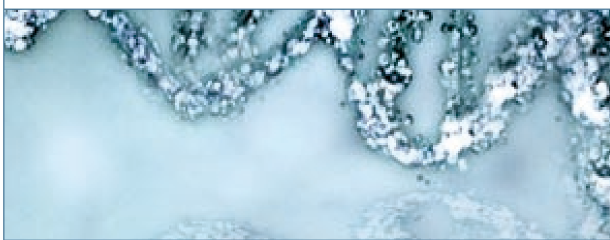
white paper on

NANOTECHNOLOGY

RISK GOVERNANCE



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NANOTECHNOLOGY RISK GOVERNANCE

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with Annexes by Mike Roco and Emily Litten

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- Dr. Timothy Walker, former Director General, Health and Safety Executive, UK.

FOREWORD – ABOUT IRGC AND THIS WHITE PAPER

The International Risk Governance Council (IRGC), a private, independent, not-for-profit Foundation based in Geneva, Switzerland, was founded in 2003. Our mission is to support governments, industry, NGOs and other organisations in their efforts to understand and deal with major and global risks facing society and to foster public confidence in risk governance.

The establishment of IRGC was the direct result of widespread concern within the public sector, the corporate world, academia, the media and society at large that the complexity and interdependence of an increasingly large number of risk issues was making it ever more difficult for risk decision makers to develop and implement adequate risk governance strategies. Consequently, IRGC is committed to identifying new or re-emergent problem fields for which there appear to be gaps in current risk governance structures or processes and undertaking project work which has the objective of supporting these decision makers by developing risk governance recommendations for these issues. We endeavour to work and communicate in ways that account for the needs of both developed and developing countries.

We focus on those risks, whether human induced or natural, which have international implications and have the potential for harm to human health and safety, the economy, the environment, and/or to the fabric of society at large. The issues we address are prioritised by the IRGC's Scientific and Technical Council (S&TC), whose members are all acknowledged experts in risk-related fields and are, collectively and individually, IRGC's primary asset for implementing our mission. IRGC's project work is carried out by S&TC members coupled with other experts in the field in question.

We decided in early 2004 that nanotechnology was a subject meriting our attention: not only does it offer enormous potential benefits, it also presents considerable challenges to regulators, manufacturers and, ultimately, to society at large. This White Paper is the first substantial deliverable of a project, 'Addressing the need for adequate risk governance approaches at the national and international levels in the development of nanotechnology and nanoscale products', which began in early 2005. All project work has been defined and undertaken by a project team led by Mike Roco, and this White Paper is primarily the result of work by Mike and Ortwin Renn, assisted by the project team.

This White Paper on 'Nanotechnology Risk Governance' is the first in which we publish recommendations for the risk governance of a particular problem field. The document begins with a brief description of nanotechnology and its likely future development both in terms of research and the types of product that it does and could support. There are many of them, reflecting the vast range of potential applications for this exciting new science. The document then uses the IRGC's risk governance framework, which we published in 2005, to analyse and identify current deficits in nanotechnology's risk governance today. This analysis has led to the inclusion in the White Paper of a particularly innovative way of looking at nanotechnology and its risk governance. We have categorised nanotechnology in two distinct but overlapping frames, one (referred to in this White Paper as Frame 1) being for technologies and applications that are already on, or will shortly be available on, the market and the other (which we call Frame 2) being for the longer-term. Each of these frames poses a different set of risk governance concerns, although some concerns are common to both frames.

We conclude by offering initial recommendations for how decision makers may choose to deal with these risk governance gaps. These recommendations will be subject to further work, including discussions with appropriate stakeholders, such as government, industry, research organisations and non-governmental organisations. The main objectives for IRGC are: to develop and make available specific advice for improving risk governance, to provide a neutral and constructive platform on the most appropriate approaches to handling the risks and opportunities of nanotechnology and, if possible, to enable all actors to reach a global consensus.

Within IRGC, we describe a White Paper as a document in which we present work-in-progress both to those who may benefit from it and those whose feedback may enable us to further refine the document's contents. This White Paper, in common with all official IRGC documents, has been subject to a formal and rigorous external peer review. We are therefore confident of the theoretical basis for the risk governance recommendations it contains.

This document has been informed by and draws on IRGC's approach to risk characterisation and risk governance, on the knowledge of members of our S&TC and that of many experts with whom we have consulted, and on the results of stakeholder surveys undertaken as part of the project in the second half of 2005. This approach reflects the 'expertise collégiale' by which we undertake all our project work. We remain open and look forward to receiving and acting on knowledge and thoughts from people who may not have been a part of the process so far – particularly from those to whom we address the risk governance recommendations.

None of IRGC's work would be possible without the financial support we receive. In publishing this, our second White Paper, IRGC gratefully acknowledges the donations and other financial contributions we have received for our nanotechnology project, particularly those from the US Environmental Protection Agency and Department of State, the Swiss Federal Agency for Development and Cooperation, and the Swiss Reinsurance Company.

M. Granger Morgan

Chairman of the IRGC's Scientific and Technical Council

ACKNOWLEDGEMENTS

This paper is a product of collaborative effort. Substantial input was provided by an initial workshop held in Geneva, Switzerland in May 2005[1], a second workshop held in Zürich, Switzerland in January 2006[2] and four stakeholder surveys that were undertaken in the second half of 2005[3]. The members of the IRGC's Nanotechnology Working Group gave helpful advice and constructive feedback at all stages of completing the manuscript. Those members are: Lutz Cleemann, Thomas Epprecht, Wolfgang Kröger, Jeffrey McNeely, Nick Pidgeon, Joyce Tait and Timothy Walker. Emily Litten in the IRGC Secretariat edited the manuscript and, with Mike Roco, wrote the text for the Annexes. The authors are indebted to the members of the IRGC Scientific and Technical Council for their feedback, and particularly to Joyce Tait who acted as review coordinator. They are also grateful to the three reviewers of the manuscript, Gerd Bachmann, Lutz Cleemann and Arie Rip who provided constructive criticism and suggestions for improvement. Additional reviews and input were also received from Chris Bunting, Michael Garner, Timothy Mealey, David Rejeski, Joyce Tait, Ulrich Weilenmann and the participants at the above mentioned workshop in January 2006. We are very grateful for all these contributions.

1 This initial scoping workshop involved both risk practitioners and academics and was aimed at identifying the main risk governance deficits associated with nanotechnology and determining which of these were critical for further study. A workshop report is available in the projects section on IRGC's website (www.irgc.org).

2 Sponsored by the Swiss Re Centre for Global Dialogue this workshop involved experts from academia, government, industry, insurance, law and non-governmental organisations and was aimed at providing feedback on and input to the IRGC conceptual framework for nanotechnology risk governance as well as identifying risk governance deficits for nanotechnology and providing recommendations with which to address them. The workshop's background papers as well as a Chairman's Statement can be found on IRGC's website.

3 Surveys were distributed internationally to experts from government (Volume A), industry (Volume B), risk research organisations (Volume C) and non-governmental organisations (Volume D) during the period July to November 2005. The primary objectives of these surveys were to establish current risk governance practices for technology and, if appropriate, nanotechnology, determine how these practices might be applicable to nanotechnology and to obtain recommendations for future risk governance strategies. The survey reports are available on the IRGC's website.

CONTENT OVERVIEW

TABLES AND FIGURES

1 EXECUTIVE SUMMARY

Purpose of this White Paper on 'Nanotechnology Risk Governance'

In this white paper IRGC puts forward a conceptual framework for the risk governance of nanotechnology and analyses its current status in the context of the regulatory environment, international situation, the level of science-policy interface and other aspects. Our purpose is to present decision-makers with a systematic and integrated approach to analysing and managing the anticipated risks, challenges and opportunities of nanotechnology. A key objective of the paper is to offer a framework that can help to address the long-term, cross-boundary and global risk issues, and particularly those that concern multiple stakeholders and which are not addressed by any single authority. On this basis the paper concludes with high-level risk governance recommendations.

The framework includes three innovative concepts for the risk governance of nanotechnology:
- First, IRGC adopts risk governance strategies that reflect four generations of nanotechnology product development and their expected characteristics. Corresponding to the level of complexity, uncertainty and ambiguity in these generations, we further distinguish between levels of risk perception and construct two separately identifiable frames of reference.
- Second, the framework integrates a scientific risk-benefit assessment (including environment, health, and safety (EHS) and ethical, legal and other social issues (ELSI)) with an assessment of risk perception and the societal context of risk (referred to in this white paper as concern assessment). The framework also addresses the educational gap (EG), political and security issues (PSI) and the longer-term human development issues (HDI).
- Third, we elaborate risk management strategies that are based on a corrective and adaptive approach and take into account the level and extent of available knowledge and a societal balancing of the predicted risks and benefits.

Inherent in all three of these concepts and, indeed, throughout the whole risk handling chain are the needs for all interested parties to be effectively engaged, for risk to be suitably and efficiently communicated by and to the different actors, for decision-makers to be open to public concerns and, in cases of high ambiguity, for upstream public engagement to be an integral part of the decision-making process. These principles are an essential input to the recommendations we propose in this white paper.

Target Audience of this White Paper

The complexity of the subject, the different types of agency among and between the different actors, the scope of responsibilities and accountability and the trans-boundary nature of nanotechnology's many benefits and risks make it inevitable that governmental, business, scientific and civil actors cooperate for the purpose of optimising the identification, appraisal and management of the risks associated with nanotechnology. Consequently, we believe that the flexible framework and the recommendations presented in this white paper will be of interest to governments, industry, academia, non-governmental organisations (NGOs) and international organisations dealing with nanotechnology. Our recommendations are addressed to each and all of these sectors although primarily to governments, both individually and collectively, as they are responsible for developing and implementing the policies which will enable the maximum benefit to derive from nanotechnology with the minimum of risk.

Categorisation of Nanotechnology into Two Frames of Reference

The first phase of the IRGC risk governance framework[1] is a pre-assessment of what major societal actors (such as governments, companies, the scientific community, NGOs and the general public) define as areas of concern or impacts that they will label as risk problems. This risk framing places particular importance on the need for all interested parties to share a common understanding of the risk issues being addressed. For nanotechnology, risks and opportunities are commonly associated with changes in the chemical reactivity, mechanical, optical, magnetic and electronic properties of downsized material structures as compared to a bulk structure with the same chemical elements. Additionally, the potential for confluence with modern biology, the digital revolution and cognitive sciences means that we can expect nanotechnology to penetrate and permeate through nearly all sectors and spheres of life (e.g. communication, health, labour, mobility, housing, relaxation, energy and food) and have implications for human development and the environment on a global scale.

These emerging and integrated characteristics of nanotechnology create a situation whereby the risk perception of one application may create images and drive apprehension of other applications with the label nanotechnology that, in reality, require quite different risk governance strategies. For that reason this white paper proposes that nanotechnology development is not viewed as a single consolidated concept but, rather, is categorised into four overlapping generations of new nanotechnology products and processes, each generation having its own unique characteristics: passive nanostructures, active nanostructures, complex nanosystems, and molecular nanosystems (see Table 1). Furthermore, a second distinction can be made in terms of risk perception between the first generation (referred to in Table 1 as Frame 1) and the following three generations (Frame 2) as the extent of knowledge development and the ability to control nanostructure behaviour is more advanced for Frame 1 and the potential social and ethical consequences are expected to be more transformative for Frame 2. Structuring nanotechnology risk governance into these two broad frames of reference allows for research and decision-making pathways to be adapted to the characteristics of each frame and, equally, for risks and concerns to be identified separately. Table 1 provides an overview of the risk governance context for both Frame 1 and Frame 2.

