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This is a pre print version of the following article:

Original Citation:

Availability:

This version is available http://hdl.handle.net/2318/1655669 since 2018-10-31T14:40:43Z

Published version:

DOI:10.1111/risa.12954

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23 December 2024

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Journal:	*Risk Analysis*
Manuscript ID	RA-00123-2017.R2
Wiley - Manuscript type:	Perspective
Key Words:	Risk communication, Nano-regulation, Risk governance

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2nd revision submitted for publication in Risk Analysis

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Abstract

Societies worldwide are investing considerable resources into the safe development and use of nanomaterials. Whilst each of these protective efforts are crucial for governing the risks of nanomaterials, they are insufficient in isolation. What is missing is a more integrative governance approach that goes beyond legislation. Development of this approach must be evidence-based and involve key stakeholders to ensure acceptance by end users. The challenge is to develop a framework that coordinates the variety of actors involved in nanotechnology and civil society to facilitate consideration of the complex issues that occur in this rapidly evolving research and development area. Here, we propose three sets of essential elements required to generate an effective risk governance framework for nanomaterials: 1. Advanced tools to facilitate risk-based decision-making, including an assessment of the needs of users regarding risk assessment, mitigation and transfer. 2. An integrated model of predicted human behavior and decision-making concerning nanomaterial risks. 3. Legal and other (nano-specific and general) regulatory requirements to ensure compliance and to stimulate proactive approaches to safety. The implementation of such an approach should facilitate and motivate good practice for the various stakeholders to allow the safe and sustainable future development of nanotechnology.

Keywords: Decision-making; Nano-regulation; Risk communication; Risk governance; Risk management

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1. INTRODUCTION

For over a decade it has been recognized that nanotechnologies offer great opportunities for society, but for them to reach their full potential the risks, particularly of nanomaterials (NMs), must be addressed.(1) An ever-expanding heterogeneous array of NMs are being incorporated into a diverse range of industries and applications. This variety and wide-spread use has fostered a growing interest in their safety and risk management. Thus, key stakeholders worldwide invest considerable resources into the safe development and use of NMs. More specifically, governments, private companies, and other actors have sought to govern human behaviors and decisions related to NMs through the use of various tools and risk management efforts. For example, internationally much effort has been directed to support risk assessment/management related research which will both help companies implement risk prevention (and mitigation) strategies, as well as aid the development of general and specific NM-relevant regulations.(2) This work has included expert bodies (e.g. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)), regulators (e.g. European Food Safety Authority (EFSA) or the US Food and Drug Administration (FDA) and Environmental Protection Agency (EPA)), as well as academic researchers who have investigated whether existing risk assessment procedures and frameworks for conventional chemicals are applicable to NMs. In particular, these studies and reports have investigated and identified specific challenges for NMs risk assessment.(3,4) This work has been complimented by efforts aimed at fostering dialogue with civil society and the general public in order to explore risks and advantages (risk communication), and with workers to facilitate a better understanding of risks, thereby aiming to stimulate more competent decisions and risk-reducing behavioral changes.

To align these substantial efforts, a comprehensive evidence-based, optimized, and transparent risk governance framework, specifically targeted at NMs, is now needed. Against the broad range of governance definitions in the literature,(5) we understand governance as the social and institutional arrangements that systematically influence patterns of behavior. These include formal regulations, informal norms of appropriateness and established practical routines.

A coherent NM risk governance framework should address the manifold challenges that NMs pose to be addressed in a joined-up, coordinated manner, thereby avoiding piece-meal solutions to NM risk management. It would support the governance of complex and consequential risks in the presence of the specific challenges and uncertainty implied by many NMs.(6)

Such a governance framework needs to be relevant to risk-related behaviors and decisions by societal actors throughout the life-cycle of a given NM, whether they are pristine materials or incorporated into a product. It would structure decision making and influence behaviours at the institutional and individual level, allowing identification of the options available to the various actors while understanding constraints such as who is entitled or required to make a decision, who is responsible and who is liable. (7-9) Decisions related to NM risks are made within a context of both hard law (formal regulations and statues), soft law (non-binding agreements and established good practice) and non-legal social norms and expectations (e.g. public blaming and shaming, reputational risks).

