the measurement procedure and measurement system. Sometimes the use of flow diagram and computer simulations can aid this evaluation process. Examination for an incomplete definition of the test could show imperfections in the protocol. Uncertainties may be introduced if there is inadequate knowledge of the effect of errors on the measurement process, due to the environmental conditions. The context should be described including all new influencing factors.

The sample may not be truly representative and give variable results. More consistent results are obtained with homogeneous solution than heterogeneous solutions. There may be parallax errors, where there is a personal bias in the reading of analogue instruments. There is a threshold on discrimination of the scale on the instrument. The quality of the standard reference may be in doubt, the reference sample or the test sample may be deteriorated due to age, temperature or environmental conditions. In the data analysis there may have errors in the values of constants, and corrective parameters used. There may be assumptions and approximation incorporated in the measurement method which introduce uncertainties.

Local ambient conditions may vary with short-term fluctuations in the local environment, e.g. temperature, air pressure and humidity. There is the human factor of variability due to different testers.

The performance of the measuring instrument could be an important source of error since it was last calibrated.

In the context of measurement uncertainties, all these sources of uncertainties may not be independent to each other, and a combination of different factors may contribute to the overall uncertainty in a measurement. A stakeholder may need to initiate an inter-laboratory comparison program or by the use of a different measurement procedure and check the results of the examination. The stakeholder needs to ask the question if the procedure or method providing the measurement results well controlled, and the uncertainty reduced.

The framing and concern assessment should be carried out at an early stage in order to direct the allocation of resources. If the uncertainties in measurements and characterization are significant, decisions made from a measurement or characterization may introduce risks, both emerging risks and emerged risks. There are then concerns that a new process may be not considered under control, or material made within the specifications defined as examples. If key performance indicators (KPI) are required, any uncertainty in the result opens up process risks, particularly if tolerance is a key parameter. If the concern is large enough, more resources may be needed to address the issue. Dialog with the local residents is essential to reassure them of hazards that are known in the public domain.

EXAMPLE A major concern with respect to extreme storage of hydrogen is the serious risk of explosion. The elements of the risk include the material stored, pressure vessels, external influences. The risk situation includes damage by fire and explosions. Both operators of the facility and the local neighborhood would be effected by any incident. Concerns that key measurement protocols are well-defined and meaningful data obtained, which ensures a well-controlled hydrogen storage facility. The serious hazards of explosion and fire would affect both parties. Additionally the effects of an incident would impact on people and communities. Concern assessments should initiate stakeholder dialogues, interviews and surveys as acceptance of this new technology. Communication with local residents is essential to reassure them.

E.3.2.2 Step 3: Identification of risk scenarios

The outcome of the risk maturation is the risk scenario(s) for which all further considerations are made. The scenario is based on corroborated evidence about one or more early warnings (see Table 5).

After establishing the context, the next step in the process of managing risk is to identify potential risks. Risks are about events that, when initiated, cause problems. Hence risk identifications can begin with the source of problems, or with the problem itself.

The outcome of having uncertainty in a measurement or characterization could have impact on introducing risks; it may hide the true problem. The impact on the environment and the social responsibility to local residents needs to be considered, if a major accident occurred due to a process out of control, which was linked to an emerging risk coupled with uncertainty in a key measure and taken. Stakeholders may have early signals and warnings of this. A risk scenario(s) study should be made, including risk maturation. The scenarios may have been experienced (fully matured) or potential based on the information provided by early warnings. Worst case scenarios should be considered at this stage. All the scenarios should be presented. The use of a cause and effect diagram is a very useful way of analyzing the uncertainty sources, showing how they relate to each other and indicating their influence on the uncertainty of the result.

EXAMPLE For the extreme storage of hazardous materials, the main foreseen emerging risks are related to the use of a hydrogen-based fuel source are the following:

— Failure of new equipment for storage, shipping or conveying liquid hydrogen;

— Failure of new equipment for storage, shipping or conveying pressurized hydrogen;

— Condensation of oxygen-rich liquid air on uninsulated surfaces that are exposed to liquid hydrogen temperatures;

— Prevention of potentially flammable materials e.g. asphalt or tarmac beneath pipework where there is the risk of the condensation of oxygen-rich air;

— Hydrogen leaks near to enclosed areas containing electrical equipment or other sources of ignition. The risk is particularly high when the source of ignition is close to a ceiling or other impervious high-level barrier;

— Longer fuelling times for hydrogen sources are longer than petroleum technology, increasing the probability of a leakage occurring;

— New materials used to construct liners for conveying hydrogen, including metal ceramic composites, improved resins and engineering fibres. Unknown hazards associated with new materials.

E.3.2.3 Step 4: Pre-Assessment

Pre assessment needs to identify all relevant dimensions of risk, or at least, all the dimensions of interest for the various stakeholders identified (see Table 5).

Stakeholders should decide how important the accuracy of the measurements or characterizations is to assessing the full dimensions of the emerging risks. Are the results meaningful and the uncertainties insignificant, if they are not, the stakeholder may need to review using a stricter protocols and fully developed test methods.

For laboratory based tests, assessing the importance of measurements or characterization, there are different categories of tests made which are compliant with the uncertainty determination for ISO/IEC 17025 [140]. The categories are as follows:

— Category I-tests with crude measurements, more qualitative than quantitative;

— Category II-tests with recognized methods and defined uncertainty factors and ranges of results;

— Category III-tests with recognized methods, similar to metrology practice, often involving the same reference standards as calibration metrology;

— Category IV-tests with newly devised methods which require definition of the variability factors and their impact on results, and

— Category V-“other” tests which simply require GUM determination of the measurement variability.

The category IV and V tests provide the best approaches for measurements with reduced uncertainty and highest accuracy, which give the best assessment for the potential of the emerging risks.

If the uncertainties in measurements and characterization are significant, decisions made from a measurement or characterization may introduce risks, both emerging risks and emerged risks. There are then concerns that a new process may be not considered under control, or material made within the specifications defined as examples. The stakeholder should ask the question is the procedure or method providing the key measurement results well controlled, and the uncertainty reduced? If key performance indicators (KPI) are required any uncertainty in the result opens up process risks, particularly if tolerance is a key parameter. A stricter testing protocol may be required for the stakeholder.

EXAMPLE For the extreme storage of hydrogen, stakeholders have to be concerned about the risks imposed by the use of extreme conditions used to contain the hydrogen. This includes the high pressures (5000 psi to 10000 psi) and cryogenic conditions used. In pre-assessment the stakeholders have to consider all aspects of the technology used and the possible risks if something goes wrong. The risks associated with the storage vessel design for safe containment under high pressure of the hydrogen should be examined. The importance of key measurement readings for the extreme storage conditions should be considered, along with the risks of uncertainty in the measurement made. The dispensing of the hydrogen from storage facility are operations which have higher risks, which need to be considered. All measurements made at the storage facilities should be made using calibrated equipment with well-defined protocols to minimize the risks of uncertainty in measurements. If not then the full scope of the risk needs to be considered.

E.3.3 Appraisal/Assessment

E.3.3.1 Step 5: Analysis

The analysis of risk governance models revealed the importance of considering the whole life cycle of (a) product and the need to develop cumulative risk assessments; this step should include likelihood analysis and impact analysis for emerging risks (see Table 5).