Risk Appraisal of Frame 1 and Frame 2

Risk appraisal is the second phase of the IRGC risk governance framework and comprises two elements: risk assessment and concern assessment. During risk appraisal, the classic risk assessment component - concerned with hazard, exposure and risk - is particularly important for Frame 1 nanostructures where the speed of product development and application exceeds the ability of risk assessors to appraise any new risk(s). The concern assessment component - focused on risk perception and stakeholders' concerns - is particularly important for Frame 2 where there is less substantive knowledge available and actors are more concerned with the social desirability of the anticipated innovations. In this white paper, and summarised in the following two sections, IRGC has identified for each frame the current levels of knowledge available and the key risk appraisal requirements.

Risk Appraisal of Frame 1 (focusing on classic risk assessment)

There is only a limited understanding of the potential EHS risks of nanomaterials and further studies are required for both: (i) hazard characterisation, in areas such as toxicity, ecotoxicity, carcinogenicity,

1 The IRGC's risk governance framework is described in detail in our White Paper No.1 'Risk Governance – Towards An Integrative Approach', published in 2005.

Table 1: The Different Generations and Frames of Nanotechnology Development

	Four Generations	Generation Characteristics	Risk Governance Context
FRAME 1	**First Generation** – passive (steady function) nanostructures e.g. nanostructured coatings and non-invasive; invasive diagnostics for rapid patient monitoring *From 2000 -*	*Behaviour:* inert or reactive nanostructures which have stable behaviour and quasi - constant properties during their use. *Potential risk:* e.g. nanoparticles in cosmetics or food with large scale production and high exposure rates.	*Current context for Frame 1 products and processes:* interested parties are seeking to develop knowledge about the properties of nanomaterials and their EHS implications so that risks can be characterised internationally. Debates are focused on the design and implementation of best practices and regulatory policies. *Risk characterisation:* the nanoscale components of the nanoscale products and processes result in increased system component complexity. *Strategies:* the establishment of an internationally reviewed body of evidence related to toxicological and ecotoxicological experiments, and simulation and monitoring of actual exposure. *Potential conflict:* the question of how much precaution is necessary when producing the nanomaterials (focusing on changes to best practices and regulation) and over their use in potential applications.
FRAME 2	**Second Generation** – active (evolving function nanostructures) e.g. reactive nanostructured materials and sensors; targeted cancer therapies *From 2005 -*	*Behaviour:* the nanostructures' properties are designed to change during operation so behaviour is variable and potentially unstable. Successive changes in state may occur (either intended or as an unforeseen reaction to the external environment). *Potential risk:* e.g. nanobiodevices in the human body; pesticides engineered to react to different conditions.	*Current context for Frame 2 products and processes:* interested parties are considering the social desirability of anticipated innovations. Debates are focused on the process and speed of technical modernisation, changes in the interface between humans, machines and products, and the ethical boundaries of intervention into the environment and living systems (such as possible changes in human development and the inability to predict transformations to the human environment). *Risk characterisation:* the nanoscale components and nanosystems of the Frame 2 products and processes result in knowledge uncertainty and ambiguity. *Strategies:* stakeholders must achieve understanding, engage in discussion about ethical and social responsibility for individuals and affected institutions and build institutional capacity to address unexpected risks. Projected scenarios need to be explored that show plausible (or implausible) links between the convergence of technologies and the possible social, ethical, cultural and perception threats. A major challenge is that decisions need to be undertaken before most of the processes and products are known. *Potential conflicts:* the primary concern of Frame 2 is that the societal implications of any unexpected (or expected but unprepared for) consequences and the inequitable distribution of benefits may create tensions if not properly addressed. These concerns about technological development may not be exclusively linked to nanotechnology but are, at least partially, associated with it and will impact upon stakeholder perceptions and concerns.
	Third Generation – integrated nanosystems (systems of nanosystems) e.g. artificial organs built from the nanoscale; evolutionary nanobiosystems *From 2010 -*	*Behaviour:* passive and/or active nanostructures are integrated into systems using nanoscale synthesis and assembling techniques. Emerging behaviour may be observed because of the complexity of systems with many components and types of interactions. New applications will develop based on the convergence of nanotechnology, biotechnology, information technology and the cognitive sciences (NBIC). *Potential risk:* e.g. modified viruses and bacteria; emerging behaviour of large nanoscale systems.	
	Fourth Generation – heterogeneous molecular nanosystems e.g. nanoscale genetic therapies; molecules designed to selfassemble *From 2015/2020 -*	*Behaviour:* engineered nanosystems and architectures are created from individual molecules or supramolecular components each of which have a specific structure and are designed to play a particular role. Fundamentally new functions and processes begin to emerge with the behaviour of applications being based on that of biological systems. *Potential risk:* e.g. changes in biosystems; intrusive information systems.	

volatility, flammability, persistence and accumulation in cells; and (ii) exposure, including the potential for oral, cutaneous and inhalative uptakes of nanomaterials during production, transport (in air, water, soil and biosystems), decomposition and/or waste disposal.

- Human health risks. Several studies have shown that: (i) due to the high surface-area-to-volume ratio and higher reactivity of nanostructures, large doses can cause cells and organs to demonstrate a toxic response (in particular inflammation) even when the material itself is non-toxic; (ii) some nano-sized particles are able to penetrate the liver and other organs and to pass along nerve axons into the brain; (iii) nanomaterials may combine with iron or other metals, thereby increasing the level of toxicity and presenting unknown risks; (iv) engineered nanomaterials raise particular concerns because of the unknown characteristics of their new properties and their potential use in concentrated amounts; and (v) some nanomaterials may have similar characteristics to known high-risk materials at the microscale.
- Explosion risks. The higher surface reactivity and surface-area-to-volume ratio of nanopowders increases the risk of dust explosion and the ease of ignition.
- Ecological risks. The impact of nanostructures on the environment may be significant because of the potential for: (i) bioaccumulation, particularly if they absorb smaller contaminants such as pesticides, cadmium and organics and transfer them along the food chain; and (ii) persistence, in effect creating non-biodegradable pollutants which, due to the small size of the nanomaterials, will be hard to detect.

The following societal impacts of nanotechnology development have been raised for Frame 1, many of which are also applicable for Frame 2.

- *Political and security risks.* Decisions taken about the direction and level of nanotechnology research and development (R&D) may result in: (i) insufficient investment in key areas to benefit future economic development; (ii) an uneven distribution of nanotechnology risks and benefits among different countries and economic groups; (iii) use in criminal or terrorist activity; and (iv) a new military technological race.
- *Educational gap risk.* If the knowledge within professional communities is not appropriately shared with regulatory agencies, civil society and the public, and, consequently, risk perception is not based on the best available knowledge, innovative opportunities may be lost.

Risk Appraisal of Frame 2 (focusing on concern assessment)

The potential for risk identified in Frame 1 is also relevant to Frame 2 where there is an even lower level of knowledge and understanding of the nanostructures and their behaviours. Over and above this, the risks requiring further study in Frame 2 are primarily related to the assessment of stakeholder concerns including the impact of concern prioritisation amongst the different stakeholders, which is itself dependent on different value-judgements. In this white paper we identify the following as the most significant potential risks:

- *Human development risks.* There is apprehension about the use of nanotechnology to change human identity. Examples include: (i) genetic modification to control factors such as sex or eye colour; (ii) devices to control the human brain and body; (iii) changes to the environment, human safety and quality of life; and (iv) new economic and cultural class systems based on the ability to purchase human improvement technology.
- *Society structural risks.* Risks may be induced and amplified by the effect of social and cultural norms, structures and processes, such as: (i) the inability of the regulatory environment to react rapidly to

new technologies; (ii) the unintended availability to the mass market of products based on applications developed by and for the military (e.g. tiny airborne surveillance devices); and (iii) the impact of the mass media on risk perception (such as in movies and books).
- *Public perception risks.* Recent surveys have shown that public concern is currently less linked to any particular application or risk but rather to the capacity for human misuse, to unexpected technological breakouts, or to nanotechnology's potential to exacerbate existing social inequalities and conflicts. This situation may change if nanotechnology becomes associated with specific incidents and, meanwhile, there remains a deep suspicion of the motives of industry and doubts regarding government ability (or desire) to act if required.
- *Transboundary risks.* The risks faced by any individual, company, region or country depend not only on their own choices but also on those of others. Evidence that control mechanisms do not work in one place may fuel a fierce debate in other parts of the world about the acceptability of nanotechnology in general.

Characterisation and Evaluation of the Benefits and Risks

The third phase in the IRGC risk governance framework – risk characterisation and risk evaluation – characterises the different states of knowledge in each particular frame and evaluates the extent of risk based on a societal balancing of the levels of tolerability or acceptability. This phase is important because it guides risk managers towards risk governance decisions that are practicable for each frame and which take account of the views and needs of different stakeholders. In this white paper IRGC has characterised the current state of knowledge for each frame as simple, complex, uncertain or ambiguous (using (i) a scientific, evidence-based approach and (ii) a societal, value-based risk profile) and provided recommendations for how an appropriate risk evaluation could be undertaken.

Risk-related knowledge for Frame 1 can be best characterised as complex for those system components which contain nanostructures with new properties and functions while impacts on the societal system are expected to be less substantial. Risk-related knowledge for Frame 2 can be best characterised as uncertain for active system components (second generation) and nanosystems as a whole (third and fourth generations). For the more ambiguous large nanostructured systems (third generation) and molecular nanosystems (fourth generation), an appropriate evaluation will require the use of conflict resolution methods in order to resolve problems between stakeholder groups of perception and interpretation.

Risk Management Strategies for Frame 1 and Frame 2

Risk management, the final phase of the risk governance framework, comprises the selection of a strategy or strategies designed to avoid, prevent, reduce, transfer or self-retain risks. For both frames there are factors particular to nanotechnology that will impact on the choice of measures. These include: (i) its multidisciplinary, cross-sectoral and multiple stakeholder nature; (ii) its characterisation as more-or-less complex, uncertain or ambiguous (depending on the specific development or application under consideration); and (iii) the need to ensure the consistent participation in the risk management process of all countries concerned in nanotechnology research, development and application.

This white paper proposes a risk management strategy based on adaptive and corrective measures rather than a simple cause-and-effect approach. Furthermore, it is recommended that risk management strategies include contingency plans for dealing with a wide variety of risk scenarios, so as to prepare for changes in the economy, the societal and political arena or in the available levels of knowledge. Decision-makers also need to distinguish between Frame 1 and Frame 2, designing risk management and communication programmes that provide adequate and effective strategies for the particular characteristics of each frame. Table 2 provides a detailed proposal of our risk management recommendations for Frame 1.