In this paper, we address these issues by drawing upon social sciences, material science, legal-regulatory science, and risk-related research(10) to identify and describe essential elements of a risk governance framework for NMs. Moreover, we provide an outline of the tools needed for such a framework, and how they could be integrated effectively. Finally, we highlight the key factors required for the success of such an integrated risk governance framework. We believe that the proposed framework provides a basis for a comprehensive management of NM-related risks that will help to specify the needs for tool development to facilitate risk decision making and thus to foster trust in NM innovation.

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2. THE NEED FOR A SPECIFIC NANO-RISK FRAMEWORK

Currently the legal or regulatory requirements for nanotechnologies are spread over a fragmented set of regulations that cover general substances (e.g. Registration Evaluation Authorisation and Restriction of Chemicals (REACH), Toxic Substances Control Act (TSCA)), specific goods containing NMs (e.g. food law, chemical law, cosmetics law or pharmaceutical law), or aim to protect specific groups exposed to NMs (e.g. occupational health and safety regulation). A recent research roadmap by the European NanoSafety Cluster summarizes the current status of such regulations in Europe and the USA(11) and includes a number of general, non-nano-specific legal or regulatory procedures and frameworks that are applicable to nano-relevant risks.(12-14) With respect to REACH, a number of dedicated studies (e.g. RIPON) and a REACH Review in 2012(15) have assessed the suitability of this legislation,(16,17) leading to a Commission Communication(18) concluding that NMs "are covered by the definition of a "substance" in REACH, even though there is no explicit reference to nanomaterials." According to the European Commission, REACH is hence applicable to NMs, making such materials subject to general registration with ECHA. However, legally this interpretation is not yet binding; final clarification would only be provided through an amendment of REACH or a judgment by the Court of Justice of the European Union (CJEU). Likewise, the US FDA reviews risk concerns of NMs within the context of the specific legal standards applicable to each type of product under its jurisdiction, such as with cosmetics, food additives, etc. This product-focused regulatory assessment empowers the FDA to conduct pre- and post-market reviews, and to coordinate with established domestic and international counterparts via the Emerging Technologies Interagency Policy Coordination Committee.

This suggests that the governance of risks related to NMs should be considered within the context of existing regulatory and legal frameworks. However, although the current procedures for risk assessment of conventional chemicals may, in principle, be applicable to

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NMs,(3,4) much effort has been made to improve this process, not only to ensure that it is NM-relevant, but also with the future ambition to make the process more efficient and intelligent in order to deal with the ever expanding number of NMs (and nano-enabled products). Yet, current and future NMs pose a set of specific challenges for risk governance, which may require a nano-specific risk governance framework.(6) This demand is driven by multiple economic and regulatory factors, including the rapid pace of commercial or near-market development of NMs on a global scale. A nano-specific framework could harmonize risk-based approaches for NM assessment for actors with traditionally diverging risk assessment practices, and help indicate and ameliorate gaps in NM hazard, exposure, or effects assessment that currently drive the field's uncertainty with regard to health risks. Without such a nano-specific framework, it will be difficult for regulators and industry to resolve uncertainties posed by NMs and their unique physical characteristics.

The cross-border flow of information and the internationalization of markets necessitate the development of an international paradigm. The different regulatory regimes, in particular different attitudes towards the precautionary principle, suggest that a multi-stakeholder approach that leverages the development of NM best practices through the coordination of effort by industry, government, and other relevant parties, could be most promising in developing shared practice that fit the various regulatory environments.

One of the fundamental challenges for risk governance of NMs is that NMs often share few common characteristics besides the nanoscale, and that they can exhibit multiple forms and variations over their life-cycles.(19) For example, NMs may undergo changes in their physicochemical characteristics, such as agglomeration or de-agglomeration, in certain environmental conditions, and this change may have an impact on the toxicity of the respective NM.(6) This challenge is further compounded by difficulties in identifying, quantifying and discriminating between natural and engineered NMs.(6) Not surprisingly, this poses problems for the characterization of properties in toxicological studies, which may lead

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to diversity in the applied methods and therefore difficulties in comparing findings.(20) Consequently, any framework for governing NM risks needs to pay attention to this specific challenge and foster a viable way for risk assessment, notably for next-generation NMs, that efficiently considers potential changes in the physicochemical characteristics of NMs during their life cycles and the likely use of incomplete datasets.

Even for a seemingly "simple" question of the risk assessment process, NMs pose particular challenges in comparison to conventional chemicals: no agreement so far has been reached on a concept of dose, concentration or metric of NMs in test systems.(6) This renders the application of current risk assessment practices difficult.