This step implies that the considered risks have emerged and have to be assessed before being compared to criteria in the evaluation phase. All aspects of the measurements made should be systematically examined. The consequences of the measurement having a significant systematic or random error have to be analyzed. The stakeholders have to consider if the measurements and characterization are performed to the appropriate accuracy to give relevant data and the uncertainty determination is either required or fully developed.

Does the data and analysis give the full picture to the stakeholder of the emerged risks, or are there unforeseen risks which are going to emerge. Are there new and unfamiliar aspects to the measurement made, which have new risk influencing factors? If key parameters are very dependent on aspects of the measurements made, the wrong decision could lead to a hazardous situation, whether it is a dangerous process, material out of specification, wrong charge of a reagent, wrong limits quoted etc. Cumulative risk assessments should be made, to get a full picture of the whole life cycle of the effects of measurement, which should include likelihood analysis and impact analysis for the risks.

If the protocol and procedure is not adequate to take into account all aspects of the measurement, a likelihood analysis and impact analysis is needed, and a revised procedure needs to be developed. The stakeholder may have to consider more closely the different test categories. For categories I & II, the uncertainty considerations are not important. For categories III & IV, the test would require a review to the standard of calibrated test laboratories. Validation and verification of the variability determinations affecting accuracy of the tests would be necessary. Thus for categories II, IV, and V a written procedure would be necessary for calculating their uncertainties.

Category I tests are usually qualitative tests that are pass/fail or go/no-go. They can be judgment calls. Qualitative identifications are used in the automotive and aerospace testing. Category II tests are often more precise versions of the category I tests. Compression, tension and hardness testing of materials are in this category. Measuring and analyzing devices may be used for such tests. The uncertainty requirements and considerations are followed by the use of relevant official methods and formats in their reports. Category III tests typically call for a stricter calculation of the uncertainty and quoted on data reports. Category IV tests are developed with the use of reference standards manufacturers or specified. This includes mechanical, chemical or microbial and embraces new technologies or concepts used in their procedures. All possible sources of variability of the measurements are taken into account, and considered in the uncertainty estimations. For category V tests, the strictest controls of the measurement and characterization are enforced. The mathematical practices are compliant with the requirements of ISO/IEC 17025, and are subject to regular audits by competent assessors [140].

EXAMPLE For the use of hydrogen storage technology, the analysis should focus on the new technology taking into account the risk scenarios. The analysis should identify in a systematic way all aspects of risk from a measurement both in terms of likelihood and impact. Then analyze what are the potential consequences of this measurement to have a systematic or random error (uncertainty). The whole life cycle of the hydrogen storage process needs to be analyzed, which includes both storage and dispensing of the hydrogen. Risks due to electrostatic hazards and oxygen-rich liquid air formation risk are examples of potential emerging risks.

E.3.3.2 Step 6: Characterization

Risk characterization allows decision makers to distinguish scientific facts from policy orientations when analyzing risk assessment results. Better decisions can thus be taken. Risk categorization / classification is an optional part of the process, especially important for the cases where large amounts of risks or early warnings are to be dealt with simultaneously; also important for monitoring legal or other allowable limits (monitoring compliance) (see Table 5).

To assess the contribution of the uncertainty in measurements and characterization to emerging risks, a quantitative estimate of the uncertainty needs to be made or reviewed by the stakeholders. This helps the evaluation process and supports appropriate key judgments made by stakeholders. It is therefore necessary that there is a readily implemented, comprehensible and generally accepted standardized procedure for characterizing the quality of a result of a measurement, that is, for evaluating and expressing it's uncertainty. The ISO Guide to the Expression of Uncertainty in Measurement (GUM), provides the framework for achieving this and should be consulted for more comprehensive details [144][145][146]. For this document a simple overview of the process for calculating uncertainties is presented below, there are more advance statistical treatments used to calculate uncertainties, but they are beyond the scope of this document.

The sources of errors can be grouped together into random errors and systematic errors. The guide groups uncertainty components into two categories based on their method of evaluation, "Type A" and "Type B." Both categories are expressed in the form of standard deviations and defined as standard uncertainties. "Type A" evaluation of standard uncertainty may be based on any valid statistical method for treating data. Examples include calculating the standard deviation of the mean value of a series of independent observations. A "Type B" evaluation of standard uncertainty is usually based on scientific judgment using all the relevant information available, which may include:

- Previous measurement data;
- Experience with, or general knowledge of, the behavior and property of relevant equipment;
- Equipment manufacturer's specifications;
- Data provided in calibration and other certifications; and
- Uncertainties assigned to reference data taken from handbooks.

For Type A evaluation, the standard deviation of the measured results is calculated from the measured values by the well-established statistical methods. A number of tests which are made upon one or a number of identical samples using the identical conditions, the measured values are not necessarily the same. Conditions such as thermal or electrical noise, vibrations all contribute to the variations in measurements, which form a distribution about a mean value. The random variations all contribute to the overall uncertainty in the measurement; some components contribute more to the overall uncertainty than others. The estimated standard deviation is an estimate for the full population of random variables. Normally at least ten measurements are recommended to allow for the adequate characterize the standard deviation. If a smaller number of measurements are possible, the estimated standard deviation may be significantly underestimated.

All contributing uncertainties need to be expressed to the same confidence level by converting them into standard uncertainties. A standard uncertainty is the range which is plus or minus one standard deviation, multiplied by the appropriate sensitivity coefficient. The use of the sensitivity coefficient in the calculations allows the ability to express an input quantity to be expressed in terms of the output quantity. Uncertainty contributions must be in the same units before they are combined.

The individual standard uncertainties from the different uncertainty components can be combined and the overall combined standard uncertainty can be calculated by squaring the individual uncertainties, adding them all together, and then taking the square root of the total. It may be the combined standard uncertainty calculated is not set to acceptable confidence levels. A re-scaling of the combined standard uncertainty by multiplying with a coverage factor gives the expanded uncertainty. It is quite common to use a coverage factor of 2 which gives a level of confidence of approximately 95 %. There can be situations when the expanded uncertainty is known and the standard uncertainty is required. When presenting the measure and with a quoted uncertainty, the numerical value (in specified units) is quoted along with the statement of the coverage factor and the level of confidence, e.g. “the reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, providing a level of confidence of approximately 95 %.”

For Type B evaluation, a similar approach is used, the equivalent standard deviation of each contributory component; however the process is supported by additional data. Calibration certificates for an instrument will give the calibrated value plus the uncertainty of measurement together with either its confidence level or the coverage factor used.

EXAMPLE For the extreme storage of hydrogen, given the extreme high pressures and temperatures used, the hazards connected with storage processes may be dependent on the material and on the conditions of storage. Key hazard evaluation of the effects may be based on either on deterministic, probabilistic and empirical methods. Pressure vessel equipment for storing hydrogen should be subject to rigorous checks. The pressure tests should be run against well-defined protocols and calibrated test equipment. Any deviation from this ideal scenario would provide uncertainty in the results, which mask significant emerging risks.

E.3.3.3 Step 7: Evaluation of tolerability and acceptability

In the lack of reliable data, use of conventional methods such as risk matrices or the ALARP principle might be difficult. Furthermore, the assessment of acceptability and tolerability should go beyond the technical dimension of risk to consider social, regulatory, cultural or ethical dimensions. Specific or complementary approaches/rules should be considered in this phase (see Table 5).