Table 2: Risk Management Recommendations for Frame 1

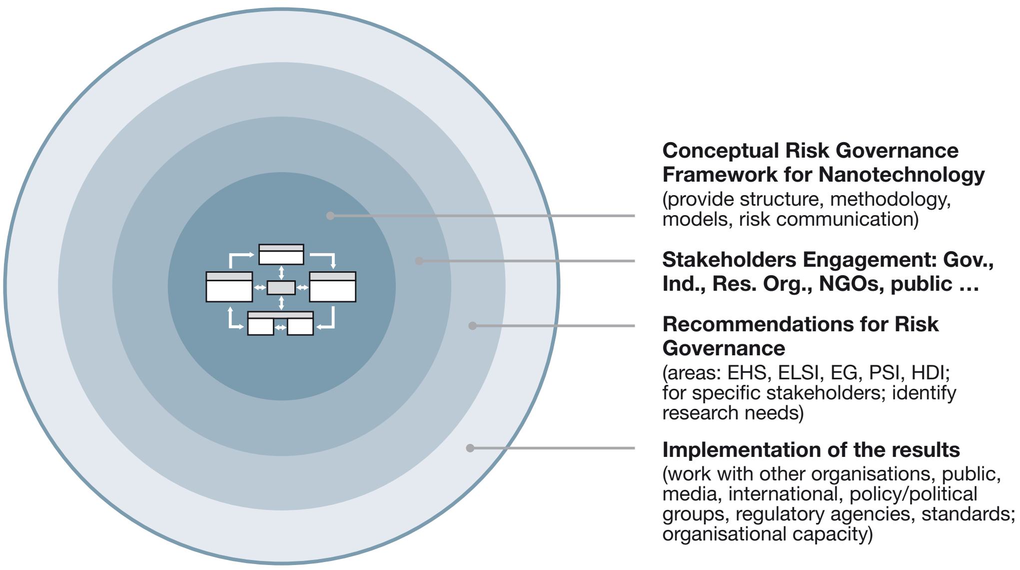
<table>
<tr><th colspan="3">Risk Management Recommendations for Frame 1</th></tr>
<tr>
<td>Hazard Recommendations
• Testing strategies for assessing toxicity and ecotoxicity.
• Best metrics for assessing particle toxicity and ecotoxicity.
• A nomenclature which includes novel attributes, such as surface area.
• Pre-market testing, full lifecycle assessment and consideration of secondary risks.
• Disposal and dispersion methods for nano-engineered materials.
• Development of waste treatment strategies.</td>
<td>Exposure Recommendations
• Exposure monitoring methodologies.
• Methods for reducing exposure and protective equipment.</td>
<td>Risk Recommendations
• Risk assessment methodologies.
• Guidelines and best practices available internationally.
• Evaluation of the probability and severity of risks, including loss of benefits.
• Balanced knowledge-based communication and education of EHS and ELSI, including uncertainties and ambiguities.</td>
</tr>
<tr><td colspan="3">Institutional Recommendations
• Systematic liaison between government and industry.
• Sufficient resources and capabilities for conducting concern assessments along with risk assessments.
• Information for consumers enabling them to make informed choices.
• Transparent decision-making processes for R&D and investment.
• Non-proprietary information on test results, impact assessments and their interpretations on the internet.
• Systematic feedback about the concerns and preferences of the various actor groups and the public at large.
• Incentives for promoting and sustaining international cooperation.
• Critical examination of intellectual property rights for basic natural processes and structures.
Risk Communication Recommendations
• Information about the benefits and non-intended side effects. Communication tools include: internet-based documentation of scientific research, product labelling, press releases and consumer hot lines.
• Public information on the principles and procedures used to test nanotechnology products, to assess potential health or ecological impacts and to monitor the effects.
• International disclosure of risk information by large transnational companies (not competitive information).
• Risk communication training courses and exercises for scientists.
• Integrated risk communication programmes for scientists, regulators, industrial developers, representatives of NGOs, the media and other interested parties.
Transboundary Recommendations
• Incentives for all countries to participate in risk governance. Possible tools include: policies by insurance companies, certification programmes, education programmes, R&D programmes, response to disruptive technological and economical developments, and international studies on cost and benefit/risk analysis.
• Explore the role of international organisations, international industry and academic organisations and NGOs.
• Public-private partnerships when participants are reluctant to adopt protective measures. Possible method include: government standards and regulations coupled with third party inspections and insurance.
• Global communication of international standards and best practices to both developing and developed countries in a reasonable timeframe.</td></tr>
</table>

Given the lack of nanotechnology-specific regulation, one of the most promising management strategies for Frame 1 is to establish internationally-applicable voluntary codes or rules for ensuring safety and risk control in the short term, allowing time for the necessary development and establishment of formal norms. The risk management strategies identified for Frame 1 will also be applicable for Frame 2. Over and above this, given the ambiguity and lack of substantive knowledge in Frame 2 a more discursive and participatory approach is required in which all actors, including industry and NGOs should be involved from the beginning. Table 3 provides a more detailed proposal of risk management recommendations for Frame 2.

Table 3: Risk Management Recommendations for Frame 2

Risk Management Recommendations for Frame 2 (in addition to those listed for Frame 1 in Table 2)		
Hazard Recommendations • Identifying hazards using scenarios. • Matrix for assessing the identified hazards.	**Exposure Recommendations** • Estimation of exposure for events with great uncertainties using methods such as casual chain.	**Risk Recommendations** • Identifying, communicating and educating others on EHS, ELSI, Human Development Implications and Political and Security Issues. • Developing capacity to address uncertain/ unknown and ambiguous developments at national and global levels. • Identifying and analysing highly controversial developments.
Institutional Recommendations • Communication platforms that help address the purposes for future technologies. • Common scenario development exercises for future applications of nanotechnology. • Common rules and standards for potentially high-impact, long-term projects for nanotechnology. • A process of periodic review of national and international institutional frameworks. **Risk Communication Recommendations** • Debate on the desirability of special applications of nanotechnology in the light of ethical and social issues.		

Figure 1: Risk Governance for Nanotechnology: key activities envisioned in this report



This paper presents a conceptual framework for international nanotechnology risk governance for both short (mostly linked to what we have termed Frame 1) and long term issues (which are more dominant in Frame 2). By considering the particularities of nanotechnology as an emerging technology, the proposed framework and respective guidelines on risk governance assist governments, regulators and business to integrate scientific assessments and concern assessments into a unified risk appraisal process and to select the appropriate risk management and stakeholder involvement strategies. The final phase in the risk governance process requires that risk assessors and risk managers work together to implement the results. Figure 1 provides an overview of the risk governance activities reflected in this white paper.

2 BACKGROUND

Defining Nanotechnology

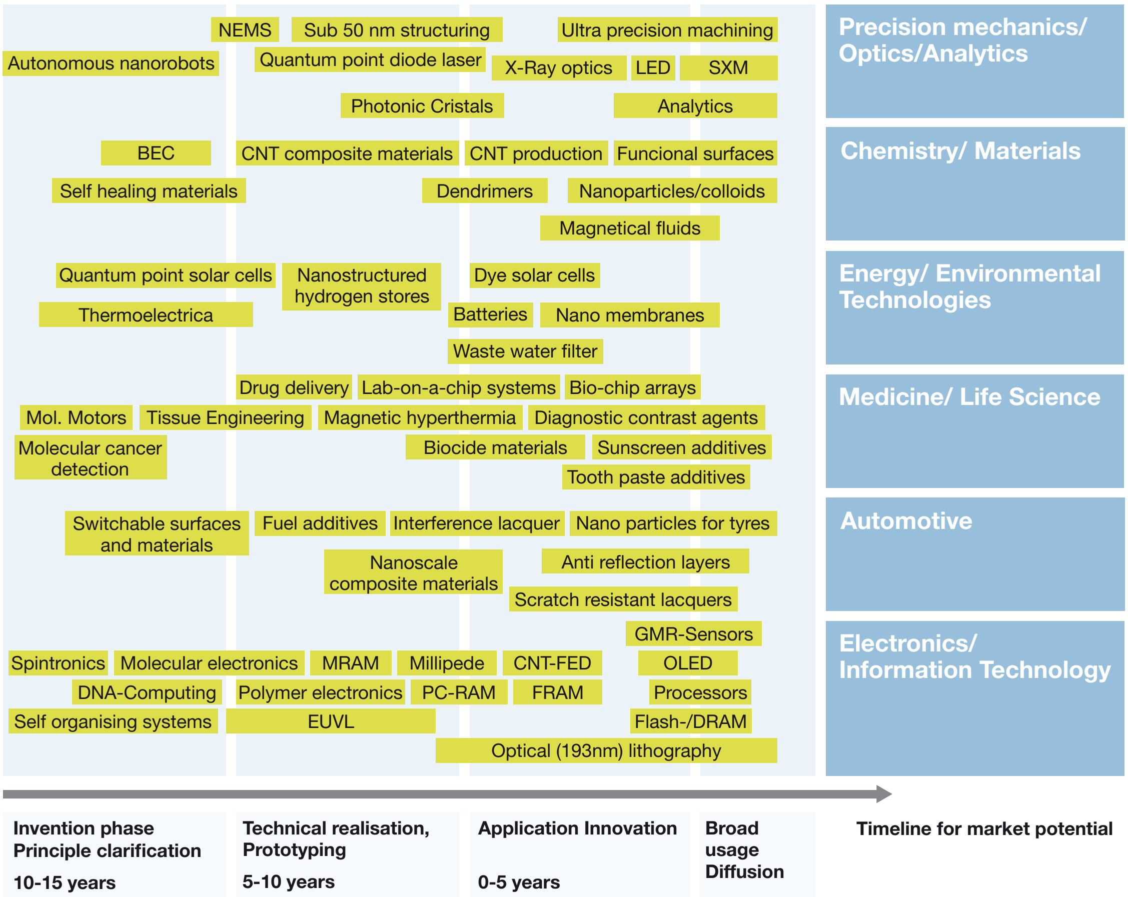
Nanotechnology is still in an early phase of advancement and is sometimes compared in the literature to information technology in the 1960's and biotechnology in the 1980's. Nanotechnology refers to the development and application of structures, materials, devices and systems with fundamentally new properties and functions which derive from their size in the range of about 1 to 100 nanometers (nm) (Siegel et al. 1999). It involves the manipulation and/or creation of material structures at the nanoscale in the atomic, molecular and supramolecular realm. At the nanoscale the characteristics of matter can be significantly changed, particularly under 10-20 nm, because of properties such as the dominance of quantum effects, confinement effects, molecular recognition and an increase in relative surface area. Downsized material structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties, as well as their chemical reactivity, leading to surprising and unpredicted, or unpredictable, effects. In essence, nanodevices exist in a unique realm, where the properties of matter are governed by a complex combination of classical physics and quantum mechanics. At the nanometer scale, manufacturing capabilities (including by self-assembly, templating, stamping, ultra-precision engineering and fragmentation) are broad and can lead to numerous efficient outcomes.

Nanoscience is the result of interdisciplinary cooperation between physics, chemistry, biology, biotechnology, material sciences and engineering in studying assemblies of atoms and molecules. More than in other domains, nanotechnology requires the integration of many scientific, engineering and technical disciplines and competences. Applications of nanotechnology will penetrate and permeate through nearly all sectors and spheres of life (e.g. communication, health, labour, mobility, housing, relaxation, energy and food) and will be accompanied by changes in the social, economic, ethical and ecological spheres (see Figure 1).