As well as complying with existing regulatory and legal frameworks, any risk assessment framework needs to be sufficiently flexible or adaptable to align with new regulations as they adapt and evolve. Examples of this include considerations of environmental, occupational, and food/drug-based regulatory requirements and oversight driven within the US by the EPA, the Occupational Safety and Health Administration (OSHA), and FDA, (13,21,22) or in Europe by the European Environment Agency, EU-OSHA or the EFSA.

Above we have addressed challenges relating to risk related research, material science and the legal-regulatory environment, but in addition a governance framework will benefit from integrating perspectives from other domains, in particular social sciences(10) in order to develop practical solutions for the important, urgent and complex risk decisions(23) regarding NMs at all societal levels. Such a risk governance framework would significantly contribute to the goal of achieving sustainable development for nanotechnologies. Furthermore it could act as a model on which to build governance frameworks for other key emerging technologies (KETs). Therefore, in order to spur discussion about such a comprehensive NM risk governance framework and to suggest some key features and tools, we proffer a tentative version of such a framework in the following.

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3. A FRAMEWORK FOR NM RISK GOVERNANCE

3.1. The Essential Elements of the NM Risk Governance Framework

We propose that to construct an effective risk governance framework for NMs, three element groups are required (see Figure 1):

1. A set of *advanced tools and strategies to support risk decision making*. These start with assessment of the needs of the users (where do they work, what experience do they have in risk decision making, etc.) in order to ensure that the information provided is appropriate in content, style and level of detail.(24) This assessment of user needs will be linked to tools for risk assessment (spanning hazard, exposure and physicochemical characterization), mitigation (e.g. prevention of exposure, or reduced hazard using Safer by Design approaches) and transfer (e.g. insurance), which all feed into a tool for risk decision making.(25) The tools and strategies, which address potential risks posed by NMs along their value chain/life cycle, are currently both experimental and computational (see Table I, and Figure 1, central multi-colored circle). In line with ITS-NANO,(26) we propose that the reliance on testing should decrease over time as computational models become more comprehensive and robust.
2. An integrated model of *human behavior and decision making* (based on empirical data gathered at the individual, organizational, national and international level) that influences how the framework is refined, used and interpreted (Figure 1, green circle).
3. An integrated overview of *nano-specific and general legal regulatory requirements,* the options within which are informed by a series of interlinked decision-making points along the value chain and life cycle of NMs (Figure 1, grey boxes). Regulations evolve with time, and so the framework needs to be able to adapt to changes in the broader regulatory environment.(27) Simultaneously, by demonstrating the need and/or ability to deal with NMs of high or unknown risk, the framework can guide development of NM-specific regulations.

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We believe that the integration of these three elements has the potential to generate a robust and encompassing risk governance framework for NMs, which fulfills the six criteria outlined below.

3.2. Criteria for a Promising NM Risk Governance Framework

The goal of achieving sustainable development for nanotechnologies – by instilling trust into NM innovation and avoiding piece-meal solutions to risk governance – forms the starting point for our risk governance framework. Criteria for such a NM risk governance framework therefore include:

The need to fully leverage existing knowledge and tools. A risk governance framework is most likely to further trust in NM innovation when integrating and exploiting the best, currently available tools (see Table I). Projects such as caLIBRAte (European Commission funded via Horizon 2020) are already working towards the calibration of such tools, and aim to collect and analyze existing control banding tools and quantitative hazard, exposure and risk assessment models and risk management systems for nanomaterials. Further, these tools are selected for sensitivity analysis, performance testing, further improvement and calibration with a final aim that the framework and its underlying tools represent the state of the art in analytical capacity to inform nanotechnology risk governance decision making.

Robust protocols to address incomplete knowledge. Risk assessment, notably for next generation NMs, is likely to be based on incomplete datasets and subject to high uncertainty. Therefore, a framework which employs effective strategies to deal with gaps in knowledge is required.

Ability to adapt to new insights and new NMs. Given the high velocity of developments in the NM field, static frameworks risk falling out of sync quickly. Therefore, a framework must be sufficiently adaptable as to allow the included tools to be updated for future generations of NMs, and to incorporate learning over time. Such an adaptive style of governance should be flexible enough to account for the unique political and institutional

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realities of a given jurisdiction, and allow existing regulatory structures to iteratively incorporate new risk knowledge over time such as via TSCA in the United States, or REACH regulations in the European Union.(28)

Comprehensive consideration of the motivation of various users: For a framework to be effective, it has to accommodate the responses of the various parties (e.g., employers, workers, regulators, policy makers, insurers, general public) in order to motivate compliance and best practices. Motivations can be provided in a variety of forms, e.g., as financial incentives, as legal liabilities, socially embedded norms of appropriateness, role models or via a corporate code of conduct.