The purpose of risk evaluation is to assist in making decisions, based on the analysis of the risk assessment. Once risks have been identified and the uncertainty in the measure is established, they must then be assessed as to their potential severity of impact and the likelihood they will occur. These quantities can be either simple to measure or impossible to know in the case of the probability of an emerging risk occurring. The assessment should go beyond the technical dimension of risk to consider social, regulatory, cultural and ethical dimensions.

When the data is in hand, the evaluation of the results with respect to both the measured value of the measure and the uncertainty presented is made. Within the context of risk evaluation, does the data indicate established risks or new merging risks are those risks tolerable and acceptable? If the data is said to be tolerable, the process or activity may proceed, but it is advisable to have additional controls developed and in place to reduce the risk to the principle of ALARP. If the data is said to be acceptable, the process or activity may proceed, as the risk is seen to be low and additional controls will not have a significant effect on risk reduction. The estimation of the uncertainty must successfully take into account all the components contributing to the overall uncertainty. Can modifications of the measuring or characterizing procedures and protocols, reduce the degree of uncertainty? The sensitivity of the result to uncertainty could be a key factor. This could shift the risk from unacceptable to acceptable. The uncertainty on an acceptability level is critical for making valid judgments. A risk rating evaluation of emerging risks would help to systematically decide between tolerable and acceptable scenarios. The risk evaluation will help to assist in making decisions, and allow for the implementation of additional controls for emerged risks or emerging risks? This is covered in the main document (see 5.3 to 5.5).

EXAMPLE For the extreme storage of hydrogen the stakeholders, the wider context of the risks should be considered. The stakeholders have the responsibility of safety to their employees as well as local communities and environment close the facilities. Are the risks tolerable and acceptable with the running of the hydrogen storage facility, meeting the predetermined risk acceptance criteria? Are the parameters like pressure and temperature for safe hydrogen storage, measured to a level of accuracy which is acceptable and tolerable? There could be seasonal variations which could adversely affect the situation. The durability of the hydrogen storage facility is a key feature, at the extreme conditions deployed in this technology.

E.3.3.4 Step 8: Management and decision (treatment)

Based on the previous steps results, decisions are made to manage the risk in order to keep it at an acceptable or tolerable level.

The approaches applied in emerging risk management should

— integrate both qualitative and quantitative data,

— combine different type of criteria,

— carefully address compensation,

— consider variations/alternatives in risk scenarios,

— treat uncertainties,

— help make robust decisions (see Table 5).

For successful risk management, key decisions and process indicators come out of the risk analysis, along with analysis of the uncertainty contributions, in line with the GUM framework for estimation uncertainties. If the data is showing indications of an emerging risk or an emerged risk, stakeholders have to decide if the risk is under control and if risk mitigation measures adequate. In some cases there is a need to integrate qualitative data and quantitative data. For the management of risk, errors should be managed with an appropriate strategy, for example defining safety coefficients larger than the uncertainty.

EXAMPLE To reduce the impact and likelihood of gaseous emission of flammable hydrogen gas into the atmosphere, which has an explosion potential, risk management would identify control measures to reduce the risks with the handling of hydrogen. Extensive new research and development has identified the use of new liner materials to reduce hydrogen gas permeation, which have been exploited by good risk management. In recent times there has been research into new materials of construction such as metal ceramic composites, improved resins, and engineering fibres. Normally any new material developed will have a significant amount of testing performed, any uncertainty in the testing procedures will have an effect on the technical and safety judgments made. Standard test protocols for evaluation of hydrogen storage materials are limited, making robust decisions a challenge. Reproducibility of performance both in synthesis of the material and measurements of key hydrogen storage performance metrics is a problem. Standard test protocols related to performance over time such as accelerated aging tests as well as protocols evaluating the material's safety properties and reactivity over time are also limited. With the test methods not well defined in this industry, the uncertainty in measurements and tests made are going to be significant, but with good risk management safety coefficients larger than the uncertainty could be applied. Applicable codes and standards for hydrogen storage systems and interface technologies, which will facilitate implementation/commercialization and assure safety and public acceptance, have not been established. Good risk management would make the appropriate decisions to control the risks.

E.3.4 Continuous Activities

E.3.4.1 Step 9: Communication and consultation

Communication is an increasingly important element of dealing with emerging risks. It takes place in all phases of the overall process and among all the stakeholders, although in the way and scope adapted to the respective stakeholders' roles (see Table 5).

When dealing with emerging risks good communication and consultation are key elements. It is vital that emerging risk findings from the measurements and the uncertainty estimation are communicated to all relevant parties across functional groups; it must be effective and efficient.

The key elements needed to be communicated are:

— Call a meeting to discuss the findings with relevant stakeholders;

— Prepare a clear concise presentation of the finding;

— Communicate the measure and, the uncertainty findings and the emerging risks;

— Report the risk analysis and the action plan for dealing with emerging risks;

— Identify the necessary controls or additional experiment to tackle the issue;

— Assign the specific tasks to deal with the issues;

— Agree on monitoring methods to review the effect of changes on the process.

EXAMPLE Effective communication is essential in the area of hydrogen storage technology. The management of communicating uncertainties in key performance measurements to stakeholders is essential. As new developments and understanding in handling hydrogen storage become available, updates of this information to the relevant parties is important. Communicating that the standard testing protocols in place are adequate to provide meaningful and accurate data, with uncertainty budgets defined.

E.3.4.2 Step 10: Monitoring, review and continuous improvement

This requirement means that the procedures to be established have to ensure

— continuous improvement,

— effectiveness & efficiency,

— sustainability & evergreening (see Table 5).

Monitoring and auditing the situation should be constantly performed. Initial risk management plans will never be perfect. Risk analysis results management plans should be updated. Particular attention should be made on any notable changes which may influence the current status. The whole emerging risk management process (step 1 to 10) should be regularly reviewed and continuously improved, especially if new risks emerge. Changes to important standards like the ISO GUM frameworks should be carefully reviewed. Changes to the local environment should be monitored and potential social impact identified.

EXAMPLE For the use of hydrogen storage technology, the storage should be regularly tested to make sure there is no deterioration in the key components of the facility, which should be monitored regularly. To ensure this happens regular checks need to be performed on all key measuring devices to make sure there are no systematic errors. Regular calibration of equipment would be necessary. The maintained performance of the hydrogen storage facility is the key driving factor. Changes to the local environment should be monitored and the impact reviewed.

E.4 Conclusions/Summary

For the management of emerging risks due to uncertainties in measurements and characterization, the ten step procedure has been presented. The possible sources of uncertainty in measurement have been reviewed, the management of uncertainty measurement has been reviewed. The effects of uncertainty in measurement and characterization on emerged and emerging risks have been presented. The ten steps to risk management have been examined. An overview of the statistical approaches for estimating uncertainty has been presented, and how stakeholders should analyze and reduce the level of uncertainty by improved procedures for collecting and recording data on a measure. The different categories of analytical tests and their importance to making decisions have been discussed. The importance of the GUM framework has been highlighted.