As with other new technologies, nanotechnology evokes enthusiasm and high expectations: on the one hand, progress in science and technology, new productive applications and potential economic gain are envisaged; on the other hand, there are concerns about risks and unforeseen side effects (Roco and Bainbridge 2001 and 2005; Roco and Tomellini 2002). At the present time the assessment of the social, juridical and ethical consequences of nanotechnology relies more on hypothetical or even speculative assumptions than on rigorous scientific analysis (Hanssen and van Est 2004). Various science fiction scenarios and literary narratives have picked up nanotechnology as a major theme of their projections for the future. For example, the work of Eric Drexler (1986), which describes the scenario of self reproductive nanoengines, has been perceived to fall into the category of scientific "phantasy" (Iglhaut and Spring 2003 p. 12). The novels of, inter alia, Anderson and Beason (1993), Stephenson (1996), Bear

(2002), and Crichton (2002) use the example of nanotechnologies as a technical catalyst for their narratives. In arguably the most famous nanotechnology-related novel, “Prey”, Crichton (2002) describes a science fiction story in which swarms of nanotechnologically manufactured micro-robots, which he terms “Nanobots”, malfunction and attempt to conquer the world and destroy it. These novels use nanotechnology only as a carrier for more destructive technologies or for the misuse of human activities. Nevertheless, the link between nanotechnology and threatened human identity has been constructed in the mind of many intellectual observers. Depending on the circumstances it can be expected that, over time, these associations will also penetrate public opinion.

Figure 1: Examples of Development Status and Application Fields of Nanotechnology (Courtesy: VDI Technologiezentrum, Germany)

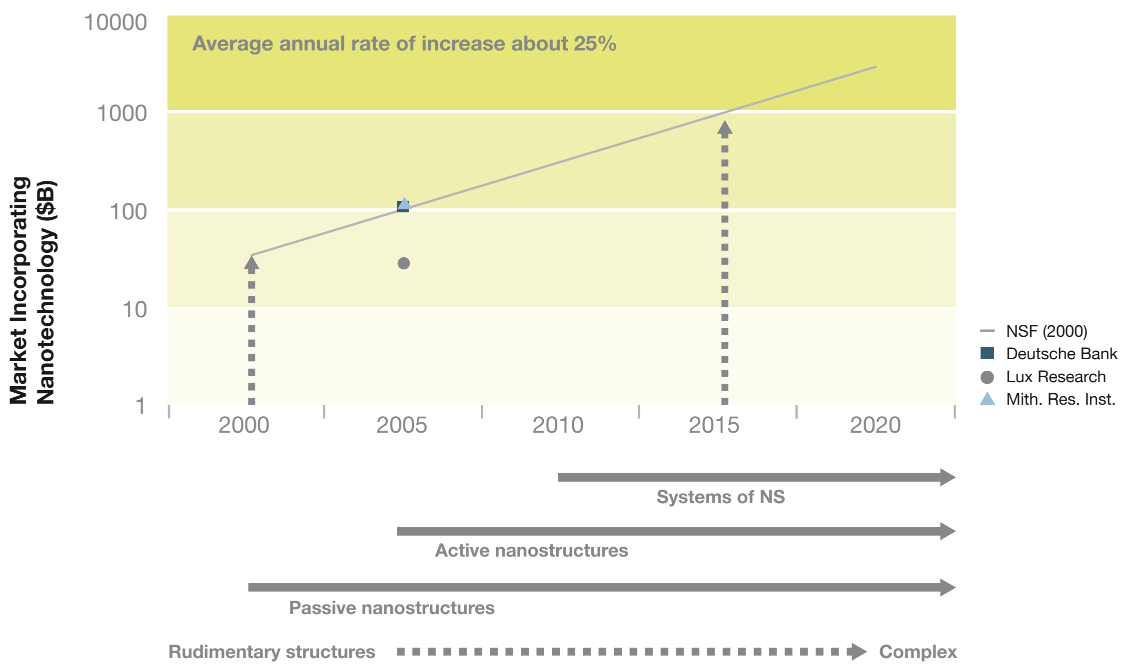


The Promise of Nanotechnology

The focus of research and development (R&D) has been shifting progressively from passive nanostructures to active nanostructures and nanosystems, as is suggested in Figures 2 and 3 (Roco 2005a). In 2000, the US National Science Foundation (NSF) estimated that $1 trillion worth of products worldwide would incorporate nanotechnology in key functional components by the year 2015 (Figure 2; Roco and Bainbridge 2001). The corresponding industries would employ about 2 million workers directly in nanotechnology, and about three times as many in supporting activities. These estimates were based on a broad industry survey and analysis in the Americas, Europe, Asia and Australia, and continue to hold in 2006. Recent forecasts by Mitsubishi Research Institute (Japan), Deutsche Bank (Germany), Lux Research (US) and other organisations, mainly based on NSF data, also support the estimated $1 trillion by 2015, even if the 2004 data of Lux Research does not include current nanoscale applications in electronics and catalysts. However, these estimates derive from variable base lines, some of which include entire products (e.g. hard disks) rather than nanotechnology components themselves (e.g. data storage layers).

Nanotechnology has the potential to become one of the defining technologies of the 21st Century. Based on the ability to measure, manipulate and organise material on the nanoscale – it is set to have significant implications (Roco and Bainbridge 2001 and 2005) – envisaged breakthroughs for nanotechnology include order-of-magnitude increases in computer efficiency, advanced pharmaceuticals, bio-compatible materials, nerve and tissue repair, surface coatings, catalysts, sensors, telecommunications and pollution control. This potential has encouraged a dramatic rise in R&D expenditure in all developed countries and many other countries have begun to invest in nanotechnology. Government R&D investments in each of the US, Japan, EU and the "Rest of the world" (including Canada, China, Australia, Korea, Taiwan, and Singapore) reached about $1 billion in 2005, with the fastest growing being the "Rest of the world". The US National Nanotechnology Initiative (NNI), announced in 2000, was followed within five years by nanotechnology R&D programmes in about 60 countries. In 2005, the US Government spent $1,081 million through the NNI, Japan about $950 million, whilst the European Commission has allocated $1.3 billion for nanotechnology, materials and production technology under its multi-annual Sixth Framework Programme (DTI 2002). Corresponding R&D investments for nanotechnology by industry worldwide are at about the same level, but with a higher rate of yearly increase as compared to government investments.

Figure 2: Worldwide Market Affected by Nanotechnology (NSF estimation made in 2000, the estimation holds in 2006)

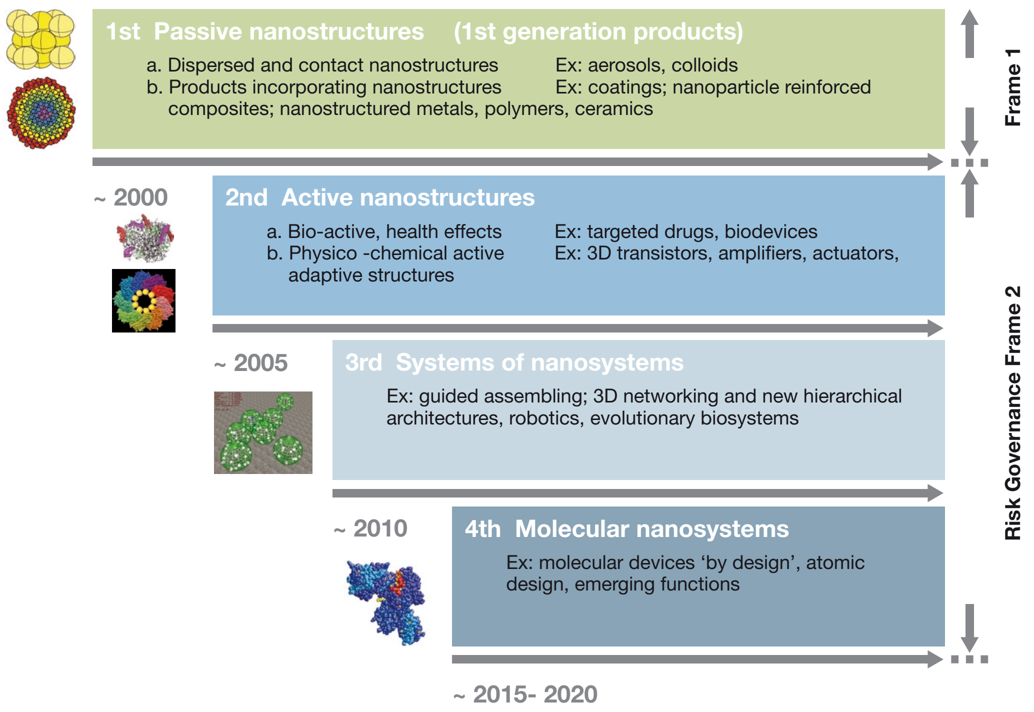


Significant applications of nanosciences and nanoengineering already exist in the fields of, inter alia, medicine, pharmaceutics, cosmetics (such as sun creams), biotechnology, processed food, chemical engineering, high performance materials, electronics, information technologies, precision mechanics, optics, analytics, energy production and environmental sciences (Jopp 2003). Currently, nanotechnology products can be found in:

- Paints (for example crack-resistant paint using antimony-tin oxide)
- Fuel cells
- Batteries
- Fuel additives
- Catalysts
- Components in transistors
- Sources of lasers and lighting
- Lubricants
- Integrated circuitry
- Medical implants
- Machine ceramics
- Water purification and remediation
- Military battle suits
- Self-cleaning windows
- Sunscreens and cosmetics
- Explosives, propellants and pyrotechnics
- Disinfectants
- Abrasives
- Food additives

Thousands of new patents are being announced in this area each year (Huang et al. 2004). Titanium dioxide, carbon black, zinc oxide and iron oxide make up the majority of the nanoparticles in industry, and there are dozens of other nanostructures and particles at the research stage that could soon enter the manufacturing world as part of the first generation of nanoproducts (see evolution of nanotechnology in Figure 3). The Small Times survey, using the NNI definition of nanotechnology, has identified over 700 products incorporating nanotechnology in the US alone (Small Times 2005).

Figure 3: Timeline for Beginning of Industrial Prototyping and Nanotechnology Commercialisation: Four Generations of Products and Production Processes



What is Special about Nanotechnology as an Emerging Field?

Nanotechnology has many characteristics which both increase its potential and produce new issues for global risk governance. The implications of nanotechnology are broad because its applications are at the confluence with modern biology, the digital revolution and cognitive sciences (nano-bio-info-cogno, converging technologies or NBIC in Roco and Bainbridge (2003)). The results of NBIC integration are expected to lead to significant long-term impacts.