Communicate the advantages of employing rules and regulations. For the rules and regulations to be effective, their rationale has to be effectively linked to the motivations, norms and interests of the various actors. This requires evidence and storylines of how they help in protecting workers, society, the environment and consequently the sustainability of nano industries.

Delivering compliance and beyond: A risk governance framework for NMs seems most promising in achieving the objective of sustainable NMs if it not only fosters organizational practices which ensure compliance with current and future legal and regulatory requirements, but also goes beyond pure compliance and stimulates proactive 'good' behavior and innovation.

By adopting these objectives the resultant risk governance framework will be responsive, rational, transparent and inclusive in the sense that it uses and constantly up-dates all available data, links them to decision-making guidance through publicly available rules and integrates the needs and concerns of a wide range of stakeholders.

3.3. Tools and strategies for assessing potential risk and risk decision making

We propose a set of four advanced tools and strategies to support risk decision making: risk banding, risk mitigation, risk transfer, and user capacities and needs. The first tool, risk

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banding, stems from risk assessment strategies. Risk assessment systematically applies scientific principles, guided by the precautionary principle, to estimate the probability that adverse human health or environmental effects could emerge from exposure to substances. The risk assessment framework is composed of problem formulation, exposure assessment, hazard assessment as well as risk and uncertainty characterization.(29)

The paradigm for risk assessment of chemicals is considered applicable to nanoscale materials,(26,30,31) however many of the tools, test protocols and guidelines for determination and assessment of physicochemical properties, fate, exposure, and effects used for conventional chemicals need modifications when applied to (the regulatory) safety assessment of NMs. The work on adapting existing methods for NMs has been ongoing in the Organisation for Economic Co-operation and Development (OECD) Working Party of Manufactured Nanomaterials (WPMN) and in many research projects. This work has resulted in an array of nano-specific or nano-relevant experimental and modelling tools suited to address the complexity associated with the identity, biological and environmental interactions of NMs in order to reduce the uncertainty in their risk assessment. These tools were comprehensively reviewed by Hristozov et al.(32)

These tools have been applied to generate extensive physicochemical, hazard and exposure datasets. However, while a significant body of data exists for some NMs, for many (including next-generation) NMs, risk assessment is likely to be based on incomplete datasets. When combined with the significant uncertainty regarding extrapolation from animal or *in vitro* hazard data to the quantification of human health or environmental risks, this lack of data could result in an under-protective or overly conservative assessment of health risks, resulting in either unacceptable risks or stifled innovation. Given the fast development of highly innovative NMs, it is not feasible to complete a risk assessment of NMs on a case-by-case basis. Hence, new approaches to risk assessment are required(33) which allow for

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accelerating the risk assessment process, for example via grouping and/or read-across of NMs.

Bodies such as the OECD and ECHA(34-36) are developing NM grouping or categorization schemes(37) in order to reduce the extensive hazard, exposure and physicochemical testing requirements to a feasible level. A number of studies have been developing risk banding tools (e.g., Stoffenmanager Nano,(38) NanoRiskCat,(39) Swiss Precautionary Matrix, NanoSafer etc), which are based on the Precautionary Principle and are designed to incorporate the full range of uncertainty in their results in order to inform risk management decisions based on worst-case scenarios.(40) In a differing approach, the US FDA, among other agencies, convene quarterly interest groups which review risk and regulatory concerns of emerging trends in NM development, including risk categorization exercises and product-specific regulatory discussion.(21,22) Moreover, risk screening and ranking schemes based on weight of evidence approaches have been proposed, which explicitly estimated the uncertainty stemming from hazard and exposure assessments. Specifically, Hristozov et al.(41) developed the first quantitative Multi-Criteria Decision Analysis (MCDA) methodology for human health hazard identification of NMs, which incorporated data quality evaluation of the available dataset, based on the criteria adequacy, reliability, statistical and toxicological significance.(42) Moreover, a quantitative MCDA approach for prioritization of nano-specific exposure scenarios was proposed for occupational settings,(43) and a quantitative MCDA methodology for human health risk ranking of NMs was developed.(44) All three approaches quantified the uncertainty in the assessments by means of a Monte Carlo methodology.