E.5 Example – Extreme storage of hazardous materials

The use of the new technology of hydrogen storage is an example of extreme storage of hazardous materials. It has a number of the serious risks associated with its implementation [141]. The new conversion technologies evoke new ways of storage, e.g. at extremely low temperatures or high pressures or at extreme storage sizes. Hydrogen is a prospective substitute for fossil fuels. Even in the most environmental–friendly technology there is build-up of waste by-products, which constitute an emerging risk. Thus, waste treatment has developed into a growing industrial sector. This demands large capacities for waste conversion and safe intermediate and long-term storage. Unlike petroleum, hydrogen can be easily generated from renewable energy sources. It is non-polluting, and forms water as a harmless by-product during use. Yet it is difficult to store, as a result its use as a fuel has been limited.

Hydrogen gas is a very flammable gas which burns with an intense flame, and is lighter than air. It readily forms an explosive mixture with air. The range of air/hydrogen concentrations that will explode is extremely wide. Mixtures containing from as little as 4 % v/v hydrogen up to as much as 75 % v/v will readily explode. The ignition energy for hydrogen/air mixtures is so low that the absence of ignition source should not be relied upon as a basis of safety. Also hydrogen is only one of two common gases which exhibit the reverse Joule-Thomson effect. This means hydrogen gas warms up slightly when released from a pressure vessel or gas cylinder configuration. A gram of hydrogen gas occupies about eleven liters of space at atmospheric pressure, so for convenience the gas must be intensely pressurized to several hundred atmospheres and stored in pressure vessels. In liquid form, hydrogen can only be stored under cryogenic temperatures. Liquid hydrogen boils at -253 °C under atmospheric pressure. Consequently, hydrogen leaking from cryogenic storage will often sink initially, leading to the formation of flammable atmospheres at low level, before warming up and becoming buoyant and rising.

The solution to these difficulties is the storage of hydrogen in hydride form. This method uses an alloy than can absorb and hold large amounts of hydrogen by bonding with hydrogen and forming hydrides. A hydrogen storage alloy is capable of absorbing and releasing hydrogen without compromising its own structure. This technology is still in early phase of development, and could have potential in the future to replace more established hydrogen storage technology. Durability of hydrogen storage system is vital. Storage media, materials of construction and balance-of-plant components are needed that allow hydrogen storage systems with a lifetime of at least 1500 cycles and with tolerance to hydrogen fuel contaminants. An additional durability issue for material-based approaches is the delivery of sufficient quality hydrogen for the vehicles power plant.

Energy efficiency is a challenge for all hydrogen storage approaches. The energy required transferring hydrogen into and out of the storage media or material is an issue for all material options. The energy needed with compression of and liquefaction of hydrogen must be considered. Thermal management for charging and releasing hydrogen from the storage system has to be efficient. The weight and volume of hydrogen storage systems are presently too high, resulting in inadequate vehicle range compared to conventional petroleum fuelled vehicles.

An explosion occurred at a Norwegian ammonia plant in 1985 showed the real dangers with the use of hydrogen gas [142]. The hydrogen leakage inside a building caused a severe explosion in an ammonia plant. A large jet fire followed the explosion. Three men were seriously injured in the accident, two of them later died of their injuries. The building was totally destroyed and remains one of the largest industrial hydrogen explosions reported. When hydrogen leaked out in the building it mixed with air and formed a combustible gas cloud. Most likely a hot bearing ignited the cloud. The explosion that followed was very violent. It was believed part of the cloud detonated and the explosion pressure inside the building must have reached at least 10 bars and lifted the roof. This damaged a pipe from a wash tower which released a new jet fire with an initial flame length of 50 meters in just 30 seconds. Hydrogen also leaked into the sewer system via a small bypass valve, which resulted in further explosions in the sewer.

Conclusions from the accident investigation were the following:

- A combination of operational error, technical failures and weakness in the design were to blame for the accident;
- 10 kg to 20 kg of hydrogen gas leaked out inside the ammonia plant;

— Hot bearing was the ignition source for the hydrogen gas cloud;

— 3.5 kg to 7 kg of hydrogen must have been violently burning in the explosion;

— The explosion caused a large number of fragments representing a severe hazard;

— Glass windows were broken up to 700 m from the center of the explosion. The broken windows were a severe hazard to humans;

— A jet fire followed the explosion;

— Domino events such as fires are common after gas explosions.

Annex F
(informative)

Examples of factors which can influence the emerging character of a risk - the 50 iNTeg-Risk factors of emergence

F.1 Introduction

The factors collected in the tables below represent the result of literature search and brainstorming among the person working in the iNTeg-Risk project and in the area of emerging risks in general.

NOTE 1 If not indicated otherwise, see to the generic scale below in Table F.1.

NOTE 2 In principle, each area of application (e.g. insurance, oil industry, any of the ERRAs in iNTeg-Risk, etc.) needs to establish its own scale defining what is high or very low.

NOTE 3 Not all the factors are applicable to each case of emerging risks – the qualified user should define which factors to use or not.

NOTE 4 Not all the factors are independent; this must be taken care of in each case when using multiple factors for determining "emergence" of an emerging risk.

NOTE 5 Not all the factors are equally important, on the contrary, they are all differently important.

NOTE 6 It is up to the qualified user to decide how to cope with the issues listed above. Use of multi-criteria decision-making methods allowing for, e.g., weighting is, therefore, highly recommended.

NOTE 7 As in most of the cases of risk analysis, the main purpose of the methods is to produce ranking lists, showing the comparative priorities and ranking of risks, rather than delivering an "absolute assessment" of the respective risks.

NOTE 8 Generally, legal requirements, regulation, standards, accepted practices and similar have to be considered together, possibly before, the analysis of emergence of emerging risks.

Table F.1 — Generic scale for classes of emergence for emerging risks

Class	Meaning
α	Very low
β	Low
γ	Medium/average
δ	High
ε	Very high

F.2 Factors using generic scale

Table F.2 — Examples of factors which can influence the emerging character (emergence) of emerging risks

Number	Factor	Short explanation; Comment
Related to general perception & communication		
1.	Misperception	Possible misperception of opportunities/benefits
2.	False positives	Influence of false positives on assessment result
3.	False negatives	Influence of false negatives on assessment result
4.	(Global) Catastrophic potential	If fatalities would occur in large numbers in a single event - instead of in small numbers dispersed over time - our perception of risk rises
5.	Sensitivity	Sensitivity of risk perception on single events (e.g. accidents), volatility of public perception [a]
6.	Communication	Dependence on communication [b]
7.	DIF-Perception	Differences in perception by different people, i.e. different stakeholders' groups
8.	Misinterpretation	Susceptibility to deliberate or other misinterpretation [c]
Single person level perception		
9.	Incertitude	An overall indicator for different uncertainty components (e.g. statistical, genuine, ignorance)
10.	Lack of familiarity	Unfamiliar or novel risks makes one worry more
11.	Lack of understanding:	If one believes that how an activity or technology works is not well understood, his/her sense of risk goes up
12.	Lack of personal control	If one feels the potential for harm is beyond one's control (like a passenger in an airplane) one worries more than if she/he feels that he/she is in control (e.g. as the driver of a car)
13.	Lack of voluntariness	If one does not choose or cannot decide personally to engage the risk or not, the risk feels more threatening
14.	Involvement of children	If the risk involves children, one tends to find it more threatening
15.	Involvement of/risk for future generations	If the risk involves future generations, one tends to find it more threatening
16.	Victim identity	Identifiable victims rather than statistical abstractions make the sense of risk rise
17.	Dread	If the effects generate fear, the sense of risk rises
18.	Lack of trust	If the institutions involved are not trusted, personal risk