Most importantly, nanotechnology is unique as it:

- Offers a broad technology platform for industry, biomedicine and environment as well as an almost infinite array of potential applications.
- Holds promises for applications which have the potential to manage many technical, economic, ecological and social problems.
- Allows manipulation at the basic level of organisation of atoms and molecules, where the fundamental properties and functions of all manmade and living systems are defined.
- Provides opportunities for reversing the trend of specialisation of scientific disciplines, unifying concepts in research and education, and for the integration of engineering and technology systems.
- Has stimulated all developed countries and many other countries to invest in nanotechnology.
- Has broadened and changed manufacturing capabilities (e.g. by self-assembly, templating, stamping and fragmentation, amongst others) with the promise of even more efficient outcomes.
- Has become one of the main drivers for technological and economic change and is already stimulating considerable industrial competition.

Reflecting the specific characteristics of nanotechnology, national R&D programmes established during the last five years have become highly integrative, involving multiple funding agencies. For example, the strategy of the NNI is based on: long-term planning; inclusiveness of potential contributors; the establishment of multidisciplinary partnerships amongst government, industry and international organisations; and the support of societal dimension studies from the beginning (Roco 2004a). Many other national programmes have since been established which reflect the need for the multidisciplinary and multidomain development of nanotechnology. However, risk governance approaches specific to nanotechnology seem to be lagging behind and there is a perception that the present speed and scope of R&D exceeds the capacity of regulators to assess human and environmental impact.

Four Generations of Nanotechnology Products and Production Process

Four overlapping generations of new nanotechnology products and processes (called below nanoproducts) have been identified with the potential for development in the period 2000-2020: passive nanostructures, active (evolving function) nanostructures, integrated nanosystems, and heterogeneous molecular nanosystems (Figure 3: Roco 2004b). Each generation of products is marked by the creation of commercial prototypes using systematic control of the respective phenomena and manufacturing processes. Products may also include components which correspond to different generations. Today's rudimentary capabilities of nanotechnology for systematic control and manufacture at the nanoscale are expected to evolve significantly in both complexity and the degree of integration by 2020.

- **First generation of products, mainly after ~ 2000- : passive (steady function) nanostructures.** For example: nanostructured coatings, dispersion of nanoparticles, surface nanopatterning, ultra-precision engineering, and bulk materials (nanostructured metals, polymers and ceramics). These nanostructured materials are relatively simple with passive or merely reactive behaviour, and have steady or quasi-steady structures and functions during their use (such as mechanical behaviour and chemical reactivity). The primary products are components (such as particles, wires, nanotubes) with improved properties and functions because of their nanostructure. One may identify two subcategories: (a) dispersed and contact surface nanostructures such as nanoscale colloids (including cosmetics), aerosols and powders that may have significant exposure to bio-systems; and (b) products incorporating nanostructures such as nanoscale layers in transistors or bulk materials. In nanomedicine, one would include the integration of joint replacement with biocompatible nanostructured materials, and non-invasive and invasive diagnostics with nanoparticles and quantum dots for rapid patient monitoring. In nanoelectronics, one would include the integration of the scaled down masked-lithography of thin-films approach with simple nanoscale components (for example, nanolayers). Potential high-risk products are nanoparticles in cosmetics or food with large scale production and high exposure rates, and ultrafine powders - the latter being potential fire and explosion hazards.

- **Second generation of products, ~ 2005- : active (evolving function) nanostructures.** For example: transistors, amplifiers, targeted drugs and chemicals, actuators, molecular machines, light-driven molecular motors, plasmonics (the technology of transmitting light-like waves along nanoscale wires), nanoscale fluidics, laser-emitting devices, and adaptive structures. An active nanostructure changes its state during operation: for example, an actuator changes its dimensions, and a drug delivery particle changes its morphology and chemical composition. The new state may also be subject to successive changes in the mechanical, electronic, magnetic, photonic and biological properties, as well as other effects. One may identify two subcategories: (a) bio-active nanostructures with potential effects on human health and ecosystems; and (b) physico-chemical active nanostructures. Typical active nanostructures include components in nanoelectromechanical systems (NEMS), nanobiodevices, energy storage devices, actuators, and sensors which change their state during measurement. In nanomedicine, one would include cognitive capacity-assisting and enhancing devices, targeted cancer therapies, sensors for in vivo monitoring, localised drug delivery, neural stimulation and cardiac therapies. In nanoelectronics, one would include directed self-assembly structures allowing the scaling down of complementary metal-oxide semiconductors (CMOS) to their ultimate limits (5-10 nm) and the possible post-CMOS (but still electron charge-based) integrating nanocomponents and nanodevices such as carbon-nanotube and single-electron transistors. Examples of potential high-risk products are: nano-bio interface devices, neuro-prosthetics, reactive devices placed in the environment, active devices in the human body, and devices for surveillance. Potential higher-risk areas are: nano-biotechnology; neuro-electronic interfaces; nanoelectromechanical systems; agriculture and food systems; and hybrid nanomanufacturing.
- **Third Generation, ~ 2010- : integrated nanosystems (systems of nanosystems).** For example: the use of various synthesis and assembling techniques such as bio-assembling; networking at the nanoscale and multiscale and hierarchical architectures; robotics on surfaces; modular nanosystems; chemo-mechanical processing of molecular assemblies; evolutionary bio- and hybrid- nanosystems; and quantum-based nanoscale systems. In nanomedicine, one would include artificial organs built from the nanoscale, improved cell-material interactions for cell conditioning, and scaffolds for tissue engineering. In nanoelectronics, one would include new devices based on states other than electric charge (e.g. electron-spin, nuclear-spin or photonic states). Examples of potential high-risk products include: emerging behaviour robotics, evolutionary artificial organs, modified viruses and bacteria, and brain modification. Several potential higher-risk areas are: nanorobotics; regenerative medicine; brain-machine interface; nano-engineering in agriculture; nanosystems used for manufacturing and product processing; and other converging technologies and applications.
- **Fourth generation, ~ 2015/2020- : heterogeneous molecular nanosystems.** In this generation each molecule in the nanosystem has a specific structure and plays a different role. Molecules will be used as devices and fundamentally new functions will emerge from their engineered structures and architectures. This is approaching the manner in which biological systems work but, in comparison,

biological systems are water-based, process information relatively slowly, and have multiple hierarchical scales. The design of new atomic and molecular assemblies is expected to increase in importance through for example: the creation of macromolecules "by design" to self-assemble on multiple scales; nanoscale machines; subcellular interventions; directed and multiscale self-assembling; controlled interaction between light and matter with relevance to energy conversion; and the exploitation of quantum control. NBIC convergence will play an increased role in this generation. In nanomedicine, one would include nanoscale genetic therapies, cell ageing therapies, and nanoscale controlled stem cell therapies. In nanoelectronics, one can envisage molecular and supramolecular components for transistors. Examples of potential high-risk products are: molecular devices "by design"; molecules with atomic design; large nano-bio or hybrid systems with emerging functions; evolutionary cells; and self-replication of large nanostructured systems. Potential higher-risk areas include: neuromorphic engineering, complex systems, molecular nanosystems used for manufacturing and product processing, and human-machine interface.

International Dimension

An international benchmarking exercise performed in over 20 countries in 1997-1999 (Siegel et al. 1999) provided the seeds for the formation of an international nanotechnology expert community. An APEC study (Tegart et al. 2001) raised the issue of opportunities for developing countries as early as 2001 and the top ten applications of nanotechnology have been identified by an expert survey (Salamanca-Buentello et al. 2005). However, the policies and regulatory frameworks of the various countries have remained fragmented. International calls for addressing global challenges in nanotechnology research (Roco 2001) and for addressing the societal dimensions of nanotechnology at the international level (Roco 2003) have both contributed to the collaborative development of nanotechnology, but have had a relatively limited effect on both nanotechnology governance efforts and the harmonisation of risk governance methods and structures. Given the enormous opportunities, there is the danger that necessary risk governance precautions will not be taken internationally in the race to gain economic advantage and to grasp the economic benefits. Such an oversight could lead to an international backlash in nanotechnology development and diffusion if, due to lax standards and practice, an incident with negative repercussions on human health or the environment occurs. Given the high potential for social amplification by the media (Renn et al. 1992), such an incident could trigger worldwide attention and increase public concern. National regulatory agencies could feel propelled to tighten regulatory rules even if the incident occurred in a different country and would not have been possible or probable in any system with working standards and effective control. This problem is beginning to be recognised and, in June 2004, the first broad international dialogue on responsible development brought together government leaders of national initiatives from 25 countries as well as the European Union (EU) (Meridian Institute 2004). The 2004 Dialogue yielded a set of principles, structured priorities, and recommended mechanisms for interaction and cooperation, including sharing data on environmental, health and safety. The follow-up meeting was hosted by the EU in July 2005 and the third Dialogue will be held in Japan in 2006.

Despite this increase in international interactions and developing knowledge for the safer use of nanotechnology, an international accord towards harmonised regulation and standards is still lacking. The risk governance of nanotechnology, including risk policies and regulatory structures, continues to pursue separate paths in various countries. Such socially important areas as investment, health and ecological risks, and the equity of development amongst countries remain major sources of concern. International cooperation and partnerships remain mostly between developed countries although amongst developing countries China has gained increased influence. In 2005 China was the second highest contributor in terms of number of publications behind only the US (Kostoff et al. 2006).

Governance and Risk Governance of Nanotechnology

Governance includes the processes, conventions and institutions that determine: how power is exercised in view of managing resources and interests; how important decisions are made and conflicts resolved; how interactions among and between the key actors in the field are organised and structured; how resources, skills and capabilities are developed and mobilised for reaching desired outcomes; and how various stakeholders are accorded participation in these processes. In the most common current usage of the term, governance is seen as implying a move away from the previous government approach, which could be characterised as a top-down legislative approach attempting to regulate the behaviour of people and institutions in quite detailed and compartmentalised ways (Lyall and Tait 2005). Governance sees the process of governing as a joint effort of industrial, public and civil society actors, usually within networks, with the goal of making best use of their respective resources, skills, and capabilities for reaching specific ends or purposes (Zürn 2000). Put more simply, it is the replacement of traditional powers over with contextual powers to. In such a system, permeable and flexible system boundaries facilitate communication and support the achievement of higher level goals, while the government role also continues. These assumptions underline the switch from government alone to governance in debates about the modernisation of policy systems, implying a transition from constraining to enabling types of policy or regulation (i.e. from "sticks" to "carrots") (Lyall and Tait 2005). Risk governance is focused on the institutional arrangements of how risk information is collected, analysed and communicated and how risk management decisions are taken (IRGC 2005). Risk governance: encompasses all the risk-relevant decisions and actions; is of particular importance in situations where the nature of the risk requires collaboration and coordination between various agencies and stakeholders (no single decision-making authority available); and calls for the consideration of contextual factors such as: (a) institutional arrangements (e.g. regulatory and legal framework and coordination mechanisms such as markets, incentives or self-imposed norms); and (b) socio-political culture and perceptions.