If successful, such grouping and categorization schemes provide the opportunity to fill missing data within groups of similar NMs using computational (*in silico*) techniques such as Quantitative Structure Activity Relationships for NMs (abbreviated as: nano-QSAR, QNAR, QNTR)(45-47) or read-across between NMs, or between NMs and other substances.(47) As a

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result, time and cost of testing as well as the use of laboratory animals could be reduced. In fact, great progress in developing *in silico* methods for risk assessment of NMs has been made by several EU FP7 “modelling projects” (NanoPUZZLES, MODERN, ModENPTox, MembraneNanoPart, PreNanoTox). These projects have jointly proposed criteria important for appropriate quality validation of nano-QSAR models to be developed in future initiatives.(48)

For such risk assessment tools to be effective they will require a combination of analytical, computational toxicology, machine learning and Bayesian methods to unravel and clearly communicate the uncertainties in the results. The risk assessment tool will need to provide information that is applicable to occupational, consumer and environmental settings, addressing different life cycle stages of the NMs in order to address risks from the design and manufacture stages through to disposal and recycling. The risk assessment tool should take into account the level of human and environmental exposure and be sufficiently flexible to accommodate new and future generations of NMs, even when the available data on hazard, exposure and physicochemical characteristics is scarce or even lacking (perhaps by using expert judgment and weight of evidence methodology in a transparent manner). Any risk assessment tool will need to push beyond the state-of-the-art by addressing the uncharted issues of uncertainty related to NM risks. This is relevant for consideration of human health and environmental impact of NMs including susceptible group(s) in the general population and susceptible species in the environment, as well as the impact of NM accumulation in environmental hot spots. It also includes consideration of human behavioral uncertainties based on diverging risk perceptions, organizational routines, and social norms.

To allow for effective risk management of NMs, the risk assessment tool could be linked with tools for risk mitigation and risk transfer. A range of practical NM risk mitigation strategies are required to reduce or prevent risks posed by NMs. These include technical risk mitigation approaches (e.g., safer-by-design), safer manufacturing processes, safer handling

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procedures, and improved exposure controls (e.g., high-efficiency filters). Currently, mitigation approaches, including methods and tools, have been or are being developed in EU FP7 funded projects such as SUN, SANOWORK, NANOMICEX, NANOVALID and GUIDEnano. Safer-by-design approaches are also the main research topics of NANoREG II and ProSAFE. Other initiatives to prevent or minimize risk include the development and application of the precautionary principle, as well as soft law initiatives to drive consideration of nanomaterial-derived product liability and insurance.(49,50) Tools designed to apply the precautionary principle are mostly inspired by the selection of appropriate levels of engineering controls (e.g., engineering techniques and personal protective equipment)(46) or green safer product design or process optimization (e.g., NIOSH's prevention though design initiative).(51)

Risk mitigation strategies also include management support tools (e.g., technical training materials for stakeholders) designed to promote adherence to health and safety policies. Development of such tools could result in improved strategic and transparent identification of approaches to mitigate human and environmental risks associated with NMs.

A governance framework has to provide guidance for the options for a relevant selection of mitigation measures especially in relation to their effectiveness and the value or quality of information about their effectiveness. Together with the definition of technical indicators (which quantify conditions in which measures success or failure) this could also facilitate the risk transfer by impacting on the reduction of risk premiums by insurance companies (see below).

The available options for risk transfer frame the risk management process in relation to factors such as non-contractual and contractual liabilities (see below), (re)insurability of risks, and the ensuing distribution of legal and financial risks that influence decision making. Currently, there is no systematic approach to qualify and quantify NM risk with regard to insurance. At present, insurers implicitly assume nano-specific risk in their health-related or

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general-purpose insurance policies,(52,53) an approach they are uncomfortable with but do not have the knowledge to exclude in a competitive business. To achieve reliable risk transfer arrangements, tools and associated guidance are required that allow mathematical quantification of risks and risk categorization in a context of uncertainty. In addition, tools are needed that identify or develop legally reliable arrangements (see below) between relevant parties involved in the life cycle and value chains relevant to NMs.