Number	Factor	Short explanation; Comment
		perception generally rises
19.	Accident history	Bad events in one's own past boost the sense of personal risk perception generally
20.	Lack of equity	If the benefits go to some and the dangers to others, one raises the risk ranking
21.	Lack of clear benefits	If the benefits of the activity or technology are not clear, it is judged to be riskier
22.	Lack of reversibility	If the effects of something going wrong cannot be reversed, risk rises
23.	Personal risk	If the risk involves oneself (involuntary), we tend to perceive the risk as higher (unless we think we are in better control than the average person)
Related to governance of emerging risks		
24.	Frameworks exist	Existing regulatory (or other accepted) framework of reference or authority, e.g. on national or international level
25.	Authorization	Availability of authorization/certification schemes (progressive authorization)
26.	Mapping	Possibility to map (e.g. on geographical or context maps)
27.	Management	Possibility to manage, especially consequences
28.	Protection/precaution	Possibility to envisage implementation of protective or precautionary measures
29.	Ingérence (intervention)	Lack of risk owner or lack of mandate or procedures to manage emerging risk (fr.: ingérence: right or obligation to intervene or interfere)
30.	Social unrest	Potential to provoke or result in social unrest
Related to global management of emerging risks		
31.	Lack of possibility to observe/monitor	Possibility to monitor the risk; if false signals resulting from monitoring are very high
32.	Lack of possibility for mitigation	Lack of inherent safety or mitigation mechanisms
33.	Susceptibility to global ignorance	The complexity of the modern world often leads to the situation in which people are flooded with information about a phenomenon or an issue (e.g. computers), but the basic understanding of the phenomenon is missing
34.	The 12 IRGC factors (see Table F.4)	1) scientific unknowns 2) loss of safety margins 3) positive feedback

Number	Factor	Short explanation; Comment
		4) varying susceptibilities to risk 5) conflicts about interest, values and science 6) social dynamics 7) technological advances 8) temporal complications 9) communication 10) information asymmetries 11) perverse incentives 12) malicious motives and acts

[a] e.g. dependence on other volatile factors (e.g. daily changes of media positions or public opinion); (wrong) public perception of vulnerability of society

[b] possible feedback influence of perception to the initial risk

[c] e.g. misuse of fear - "that technology will kill us all"

F.3Factors using specific/customized scale

Table F.3 — Examples of factors which can influence the emerging character (emergence) of emerging risks

Number	Factor	Explanation	α	β	γ	δ	ε	Comment
Related to risk characteristics								
35.	Contradiction	Contradicting/contradictory evidence	very low	low	medium	high	very high	e.g. contradicting expert opinions or statements about an important aspect of risk
36.	Incoherence	Incoherence, inconsistency and/or inhomogeneity of the environment or evidence	very low	low	medium	high	very high	e.g. different expert opinions or statements about an important aspect of risk
37.	Persistence	Persistence of a risk - the temporal extension of potential damages	very low	low	medium	high	very high	e.g. unexpected inheritance-related effect after the initial exposure
38.	Ambiguities	Ambiguities, e.g. those related to application of the precautionary principle	very low	low	medium	high	very high	e.g. ambiguous expert opinions or statements about an important aspect of risk
39.	Lack of proportionality	Lack of proportionality (small cause/change, large effect; butterfly effect), threshold in change	very low	low	medium	high	very high	e.g. 5 % shortage in supply (of e.g. fuel) causes 5 % increase in price of the item in demand; 30 % shortage stops the

Number	Factor	Explanation	α	β	γ	δ	ε	Comment
								economy.
40.	Sudden change in perception	Possibility of sudden change in perception	very low	low	medium	high	very high	e.g. for very high: An unexpected change in perception cannot be excluded.
41.	Increasing	Increasing character of a risk	small vs. long	small vs. short	large vs. long	large vs. short	large vs. abrupt	Amount of increase vs. time period in which the increase takes place
			very low	low	medium	high	very high	
42.	Origin of risk	Generally, man-made risks are perceived riskier than those of natural origin	natural only	mainly natural	balanced	mainly man-made	man-made only	man-made vs. natural origin
			very low	low	medium	high	very high	
43.	Novelty	Novelty of a risk	anticipated	anticipated but not analyzed	considered but not anticipated to materi-alize	never considered so far	never imagined	An example of a possible scale – can/should be adjusted for particular risks
44.	Time to impact	Time to impact (imminence - closely related/overlapping to/with latency, but proposing a different scale)	over 20 years	10 to 20 years	5 to 10 years	0 to 5 years	imminent	More immediate threats loom larger while those in the future tend to be discounted; e.g. insurance or decision maker's point of view – an emergency situation causing urgent action
			very low	low	medium	high	very high	
45.	Duration	Duration of impact (duration of consequences)	short	medium	long	very long	unknown, maybe	e.g. regulators point of view, defending interests of future

Number	Factor	Explanation	α	β	γ	δ	ε	Comment
							unlimited	generations
46.	Latency	Latency denotes primarily the time between exposure to a risk and experiencing its effect (closely related/overlapping to/with imminence)	very low	low	medium	high	very high	The latency between the initial triggering event and the actual occurrence of damage, the measure of which could be of physical, chemical or biological nature.
47.	Evolution in time	Stability or continuity of change/evolution/maturation	slightly un-stable or discon-tinuous	unstable but con-tinuous	discon-tinuous but stable	unstable and discon-tinuous	extremely unstable and discon-tinuous	Closely related/overlapping to/with increasing or sudden change in perception, but proposing a different scale
Related to risk assessment								
48.	Propagation	Knowledge about and controllability of propagation	very good	fair	poor	none	misleading or wrong	Examines if the information about risks spreads the usual/known ways
49.	X-uncertainties	Extreme uncertainties (e.g. related to impact and/or likelihood)	usual for that type of application	increased	extreme, in data	extreme, in model(s)	extreme, both in data and model(s)	
50.	Known-to-science	Data/model (D&M) availability/unavailability	D&M both available and certain (1)	D&M both available, some un-certainties (2)	Data available, models unavailable (3)	Models available, data unavailable (4)	Both D&M unavailable (5)	(1) - proven known knowns (2) - known knowns (3) - known unknowns

Number	**Factor**	**Explanation**	α	β	γ	δ	ε	**Comment**
			very low	low	medium	high	very high	(4) - unknown knowns (5) - unknown unknowns