Looking for governance rather than government or private industry to assess and manage the implications of nanotechnology provides a broader and more realistic picture about the forces that will shape the future of nanotechnology development. Special emphasis is given to private institutions, in particular industry, since development and application will take place within the private sector carefully watched by regulators, NGOs and the mass media. There are many indicators which suggest that nanotechnology is set to become the next focus for heated debate about the relationship between new technologies, risk and sustainability (ETC Group 2003; Burke 2003). On the one hand, nanotechnology promises smaller, lighter and faster devices using fewer raw materials and consuming less energy (Roco and Bainbridge 2001). On the other hand, as the media coverage of the Prince of Wales' intervention in May 2003 has shown, there is genuine alarm about the disruptive potential of interventions at the nanoscale (Oliver 2003; Porritt 2003). The Prince of Wales is just one in a series of commentators to express fears about self-replicating nano-machines capable of smothering the world in grey goo (Joy 2000; Porritt 2003; or, for a current fictional account, Crichton 2002). These concerns about nanotechnology resonate with a long-standing public fear of technology running out of control (Winner 1977). Along with the relatively low levels of available information about nanotechnology, and the current low public trust in industry and government (Macoubrie 2005), these factors are leading to an increasing risk of amplified public concern. A particular concern is that insufficient formal and informal training, in combination with the desire for economic gain, will result in the misuse or inefficient application of nanotechnology. Education and training is a relatively long-term process that cannot be addressed by shorter term activities such as public relations outreach. The promises of fast economic returns are known to act as powerful drivers for human behaviour even if, in the longer run, such behaviour may be counter-productive.

A survey on current risk governance activities in nanotechnology (Part A: The Role of Government) in eleven economies and nanotechnology R&D in 27 economies has been published by the IRGC (Roco and Litten 2005a, also see summary in Annex A). Summaries of surveys from industry, research organisations and NGOs are also annexed (Annexes B, C and D, respectively) (Roco and Litten, 2006).

3 DEFICITS OF THE RISK GOVERNANCE SYSTEM FOR NANOTECHNOLOGY TODAY

Types of Deficits

The main risk governance deficits for the first generation of passive nanostructures (nanoparticles, coatings, nanostructured materials) are a relatively low level of understanding of the new properties and functions of toxicity and bioaccumulation, limited knowledge of nanomaterial exposure rates and gaps in regulatory systems at national and global levels. The main risk governance deficits for the second to fourth generations of nanoproducts (including active nanodevices, nano-bio applications and nanosystems) is the uncertain and/or unknown implications of the evolution of nanotechnology and its potential human effects (e.g. health, changes at birth, brain understanding and cognitive issues and human evolution) and the lack of a framework through which organisations and policies can address such uncertainties. In the following paragraphs we list the main deficits anticipated for nanostructures. It is assumed that where deficits and recommendations are referred to as applying to first generation nanostructures these will also apply to later generations. However, there are specific deficits that are more unique to the second to fourth generations due to their expected complex and/or evolving behaviour and, where this is the case, it is specifically mentioned.

Technical and Organisational Deficits

Environment, Health, and Safety Deficits (EHS)
Current national and international governance systems reflect learned knowledge and experience developed in the research and practice of bulk and micro technology. It is as yet unknown whether the novel risk characteristics of nanotechnology applications can be adequately managed within these governance systems. This knowledge deficit is being addressed to some extent at a national level through the accumulation of available data for substances with new characteristics as in, for example the National Toxicology Program in the US (National Toxicology Program, 2005). However, there is a clear need for an international organisation to coordinate the collection of available information worldwide and to consider high-quality, globally applicable governance approaches to current and future potential risks.

Nanotechnology's potential for risk has been widely considered both for current and future applications. However, the lack or scarcity of quantitative data - and the fact that risks are as yet complex, uncertain and ambiguous - results in a largely qualitative assessment of risk based on expert elicitation. Risk perception is also subject to extensive ambiguity. There is a general convergence of views on the short-term potential benefits to humankind but not on their longer-term impact. For example, innovative cancer therapies become more contested when considering long term benefits such as longevity and birth modification. Perceptions of the risks attached to these applications are still more varied as the more risky applications are a long way from production and the market. First generation applications, such as sunscreen and self-cleaning windows, contain passive nanostructures, and although they do not have the potential to transform society, many have unknown consequences such as, for example, being able to enter the blood stream through the skin or to enter the environment when washed off. The near-future second to fourth generation applications have been largely considered hypothetically and there is extensive divergence in the assessment of potential risk and their significance for human health and the environment. For example, the ability for nanoscale structures to cross the blood-brain barrier can be considered to be of extremely high significance as this barrier is impenetrable to most substances and therefore little is known of the potential effects. However, an alternative view is that this ability is a benefit which could aid the treatment of neural diseases such as Alzheimer's and that the exercise of too much precaution over unknown effects would pose an even greater risk to society (Wildavsky 1990). There is a knowledge gap between what we need to know – especially concerning second to fourth generation nanostructures - and what we currently have available to us. The following are examples of specific EHS deficits:

- There is insufficient scientific knowledge of, and a need for a limited scientific data base with which to predict, in a general situation, the effects of nanoparticles and other nanomaterials on human health and the environment, including quantification of hazards, exposures and risk assessment (this deficit is dominant for the first generation). Nanotoxicity and nano-biocompatibility studies are not keeping up with the speed of creation of new nanomaterials. These are essential elements of governance processes for nanotechnology.
- Currently the presence and characteristics of nanomaterials in the work place and in the environment are measured and assessed sub-optimally. Some hazards and exposures are under control while others have not yet been adequately addressed (this deficit is dominant for the first and second generations). For example, there is no established system to monitor in situ nanoparticles in air, water, soil or biosystems although research is beginning to take place, as in the European funded project Nanosafe whose aim is to develop risk assessment and management techniques for nanoparticles.
- There is a need for specific metrology tools to allow for effective measurement of exposure of nanomaterials and nanoparticle delivery methods. These tools are needed for use both in the environment (particularly for ecotoxicity) and in medical fields (particularly for toxicity).
- Risk assessment based on mass is not sufficient for the characterisation of nanomaterials. Categorisation methods based on the particular properties of nanoparticles are not yet available in the pre-assessment phase, in which data has to be obtained for a range of nanoparticle sizes. Currently one must scale down the complexity into manageable pieces using techniques such as decision trees. Existing risk assessment procedures and regulatory measures need to be re-evaluated for nanoparticles.
- Existing analytic methods may not necessarily be appropriate for determining the distribution, partitioning and persistence of nanomaterials and nanosystems under various environmental conditions.
- As the dispersal of nanomaterials and evolving nanostructures may not be confined or containable within certain areas or countries there is the potential for risks to cross international borders. Current international systems may be inadequate for coping with the unique properties of nanomaterials.

Institutional Deficits

Societal Infrastructure Deficits

The current regulatory measures generally deal with a single event and its cause-and-effect, and do not consider the life cycle of products, secondary effects or interactions with other events. Regulatory organisations and measures are fragmented by the area of jurisdiction, type of regulation (product, process, etc.), intervention levels and national and international harmonisation of assessment and management procedures (or the lack thereof). An integrated governance approach for anticipatory and corrective measures is necessary for an emerging technology that will have trans-boundary and global implications. The international collaboration deficit highlights the need for more aligned global infrastructural initiatives and harmonised risk regulations. Other deficits are in approaches to education and the dissemination of knowledge, in the regulatory environment within an individual country and between countries and gaps between the portfolio of products and the portfolio of waste disposal regulations. The following are examples of specific societal infrastructure deficits.

- There is a relatively fragmented institutional structure and legal authority supporting the risk governance of nanotechnology, with gaps and overlaps in the regulatory systems at the national and global levels (this deficit is true for all generations). For example, the use of animal testing varies by country. End-of-pipe risk governance solutions should be complemented with practices to improve the behaviour and responsibility (liability) of the different stakeholders in the process of innovation. Civil organisations are asking that the testing of nanomaterials be undertaken, preferably by independent partners, with greater transparency and that the test results are disclosed.
- The simple cause-and-effect approach for single events should be replaced by a proactive corrective approach with adaptive management for a system which is disturbed by given events (Roco 2005b). For example, the current environmental protection agencies' regulations for ultrafine particles in air refer only to one measuring event; the full life cycle, the multiple nanoparticle interactions in the atmosphere, the effect of bioorganisms and the persistence of particles in the system are not considered. A corrective approach is particularly necessary for nanotechnology applications belonging to the second to fourth generation.
- A major deficit of nanotechnology risk governance today is weak coordination of nanotechnology safety issues between the different actors and stakeholders, particularly those in science, industry, consumers, government regulators, civil society and international bodies. For example, there is a gap between regulatory provisions, their areas of relevance and different standards applied to the same product. The US agencies generally regulate products while in the EU the main regulations concern processes. There is an underdeveloped science-policy interface for nanotechnology which creates a communication gap between scientists, engineers and political decision-makers. This deficit is true for all generations.
- There is a lack of the necessary resources for risk governance in R&D budgets, as compared to other technologies with similar risk profiles. Also, insufficient human resources are applied to addressing those issues. Research and education in support of safety and risk assessment should be better focused and levels of financing should be increased. There are no published methodologies or standardised risk assessment tools available (CBAN 2006). Conventional risk assessment tools for toxicity and exposure may not be suitable for nano-sized materials due to their novel properties. There is limited information on nano-sized particle behaviour in gas and fluid streams in the environment, the work place and in biosystems. Exposure routes and rates are not fully understood. This deficit is true for all generations.
- Regulatory uncertainty is hampering industrial innovation, particularly for small enterprises. There is an opportunity risk for the industrial sector in not developing nanotechnology products because of uncertainty regarding future regulation. The inability to estimate the true risk profile of companies dealing with nanotechnology results in a deficit in the risk transfer mechanism through insurance (Hett 2004). This deficit is true for all, but especially for the second to fourth, generations.
- The use of nanotechnology for potential new weapons is a sensitive issue because of its secrecy, broad spectrum of possible applications and unexpected consequences.
- The international agreements on nanotechnology are not sufficiently focused on broader issues of interest to humanity such as resources (water, energy, and food) and the environment. This deficit is particularly relevant for the third and fourth generations.
- International trade activities related to nanotechnology are not well established in key areas such as

crossing national borders, export control, dual civil-military use and the movement of experts and students.

- There is a gap in levels of control and power between those countries who are promoting nanotechnology, those who are implementing it, and those who will be impacted by it (the last of which do not have the infrastructure of the other two groups to efficiently respond to technological development). For example, the introduction of nanotechnology products in developing countries and the reduced or increased use of special metals may impact on commodity-dependent developing countries (ETC Group 2005). This deficit is true for all generations.
- There is no international framework with which to address the risk governance of nanotechnology at a global level and to provide consistency in areas such as reciprocal recognition of specific tests and regulations, although this issue is starting to be considered by, for example, the International Organization for Standardization (ISO) and the Organisation for Economic Co-operation and Development (OECD). This deficit is true for all generations.