In order for the risk assessment, mitigation and transfer tools to guide effective risk management and risk decision making, their activities and outputs need to be integrated. This can be achieved through development and use of a decision support system (DSS). Prototype risk assessment and DSSs for NM risk management have been developed in FP7 funded projects such as SUN and GUIDEnano. These tools are in their early stages of development, and are based on the exploitation of a relatively small number of NM product case studies. Hence, a substantial body of work is required to enhance their reliability and suitability for wider arrays of NMs and NM products (across their value chain/life cycle), exposure scenarios and for a broader set of stakeholders. To improve DSSs further, it will be useful in the future to integrate the risk management tools with a tool to assess the needs, values and capacities of a wide range of users. The design of such a DSS allows the individual tools to be modified and advanced as each is improved, thereby ensuring that it remains up to date and relevant. Achievement of such a DSS optimally increases the efficiency of the risk governance process, for example by reducing the requirement for testing, and assists stakeholders with practical guidance in their decision making process for NMs throughout the value chain and life cycle.

For the governance framework to be useful for stakeholders it is essential that the outputs can be adjusted to meet the needs of the user and to provide a level of detail that is relevant to their understanding and expertise.(54) Assessment of user capacities (e.g., experience and relevant knowledge) allows consideration of different types and levels of

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expertise (e.g., a ‘coal face’ worker never involved in risk assessment compared to an experienced occupational health professional).(55) According to this type of analysis the framework and tools can be adapted to provide outputs that better suit the requirements and understanding of different types of users.

Finally, the DSS outputs need to integrate stakeholder values with evidence-based input in order to recommend clear actions for decision makers. Practical and clear advice for regulatory compliance and best practice should be provided (see below). Integration of these tools allows a national, international and potentially globally applicable standard for the governance of current and future NMs and their applications to be identified.

3.4. Human behavior and decision making

Human behavior and how individuals or organizations prepare and take decisions can vary considerably. Variability in decision making is driven via a wide array of factors including the social context in which the decision is made (e.g., domestic vs. occupational settings), the perception of risks versus potential benefits, the individual or organizational routines and heuristics (i.e. using decisional shortcuts with potential for error).(56,57) These factors apply whether the decision is made by an individual or a team, and whether it is made to align with specific regulations, guidelines or ethical considerations.

To generate an effective governance framework, there is a need to identify the individual, organizational and societal determinants of decision making about NM risk management and transfer along the full value chain and life cycle of NMs. While generic analytical frameworks are available to identify such determinants (e.g., the *homo oeconomicus institutionalis* framework(58)), determinants are expected to vary across different types of contexts. Hence inputs from stakeholders and the wider public are needed to identify how user concerns and needs depend on the types of decisions (e.g., NM design, which NM to use, how to dispose of a NM) and the type of contexts (e.g., research laboratory, factory, or in a regulatory capacity). Building on such context-specific insights will allow for developing

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differentiated risk communication strategies, which need to be dialogical (two-way), to enable co-learning and to enhance trust in the governance of risks from NMs.

4. IMPLEMENTATION OF THE RISK GOVERNANCE FRAMEWORK

Before such a framework can be delivered the individual tools need to be generated and validated. The tool development will need to be evidence-based taking into account the norms and motivations of the users and the impediments to be addressed by the governance framework. The tools need to be built on existing achievements of on-going or completed national or international projects, going beyond the state-of-the-art by systematically diagnosing user needs and capacities, integrating likely behavior, dynamic links to developing knowledge about NM risks, integration of uncertainty into risk assessment. Importantly, to achieve this they need to undergo interactive testing in practice.(59) Empirical studies will therefore be required to illustrate how the tools and guidance of the framework function in a comprehensive and relevant range of practice contexts, and to verify its reliability. Case studies which do not focus on various NMs in isolation, but rather a range of NMs along their respective value chains and life cycles, including interactions with people in different settings (e.g., in industries, as regulators, as researchers, as consumers and in the environment), seem a promising way to gain these insights. Such case studies would need to include a breadth of natural and social science data. Ideally, each case study would demonstrate how an open society addresses the issue of emerging technology and its possible inherent risks in a responsible manner. This will include arrangements for the transfer of risks and the steps required by insurers before underwriting any risks. It will also include signposts for communicating the risks, in creating a narrative that informs and involves the stakeholders in making the key governance decisions to help nurture and sustain the nano industries in a socially desirable manner.