Table F.4 — The 12 IRGC Factors

Number	Name	IRGC Description (shortened or slightly adjusted at some places)
1.	Scientific unknowns	Dealing with emerging risks requires dealing with scientific unknowns. These unknowns, can be tractable or intractable, and contribute to risks by being, e.g. unanticipated, unnoticed, and over- or underestimated.
2.	Loss of safety margins	The level of connectivity in many social and technical systems is greater than in the past and the interconnections are increasing. The pace at which these systems operate is becoming faster and many are operating under higher levels of stress. This can lead to tight-coupling of components within systems and to loss of safety margins - a loss of slack or buffering capacity that leaves systems more vulnerable to disruption and thus increases the likelihood that new risks will emerge.
3.	Positive feedback	Systems exhibiting positive feedback react by amplifying a change or perturbation that affects them. Positive feedback tends to be destabilizing and can amplify the likelihood or consequences of an emerging risk.
4.	Varying susceptibilities to risk	The consequences of an emerging risk may be different from one context (situation/system/population) to another. Geography, genetics, experience and wealth are just some of the possible contextual differences that create varying susceptibilities to risk.
5.	Conflicts about interests, values and science	Public debates about emerging risks seldom witness a clear separation between science, values, and interests. The conflicts that result have the potential to contribute to fertile ground for risk emergence or amplification. E.g. emerging risks may be amplified when efforts to assess them and take early management measures encounter opposition on the grounds of contested science or incompatible values.
6.	Social dynamics	Social change can lead to potential harm, or it can attenuate it. It is therefore important for risk managers to identify, analyze and understand changing social dynamics.
7.	Technological advances	Risk may emerge when technological change is not accompanied by appropriate prior scientific investigations or post-release surveillance of the resulting public health, economic, ecological and societal impacts. Risks are further exacerbated when economic, policy or regulatory frameworks (institutions, structures and processes) are insufficient, yet technological innovation may be unduly retarded if such frameworks are overly stringent.
8.	Temporal complications	A risk may emerge or be amplified if its time course makes detection difficult (e.g., the adverse effects of the risk only become evident after a long period of time) or if the time course does not align with the time horizons of concern to analysts, managers and policymakers.
9.	Communication	Risks may be complicated or amplified by untimely, incomplete, misleading or absent communication. Effective communication that is open and frank can help to build trust. In many cases, such communication can attenuate, or lead to better anticipation and management of, emerging risks.
10.	Information asymmetries	Information asymmetries occur when some stakeholders hold key information about a risk that is not available to others. These asymmetries may be created intentionally or accidentally. In some cases, the maintenance of asymmetries can reduce risk, but in others, it can be the source of risk or the amplification of risk by creating mistrust and fostering non-cooperative behaviors.
11.	Perverse incentives	Perverse incentives are those that induce counterproductive or undesirable behaviors, which lead to negative, unintended consequences. Such

Number	Name	IRGC Description (shortened or slightly adjusted at some places)
		incentives may lead to the emergence of risks, either by fostering overly risk-prone behaviors or by discouraging risk prevention efforts.
12.	Malicious motives and acts	Malicious motives give rise to emerging risks and therefore practitioners need to consider intentional as well as unintentional causes of risk. Malicious motives and acts are not new, but in a globalized world with highly interconnected infrastructures (e.g., trade agreements and information and communication systems) they can have much broader-reaching effects than in the past.

Annex G
(informative)

Used Tools

G.1 RiskEars

iNTeg-Risk RiskEars and RiskEars Forum are offering a platform with highly sophisticated use management and supported by mapping of relevant experts for different areas. RiskEars, the Emerging Risk Early Warning & Monitoring System of iNTeg-Risk 1StopShop is a database system for acquisition and monitoring of early warnings. The word notion indicates something that can become a threat. RiskEars enables to manage and follow the further development or maturation of the notion towards a full-scale risk.

The system allows to collect notions of emerging risks (currently almost 600 in system) coming from different sources, usually persons and/or organizations of confidence, registered as the so-called iNTeg-Risk emerging risks sentinels, i.e. professionals rated as credible sources of notions about emerging risks.

Based largely on the work done for iNTeg-Risk ERRA A2: Insurance and re-insurance aspects of emerging risks including the security-related (HSSE) emerging risks of new technologies, and the IT-platform developed for the whole project, the module has reached the level of realistic test applications. RiskEars allows monitoring of the evolution of risks (e.g. from early notion to a litigation case).

A notion in itself is not a risk. It needs processing and elaboration in order to get the shape of a scenario. These scenarios in iNTeg-Risk project are denoted ERIs (Emerging Risk Issues) as being pertinent to an application area. e.g., an industrial plant (or a type of industrial plants – corresponding to the iNTeg-Risk term ERRA – Emerging Risk Representative industrial Application) undergo the risk analysis process through a number of such scenarios (see Figure G.1).

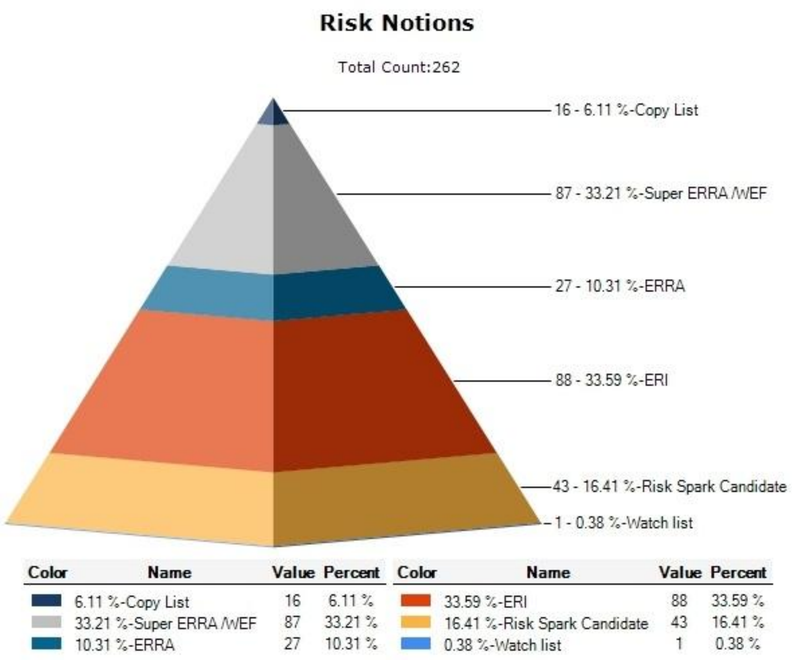

Figure G.1 — Overview of notions (RiskSparks, with notions included in watch list and copy list), ERIs, ERRAs and Super ERRAs

The emerging risks early notions consisting of weak signals, precursors and other form of collected evidence about a possible or imagined threat play an important role in ERMF because they allow modeling the process of risk maturation. Hence, the proposed concept now consists of four levels, corresponding to:

— Notions: Events, signal, and evidence, sub-subclasses and instances;

— ERIs: Issues, scenarios, subclasses;

— ERRAs: (New) Technologies, classes;

— Super ERRAs: ERRAs denoted by WEF as “global threat”.

G.2 RiskTweet

RiskTweet, a part of the iNTeg-Risk 1StopShop monitors tweets (tweet is a short message sent using social network Twitter) posted in Twitter, as one of the indicators that shows the current hot topic in the community, and also provides information about the amount of tweets per day/month on the topic, geographical and other relevant details including possible links/cross-reference to other media. This enables a decision maker to decide on how notion/ERI/ERRA is a hot topic for users of the Social Media network. The yellow and the red line, shown in Figure A.2, are customizable alert and alarm levels that can be introduced for creating automatic notifications. RiskTweet is also offering possibility to check, if available, Google Trends for searched notion (see Figure G.2).