Social and Political Deficits

- Coordination of policy at national and international levels may be significantly challenged by the increasing list of government departments and agencies involved with nanotechnology.
- Current investment patterns with respect to nanotechnology products do not adequately address wider human needs such as clean water, energy and conserving biodiversity. This deficit is true for all generations.
- From a trade perspective, differences in national regulations and their application may make it difficult for companies to manufacture standardised products and use standardised production processes. A consequential implication is that the significantly new properties and issues of nanotechnology may allow for the transfer of risk, as when products are developed in a country with weaker controls and exported worldwide. This deficit is true for all generations.
- Broad-based and rapid changes in nanomanufacturing processes and the associated new products may lead to a displacement of jobs and major changes in trade balances between countries at a faster pace and in more sectors of the economy as compared to the introduction of other technologies. This deficit is true for all generations.
- The societal infrastructure and legal system are poorly prepared for the potential broad changes in daily human activities (such as learning, working, increasing life expectancy, neuromorphic engineering and brain-machine interface). The need to develop limits for applications rather than to limit technologies has not been recognised by most legal and political systems. For example, devices which help blind people to process visual information in their brain rely on similar technological and scientific accomplishments to a device that automatically releases serotonin when someone feels depressed. Yet the acceptability of an aid to sight for the blind must be judged very differently from implanting an automatic happiness-drug release machine in the brain. This is especially true for the second to fourth generations.
- The long-term effects on human development have not been well addressed, in part because of limitations in the development of scenarios for the second to fourth generations of nanoproducts. For example, it is difficult to evaluate changes in human cognition which may result from understanding the brain nanostructure and applying nanomedicine. In another example, it is difficult to evaluate changes in life expectancy that may result from artificial tissues and organs developed using nanotechnology. There is a need to better understand the implications of nanotechnology in the long-term, including potential technological breakthroughs, human development and societal changes. This is especially true for the second to fourth generations.
- The application of nanotechnologies, in combination with biotechnology and medical research, may lead to major equity conflicts if targeted at individual customers. For example, by designing drugs

tailored towards the needs and pre-dispositions of specific individuals. Such tailored medicare will be expensive and, at least in the beginning, only available to the rich. Equity issues will also be of major concern if the pace of development differs between and among nations. This issue has been partially addressed in the context of technology transfer and diffusion of innovation, yet there remains a lack of understanding of how equity and justice will be affected by the further development of active nanotechnologies. This is especially true for the second to fourth generations.

- Heuristics and biases relating to cognitive processes may affect nanotechnology risk governance. First, research has shown that human processing of risk information is subject to cognitive limitations and biases; examples include status quo bias, overconfidence bias (people's overestimation of the degree of control over their environment and other people) and false consensus (seeking out opinions that confirm our beliefs and hypothesis) (Slovic 1992; Roxburgh 2003). Second, with respect to the well-known qualitative characteristics of risk perception, one would expect that active nanoparticles are likely to have many negative associations (Slovic 1987; Renn 2004a), such as dread, lack of personal control and artificiality. These characteristics make people even more concerned about the negative impacts than warranted by the predicted health effects and environmental impacts alone. Third, the beliefs associated with the risk source - for example, industry - centre around greed, profit-seeking and alleged disrespect for public health. Fourth, if susceptibility to risk varies considerably among individuals or relies upon probabilistic balancing, the potential for consumers to be exposed to risks without their consent raises serious equity concerns. These traits of public perception do not only affect people's judgement about nanotechnology, they also exert influence on public trust in regulatory regimes (Slovic 1993). This problem has been recognised by many observers but it has not been adequately addressed. This deficit is true for all generations but is particularly important for the third and fourth generations.
- The hype caused by fantasy theories such as grey goo has led to the many serious and realistic social implications of active nanostructures being dismissed as science fiction. Many concerns about long-term impacts of the third and fourth generation of nanotechnologies are purely speculative and scientifically improbable. However, many are realistic or at least fairly probable scenarios which warrant special societal attention and which need anticipatory regulatory actions. This is especially true for the second to fourth generations.
- Political and security risks include long-term changes in global economic and military balance. More powerful and covert tools may be used with criminal or terrorist intent although, at the same time, nanotechnology applications may help police to locate criminals or detect explosive devices in advance. The political system needs to be responsive to socio-economic changes caused by technological transformations. This is especially true for the second to fourth generations.

At the present time, the public does not have a strong awareness of the nature and potential benefits and risks of nanotechnology. This is likely to change rapidly as more products enter the market and the media become more active in publishing the applications and potential risks to a wider audience. Public awareness of risk tends to be higher if it is felt that: individuals or societal institutions are not able to exercise personal or institutional control over it (e.g. lack of labelling on products containing an engineered nanostructure compounded by the lack of routine measurement methods and the inability to foresee future impacts); if the technology is stigmatised (e.g. uncertain scientific knowledge and media hype); or if insufficient information is communicated concerning how risks are and can be controlled (IRGC 2005). It is therefore essential that the potential for risks and the governance systems in place to deal with these risks are communicated to the public as soon as possible. Trust between governments, businesses, academics, civil society, international organisations and the public needs to be enhanced through open dialogue and public involvement. As trust is highly related to the perception of performance and institutional agency, nanotechnology risk governance structures and processes need to be adaptable and flexible so that the benefits can be harnessed and unavoidable risks mitigated. The patience of the public may also be short while waiting for the appearance of new nanoproducts as the production of revolutionary new products typically takes over 10 years.

Risk Communication Deficits

- There is a gap in the communication of interdisciplinary research results between science communities. Nanotechnology requires interdisciplinary approaches which often conflict with the organisational structure of scientific institutions. This is particularly true for interdisciplinary assessments ranging from the natural, technical, medical and ecological sciences to economic, social and psychological approaches. This deficit is true for all generations.
- There is a gap in communicating the state of the art in science and development between the scientific community and the other network members, particularly regulators, members of concerned NGOs, the media and the public at large. The knowledge gap outside science regimes has major negative repercussions on political decision-making regimes and regulatory risk management activities. In addition, misinformation and pure speculation can heighten public fear without there being a realistic knowledge base.
- There is a gap in communication between the risk management agencies and the attentive public of risk assessment results and their implications for regulation and control. Low trust in governmental regulation, together with a general feeling that profit may be more important than health and environmental impacts, creates a climate of sceptical attitudes towards governance institutions and risk management organisations. Communicating what has been and will be done to reduce and control risks is an important task which so far is ineffective and insufficient in most countries.
- There is a gap in communication of sufficient background material with which relevant parties can conduct their own risk-benefit comparison, base their own political judgement on the best available knowledge or make a balanced reflection about the social and ethical acceptability of the likely positive and negative impacts.
- There is a gap between the pace of risk communication and the speed of technological development. Often risk communication lags behind the rate of development or the state of knowledge and the effectiveness of public debate may depend on reducing this gap earlier. This deficit is true for all generations.

Role for the IRGC

Governments and industry around the world are searching for the best risk governance practices, risk assessment and risk management models. The EU, the US, Japan and over twenty other countries are already discussing the safe development of nanotechnology (Meridian Institute 2004). Yet these activities have not focused on risk governance or on the barriers and deficits in communication which were noted in the previous section. The novel attributes of nanotechnology demand different routes for risk-benefit assessment, appraisal of concerns and risk management and there is a niche for an independent, international and multi-disciplinary organisation such as IRGC to contribute to the development of risk policy and regulations for nanotechnology. IRGC has identified a governance gap between the requirements pertaining to the micro- rather than the macro- technologies and, at present, nanotechnology innovation proceeds far ahead of the policy and regulatory environment. In the shorter term, the governance gap is most relevant for passive nanostructures that are already in production and have high exposure rates and, in the longer term, for active nanoscale structures and nanosystems. It is essential that advice and recommendations are provided to governments, businesses, scientific communities, civil society and international organisations so that public awareness can be stimulated by trust through open dialogue and action rather than media hype and stigmatisation. A for a potential means of looking at nanotechnology risk governance issues is the risk governance framework developed by the International Risk Governance Council (IRGC 2005). The framework provides an orientation for developing a best practice approach to risk governance for emerging technologies.

4 THE IRGC RISK GOVERNANCE FRAMEWORK AND ITS SPECIFIC APPLICATION TO NANOTECHNOLOGY

Purpose of the IRGC Approach

The IRGC framework introduces an integrated concept for risk governance, providing guidance for the development of comprehensive risk assessment and management strategies, particularly for emerging global risks. The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders (IRGC 2005). The concept of risk governance comprises a broad picture of risk. Not only does it include what has been termed *risk management or risk analysis*, it also looks at how risk-related decision-making unfolds when a range of actors is involved, requiring coordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. The IRGC framework offers two major innovations to the risk field: the inclusion of the societal context and a new categorisation of risk-related knowledge.

The IRGC contribution to nanotechnology risk governance is a conceptual framework for understanding, analysing and designing risk governance systems at the international level. This framework has two generic and several application-specific components that are innovative for the risk field. The two generic components are: the categorisation of nanotechnology products and processes into four generations; and the categorisation of nanotechnology evaluation into two broad frames of reference based on the evolution of knowledge, level of complexity and potential social and ethical consequences (the purpose of this distinction being to evaluate the relatively simple, passive nanostructures versus the more complex and evolving nanostructures and nanosystems). The application-specific components include a consideration of international dimensions, educational implications, human development implications (HDI), political and security issues (PSI) (in addition to the generally accepted EHS and ELSI issues), as well as the adoption of a holistic, adaptive and corrective response alongside the cause-and-effect approach currently used (see Roco, 2005b, page 140). This last component ensures that corrective actions have a time-scale comparable to the time-scales of corresponding disruptive events.

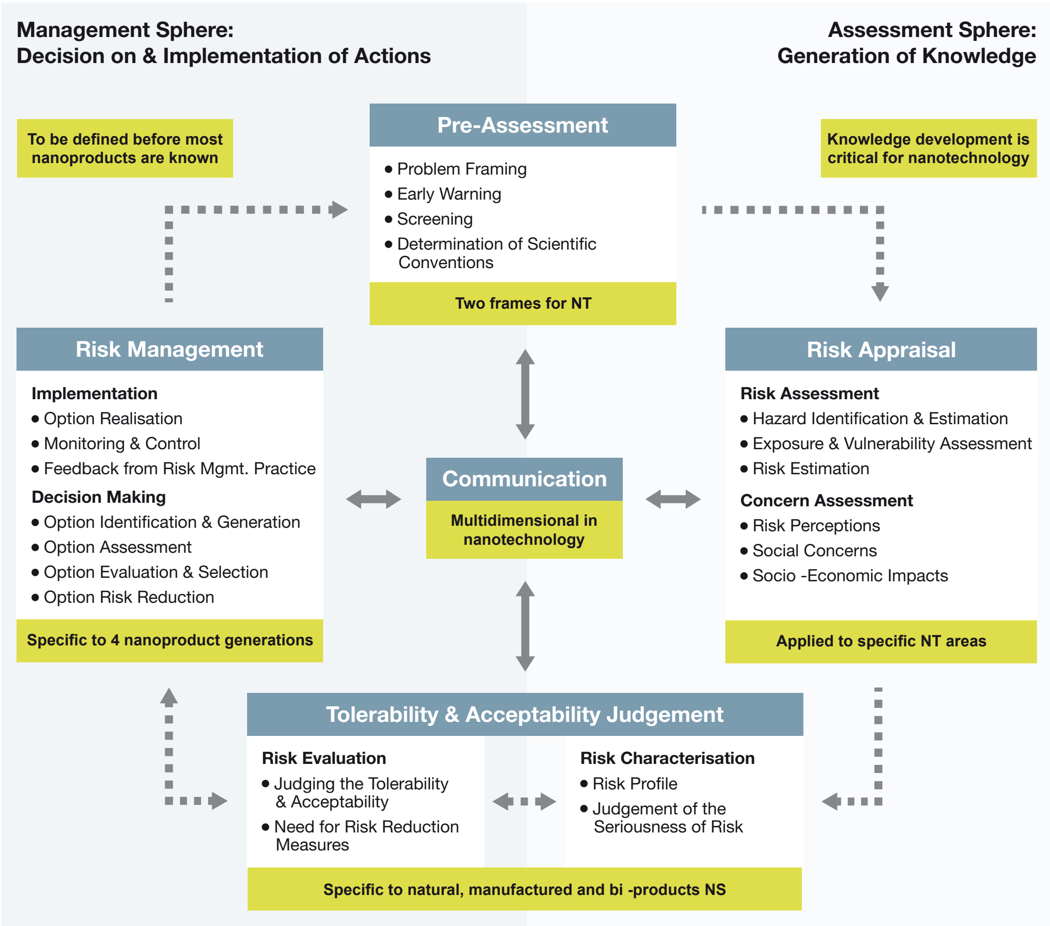
- **Inclusion of the societal context:** The IRGC risk governance framework gives equal importance to the classic risk governance components (assessment, management and communication) and to the unique contextual aspects. Contextual aspects include the structure and interplay of the actors dealing with risks, how these actors may differently perceive the risks and what concerns they have regarding their likely consequences. In addition, the framework takes into account institutional responses, such as policy-making or regulatory style, the socio-political impacts prevalent within the entities and institutions involved in the risk process, their organisational imperatives and the capacity needed for effective risk governance. Consideration should also be given to the power relationships that are at work in society, and the sources and levers of power that different groups use to pursue their interests and objectives. An example of the societal context is the increased role of rapid communication via the internet and of the general media in identifying and shaping risk factors. Linking the context with risk governance, the framework reflects the important role of risk-benefit evaluation and the need for resolving risk-risk trade-offs. Consideration of the societal and cultural context in nanotechnology governance is essential because of the broad implications of the new technology on society (Roco 2003). The inclusion of social implications should be undertaken using expertise knowledgeable about and specific to nanoscience (Collins and Evans 2002).