We believe that an international strategy to build such a governance framework is necessary in order to ensure that the framework is sufficiently adaptable to allow and

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encourage improved national, international and global harmonization as well as sustain and likely expand the global market for nanotechnology. Such a framework needs also to empower the broad range of stakeholders in nanotechnology governance with tools that improve practical decision-making in a governance framework that is perceived by society as fair, trustworthy and effective. Furthermore it provides a vehicle to share and organize information, thereby improving the efficiency of risk decision-making.(60)

5. FUTURE STEPS

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With this article, we would like to call for an international strategy to develop an integrated risk governance framework for NMs. This would enable a cooperative and international approach to the governance of NM-related risks through the systematic consideration and integration of stakeholder and user needs, dynamic risk assessment tools and consideration of the various regulatory requirements in multi-layered and fragmented regulatory environments. For rendering such an effort successful, the essential elements of the framework need to be delivered and integrated effectively. The outlined strategy will support stakeholders with diverse backgrounds and knowledge requirements, essentially providing a ‘user paradigm’ consisting of practical advice and solutions for existing and innovative NMs entering the market. Continued involvement of all relevant stakeholders throughout the construction of the framework will be essential. This *inclusive* approach guarantees the maximal stakeholder involvement through construction, consultation, and revision phases. Furthermore, the strategy involves the stakeholders in the design, testing and implementation of the framework and this process of co-production thereby safeguards its relevance and *transparency* leading to enhanced potential for *trust*.(61)

In achieving this risk governance strategy, new solutions will be provided to evaluate the risks potentially arising from the use of NMs, including future NMs. In this regard, the governance framework will likely have significant impact on nanotechnology industries and for investors in nanotechnology, supporting SMEs and large companies in the selection of safer products and processes, limiting the potential adverse effects of NMs on workers and consumers, and reducing insurance costs and risks to public budgets derived from any potential future major accidents or diseases.(62)

By enabling the emergence of reliable expectations about the behaviors and decisions along the value chain, the governance framework proposed here would be attractive for key stakeholders, including the insurance industry which underwrites the risks of these technologies, and the financial industry which invests in it. It would facilitate coordinated risk assessment, management and communication across diverging regulatory environments. Achievement of such a governance framework will help to realize informed, effective, responsive and proportionate governance of NM risks for humans and the environment. It is thus a cornerstone for optimizing social and economic benefits of nanotechnology.

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Table I.

Definitions for risk management tools

Tool	Definition
Risk banding	Allows risk assessment to be performed with incomplete hazard, exposure and physicochemical characterization
Risk mitigation	Provides advice on technical interventions that can reduce the risk and supports worker/decision-making training
Risk transfer	Enables consideration of legal, contractual and insurance arrangements to be made in the decision-making process
User needs and capacities	Assesses expertise and experience of user to determine the format of the information required and the level of detail

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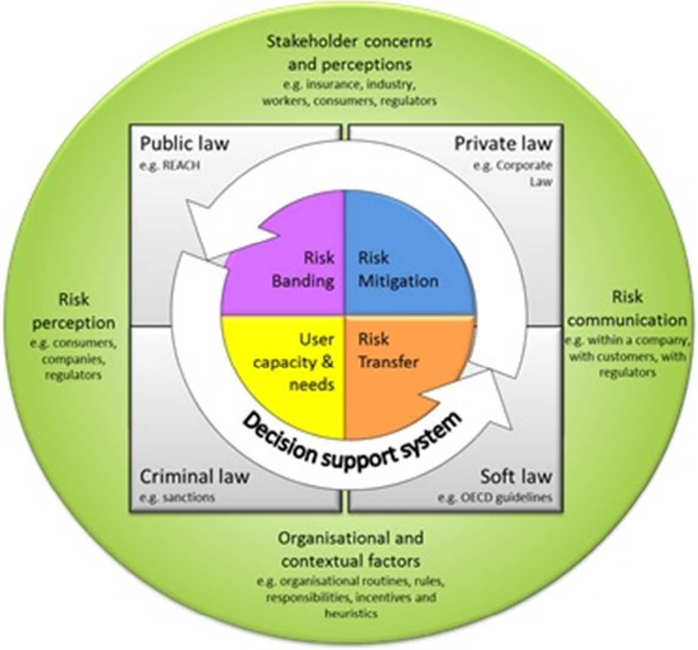
Figure 1.

Essential elements for a risk governance framework for nanomaterials. The central circle houses tools that feed into a decision support system. The decisions generated are guided by the legal/regulatory frameworks (grey boxes), which are determined and interpreted by humans in real life situations (green circle).



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