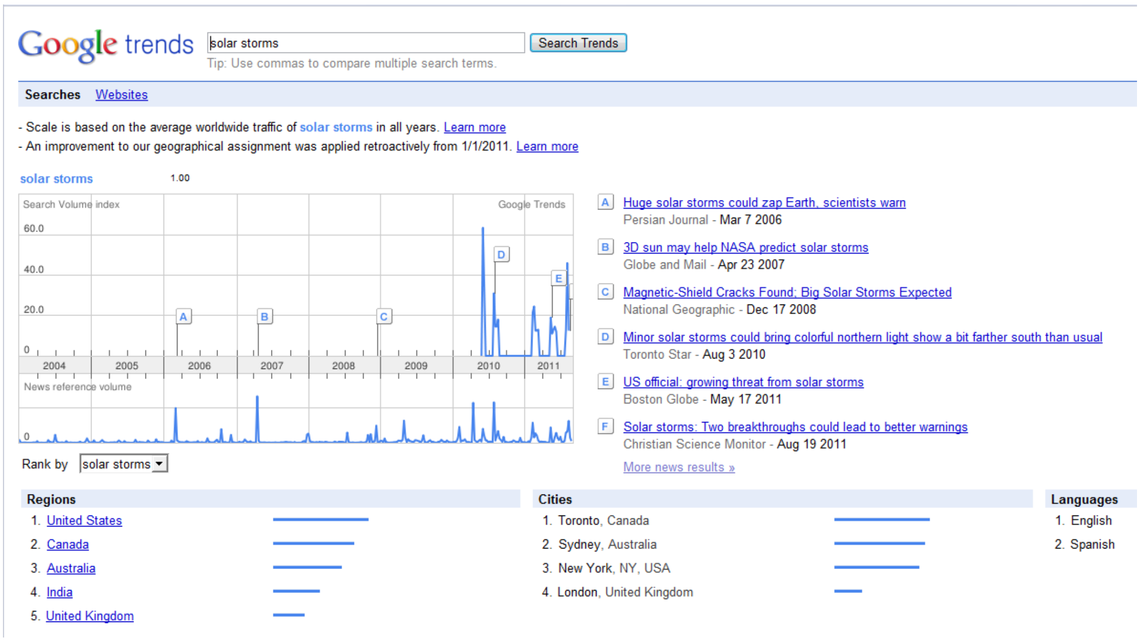

Figure G.2 — Reference to Google trends results for geomagnetic storms

RiskTweet is tracking notions based on three important aspects:

— Activity;

— Trend; and

— Criticality.

G.2.1 Activity

On each day RiskTweet counts the number of tweets with a keyword (volume) and compares this number to the average volume. Depending on the volume of keyword on the given day and the average volume of tweets per day, activity can be between +1 and -1 and it measures how close the volume is to its all-time high or all-time low, irrespective of actual volume.

$$activity = \begin{cases} -1 & \text{tweeting is at all-time low} \\ 0 & \text{tweeting is at average volume} \\ +1 & \text{tweeting is at all-time high} \end{cases}$$

G.2.2 Trend

The trend is measured by computing the MACD (moving average convergence/divergence) of the normalized volume time series, shown in Figure G.3.

Figure G.3 — MACD

Moving average is a statistical tool used to analyze a set of data points by creating a series of different subset averages of the full data set. It is called moving because it is continually recomputed as new data becomes available. The **fast moving average** is a short term moving while a long term is **slow moving average** as it sums data over a large period of time. The MACD is the difference between the two averages.

G.2.3 Criticality

Criticality measures if the respective issue is currently undergoing major shifts or changes in behavior. It lies per construction in the range (0 to1) and it is largest if the keyword has the highest volume in history and the trend is still increasing.

G.3 S-RDI tool

The S-RDI tool (Semantic Risk Distance Index) developed within iNTeg-Risk project provides graphical representations based on similarity score calculated by overlap of properties plus semantic similarity of text in order to identify similarities between well known and well managed risk scenarios and new, emerging risk scenarios related to the to-be introduced technology.

A technique for developing relevant keywords, by focusing tightly on keywords and keyword phrases that are associative and closely related, is referred to as semantic clustering. This is a technique that has been adapted by S-RDI tool. The S-RDI tool measures the semantic similarity between key words that has been given as input to the tool and using this result a graph is mapped. Node size is proportional to its eigenvector centrality (~Google's page rank - a measure for importance). The color indicates the node's degree (e.g. the deeper the color, the higher the degree). Thickness of links indicates projects' similarities.

The S-RDI tool is designed to visualize and analyze similarities and interconnections between vast numbers of elements for which a textual description is available. Suppose one is confronted with, say, thousand documents containing descriptions about different emerging risks and one is interested in finding connections between individual risks in this dataset, cluster these documents around a given number of themes or find out which of them have the largest potential to contribute to systemic risks. The S-RDI tool provides a fully automated way aiding this process.

The strategy implemented here can be roughly outlined as follows. For the data it is only required to be a structured text with identifiable labels and content, such as provided by the iNTeg-Risk RiskEars system. Each pair of texts is searched for keywords co-occurring in both of the documents. From this a similarity score i.e. the S-RDI (semantic risk distance index) is computed. Based on this measure the documents are clustered by a complete linkage algorithm. To visualize these results network theoretic tools are employed. From the matrix of pair-wise similarity scores the maximum spanning tree is constructed, that is the network with the smallest number of edges with the highest values of similarity scores spanning the entire set of documents. This maximum spanning tree is made ready for visualization by a force-directed drawing algorithm.

G.4 Agent based modeling

Agent Based Models (ABMs) are a class of computational models simulating (inter-) actions of individual agents and their environment. The ABM was implemented in Microsoft.NET Framework as a Silverlight application. The focus lies on understanding, reproducing and predicting complex patterns of the entire system from the individual agents' behavior. It is also the easiest route to model systems exhibiting path dependence, memory, fractal behavior and other complex phenomena. They are especially suited if one is interested in systemic, large scale properties (macro-level) of systems composed of a large number of heterogeneous, interconnected stakeholders. Each agent is an autonomous decision-making unit. The agent evaluates his situation and takes actions based on a pre-defined set of rules. They are flexible and hence once a model is built, it is easy to add, change or remove rules and agents. Apart from being quantifiable, there are no restrictions to which agent properties and rules can be modeled (non-linear and threshold dynamics, if-then rules, etc.).

The process of developing an ABM can be briefly outlined as follows:

The first point is to identify the agents or key stakeholders of the problem and get a theory of their behavior. An important principle to bear in mind at this point is parsimony. One should only include those agents with the largest influence or importance. Each agent is to be described by a set of quantifiable properties which can be used to express the agent's utilities and payoffs.

The next step in developing an ABM is to identify relations between the agents and get a theory of their interactions. Again, this should be done in a parsimonious way by including only key relations which can be quantified. It is crucial to validate the agent behavior and interaction models with real-world data. To this end data needs to be acquired from reliable and unbiased data sources. This data should be fit to allow comparison with the model data in order to validate the ABM. Social web mining techniques offer an interesting avenue to explore data acquisition and model validation of ABMs.

The model's output should be analyzed in terms of linking individual agent behavior to large scale patterns of the system. Special attention has to be paid to the robustness of these large-scale patterns with respect to changes in model parameter. If these patterns are robust and not sensitive to special choices of model parameters and assumptions, one can attempt to draw conclusions to the real-world problem from the model. If successful, ABMs can play a vital and important role in singling out key factors and components in complex scenarios with a vast number of interdependent entities.

The general strategy in conducting simulations of "What-If" scenarios is to initialize the simulation and simulate a couple of time steps. One may then re-adjust some agent properties and observe the consequences. ABMs have to be developed on a case-by-case basis for specific problems.

Annex H
(informative)

Sample list of emerging risks

Table H.1 — Sample list of emerging risks

Short Title	**Description**	**Technological**	**Environmental**	**Socio-Political**	**Economic/ Financial**	**Regulatory/ Legal**	**Possible positive impact**	**Possible negative impact**	**Likelihood**
Smart grids	The term smart grids as used here refers to a concept of an electricity network using monitoring and communication technologies to intelligently integrate the behavior and actions of all its components and possibly also include an increasingly decentralized energy generation. Smart grids could create a new type of dynamic and interactive “mega-infrastructure”, which has the potential to change the risk landscape by introducing a new information technology component to the electric grid.	■		■			Medium	Medium	Medium
Cyber vulnerability	Most critical infrastructures (e.g. power generation/distribution, oil/gas production/distribution) are controlled by a web of dedicated computers typically known as Supervisory Control and Data Acquisition (SCADA) systems. Cyber-attacks on SCADA systems may lead to physical damage and may trigger property fire, machinery breakdown or business interruption (BI/CBI).	■			■		Very high	High	Very high

Short Title	**Description**	**Technological**	**Environmental**	**Socio-Political**	**Economic/ Financial**	**Regulatory/ Legal**	**Possible positive impact**	**Possible negative impact**	**Likelihood**
Geomagnetic storms	The impacts of the intense space weather related phenomenon are ranging from space-borne technology damages due to showers of charged particles and energetic radiation, disturbances of radio communication systems and air transportation problems to extensive damage of the electrical power system through geomagnetically induced currents (GICs).	■		■	■		Not assessed	Very high	Medium
Unmanned surveillance in industry	Breakthroughs in surveillance technologies and practices for more efficient identification of undeclared yards can produce a real decrease of e.g. pipeline failures. The main risk management driver is to decrease failure frequency via external damage prevention activities. Several emerging technologies are candidates for improved surveillance, a combination of which are drones for image acquisition and automated image processing for alarm information extraction.	■			■	■	Medium	High	High
Underground hubs-safety	Given the technological development in the underground construction area and in addition the increasing need for public transportation, more and more tunnels are built and underground spaces are used for more than only transportation of passengers. The involvement of several stakeholders, e.g. constructors, operators, users and first responders, leads to a challenging situation in case of an incident followed by the need for evacuation.			■		■	Very high	High	Medium

Short Title	Description	Technological	Environmental	Socio-Political	Economic/ Financial	Regulatory/ Legal	Possible positive impact	Possible negative impact	Likelihood
Nano technologies – SMEs	Nanotechnology deals with matter on a near-atomic scale to produce new structures materials and devices. Legislation does not cover the relevant issues completely. Especially for new start-up companies or traditional SMEs this situation creates the problem of how to keep in touch with the rapid market development and at the same time establishing a responsible and safe production environment. SMEs facing the situation of introducing nanotechnology into their production will have additional problems.	■ (red)		■ (yellow)		■ (yellow)	High	Medium	Medium
Nano technology based industry	Nanotechnology bears the potential to transform many industries and to be applied in a variety of different areas ranging from the automotive industry to medicine and surgery. For many of these substances there is little or no knowledge about their physiological or toxicological behavior in contact with human beings, animals and the environment.	■ (red)		■ (red)			Very high	High	Medium
Advanced materials	The major objective is to identify issues related to the introduction of new materials and the effect that advanced materials will potentially have on the environmental, health and safety risk of the current and future products throughout their life cycle. The new materials and structural concepts that are likely to be incorporated into next-generation products and the factors influencing application decisions should be investigated in view of the potential risks.	■ (red)	■ (yellow)				High	Low	Low

Short Title	Description	Technological	Environmental	Socio-Political	Economic/ Financial	Regulatory/ Legal	Possible positive impact	Possible negative impact	Likelihood
Outsourcing - critical tasks	The past has shown and proved that companies which outsource critical tasks may experience major accidents where contributing causes can be traced back to effects to outsourcing. Also companies which decide to shift the “to be in place” and domestic production of non-specific products into countries with low labor costs triggers an increase of product liability or recall cases.		■		■		Low	Low	Medium
Oil spill in sensitive area	The production of oil and gas (with increased use of more cost efficient integrated operations/remote operations) in environmental sensitive areas (previously not opened for oil production) constitutes an emerging risk – a risk of environmental destruction due to oil spills. The challenge is to provide confidence that oil and gas can be explored and produced in sensitive areas in a defensible manner by way of integrated operations managed by cooperating (virtual) organizations.	■	■				Very high	High	High
One of the kind major accidents	The reduction in one of the kind major accidents has been difficult to achieve, despite the considerable investment in response to the relevant European Directives and their implementation in member states. One factor is that several major incidents in Europe in recent years (e.g. Buncefield, Toulouse) were not considered by their site Seveso II Safety Case	■	■		■		Medium	Very high	Low
Security of energy supply	The EU has faced energy supply problems as portrayed by events such as blackouts (in various EU countries in 2003, 2004, and 2006) and gas shortages (all over Europe in 2006). New solutions are thus needed for addressing this issue where data are missing, when inputs are uncertain.			■		■	High	Low	Medium

Short Title	Description	Technological	Environmental	Socio-Political	Economic/ Financial	Regulatory/ Legal	Possible positive impact	Possible negative impact	Likelihood
Distributed Energy Resources	Distributed generation is the move of power generation closer to the consumer (industrial, commercial, domestic). Distributed Energy Resources (DER) approach is basically different from the traditional model of centralized production of electricity. DER will involve either new technology (e.g. fuel cells) or established technology both operating in novel situations, where emerging risks have not been clearly identified.			■		■	High	Low	Medium
Natural-technological accidents (NaTech)	Natural-technological accidents, or NaTechs, reveal a particular exposure and vulnerability of industrial facilities to extreme, intense or more generally localized natural hazards. As defining characteristics of the environment surrounding industrial facilities, natural hazards can be considered as "systemic" features.	■	■				Not assessed	Very high	Low
New risk of biogas	Biogas is a promising energy resource in the context of the new European Energy Strategy 2020. It represents a valorization of wastes (water or biomass) and can be produced all over Europe for a great variety of applications: transport, stationary energy use, etc. The main emerging risk issues related to quick development of biogas, which is explosive, toxic, and pathogen (microbiological hazard), are: diversity of process, the lack of regulation and the lack of organized communication channels to share the experiences	■				■	High	Medium	High
Fracking	Fracking is a process in which water and toxic chemicals are injected at high pressure into the ground to break up rocks and release gas trapped there. For decades, oil and gas industry executives as well as regulators have maintained that this drilling technique, which is used for most natural gas wells has never contaminated underground drinking water. But is that the case, or is there risk of contamination?		■	■			High	Very high	Medium

Short Title	Description	Technological	Environmental	Socio-Political	Economic/ Financial	Regulatory/ Legal	Possible positive impact	Possible negative impact	Likelihood
Unconventional gas	Unconventional gas refers to a part of the gas resource base that has traditionally been considered difficult or costly to produce. The main issue is the question whether using these "new" resources will help boost state's economy or if it will make new problems with respect to regulations needed for safe extraction of gas.	■	■				Medium	High	Medium

NOTE Assessment marked with dash line (⬚) represent categories of second or third order of importance (mainly for assigning risk category), assessed by experts in iNTeg-Risk project from January 2013. Used color code is for scoring emerging risks as suggested in section 5.4, table 1.

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