- **Categorisation of risk-related knowledge:** The framework also proposes a categorisation of risk which is based on different states of knowledge about each particular risk, distinguishing between *simple, complex, uncertain and ambiguous* risk problems.
  - *Simple* risk refers to products where there is a clear cause-and-effect connection to behaviour of materials and their implications.
  - *Complexity* refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects in a system or a system component. The nature of this difficulty may be traced back to interactive effects among these agents (synergism and antagonisms), long delay periods between cause-and-effect, inter-individual variation, intervening variables, and other causes. Scientists and technologists have insufficient knowledge about the cause-and-effect chains of technological developments as well as their possible impacts on the various areas of nanotechnology applications. However, understanding the characteristics of a complex system component rather than the entire system may still be sufficient for designing risk management measures that are able to reduce or control risks that pertain to the entire system.
  - *Uncertainty.* In the context of technological systems and their impacts, human knowledge is always incomplete and selective and thus contingent on uncertain assumptions, assertions and predictions (Functowicz and Ravetz 1993; Ravetz 1999). It is obvious that the modelled probability distributions within a numerical relational system can only represent an approximation of the empirical relational system with which to understand and predict uncertain events. It therefore seems prudent to include other, additional, aspects of uncertainty such as variability of impacted individuals and organisations, strategic responses to opportunities, system boundaries in modelling effects, and plain ignorance (Morgan and Henrion 1990; van Asselt 2000 pp. 93-138). All these different elements have one feature in common - they reduce the strength of confidence in the estimated cause-and-effect chain. If uncertainty plays a large role the estimation of technological impacts becomes fuzzy. The evolution of an active nanostructure may be typically uncertain within a given system. Uncertainty can often be addressed by collecting new data, developing better assessment models, and by singling out discrete cause-and-effect chains and the system components from the system as a whole.
  - *Ambiguity* has different connotations in everyday English language. In the context of risk governance it includes two aspects. Firstly, it denotes the variability of (reasonable) interpretations based on identical observations or assessments. What does it mean if, for example, nano-particles are able to penetrate brain tissues but do not cause any observable harm? Can this be interpreted as an adverse effect or is it just a bodily response without any health implications? Secondly, it denotes the variability of normative evaluation with respect to the tolerability or acceptability of observed effects on a given value or norm. Many scientific disputes do not refer to differences in methodology, measurements, or dose-response functions, but to the question of whether the observed or assumed impacts violate or meet predefined values. Often it is also contested which values are (will be) at issue or are (will be) subjected to discussion and how essential these values are and for which groups. High complexity and uncertainty favour the emergence of ambiguity, but there are also quite a few simple and highly probable risks that can cause controversy and thus ambiguity.

The first three categories (simple/ complex/ uncertain) relate to the properties of our knowledge about nanostructures being able to generate specific hazards, while ambiguity is a property of knowledge about human responses to the hazard. For all risk-generating nanoproducts we will have to consider the degree of complexity (simple to highly complex) and uncertainty (from certain to highly uncertain). Ambiguity as a property of the public response can be overlaid on any of the other two categories and when this happens it dramatically changes the approach to dealing with the risk issues involved. Applying this to the field of nanotechnology, risk-related knowledge can be characterised currently as complex for passive nanostructures with new properties and functions, uncertain for active nanostructures and nanosystems and ambiguous for large nanostructured systems and molecular nanosystems. These categories could change as knowledge and public perception evolve further and the complexity, uncertainty and ambiguity dimensions interact together within the domain of nanotechnology. Many diverse actors are dealing with this technology. On the one side there are the promoters, producers and embedders of nanoscience and nanotechnology (e.g. scientists, technologists, technology assessment experts and administrative promoters) also called insiders (Garud and Ahlstrom 1997) or enactors (Rip 2002, 2004a, 2004b). There are, furthermore, interested organisations, pressure groups, individual consumers, citizens and public authorities on the demand side (also called outsiders or comparative selectors). The diversity of the involved actors inevitably makes innovation in the domain of nanotechnology a social learning process (Tait and Williams 1999; Williams and Russell 2002). Since nanotechnology development is part of such an open and complex system, a suitable risk governance approach is the use of adaptive, corrective measures on the system rather than the adoption of simple cause-and-effect measures for individual activities. Nanotechnology processes and applications are expected to evolve significantly and one will need to adapt the risk related measures over time. Such measures should be based on the understanding of the societal system where all events are interconnected and cannot be evaluated in isolation.

Beyond these component parts the IRGC framework includes three major value-based premises and assumptions. First, the framework is inspired by the conviction that both the factual and the socio-cultural dimensions of risk need to be considered if risk governance is to produce adequate decisions and results. While the factual dimension comprises physically measurable outcomes and discusses risk in terms of a combination of potential – both positive and negative – consequences along with the probability of their occurrence, the socio-cultural dimension emphasises how a particular risk is viewed when cognitions, associations, values and emotions come into play. Preparing factual information for nanotechnology is challenging because the field is at the beginning of development and it is difficult to formulate scenarios for the future. Inclusion of socio-cultural dimensions must be fully considered because nanotechnology works at the foundation of matter where life can be affected and has broad societal implications in almost all sectors of activity. The second major premise concerns the inclusiveness of the governance process, a necessary although not sufficient, prerequisite for tackling risks in both a sustainable and acceptable manner. Consequently, this imposes an obligation to ensure the early and meaningful involvement of all stakeholders and in particular, civil society. Earlier and meaningful inclusion of researchers, industry, government, technology users, public and all interested stakeholders is important for nanotechnology development because it can affect many groups and the implications are cross-correlated in time. The third major premise involving values is reflected in the framework's implementation of the principles of good governance, including participation, transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law and the need for the chosen solution to be politically and legally realisable as well as ethically and publicly acceptable. Nanotechnology is advancing with a rapid rate of change and at a global level; its rate of change is estimated to be faster than was the case for both information technology and biotechnology. A risk governance framework for nanotechnology should ensure that development is stable, equitable and beneficial, with the adoption of corrective and anticipatory measures including the principles of good governance.

Figure 4: Steps in IRGC Risk Assessment and Management Framework for Nanotechnology (NT); NS Denotes Nanostructures.



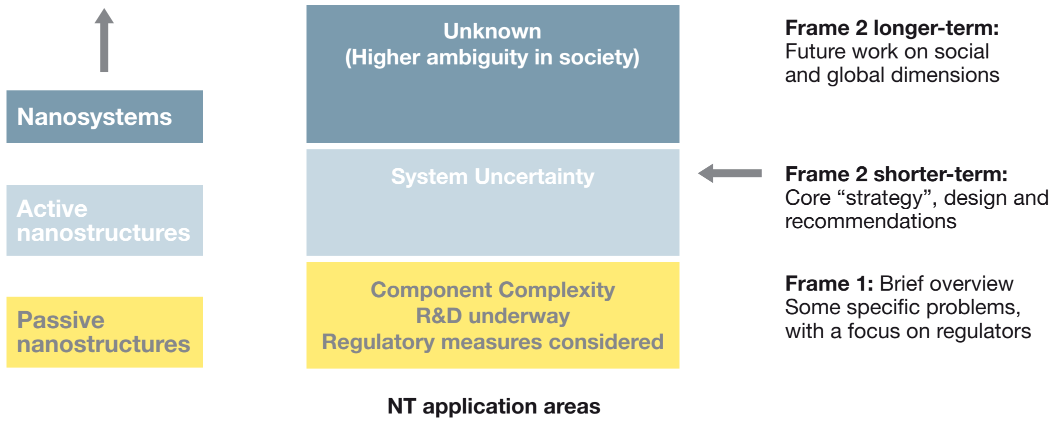
The framework's risk process, or risk handling chain, is illustrated in Figure 4. It breaks down into three main phases: *pre-assessment* (see p.37), *appraisal* (see p.41) and *management* (see p.50). The appraisal step includes traditional risk assessment and the novel element of concern assessment, both directed towards best scientific analysis of physical impacts as well as the social impacts expected from the application of the technologies. An interim phase, comprising the *characterisation* and *evaluation* of risk, can be assigned to either the appraisal or management phases – thus concluding the appraisal phase or marking the start of the management phase. This allocation depends on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks. Risk evaluation refers to the judgement of tolerability or acceptability of a given risk. The risk process has *communication* as a companion to all phases of addressing and handling risk and is itself of a cyclical nature. However, the clear sequence of phases and steps offered by this process is primarily a logical and functional one and will not always correspond to reality.

For nanotechnology, there are significant differences in application of the framework's main phases for each of the four generations of nanotechnology products. A critical aspect is the extent of knowledge development and a major challenge is that decisions and implementation actions (for example, R&D, infrastructure investments and regulations) need to be undertaken before most of the processes and products of nanotechnology are known. The following sections will follow the risk governance framework step by step and explain in which way the framework could help to establish more effective and publicly responsive governance structures for the risks and benefits of potential nanotechnology applications.

Pre-Assessment: Two Frames for Nanotechnology Risk Debates

The IRGC framework addresses wider governance issues pertinent to the context of a risk and the overall risk process, thus acknowledging the many different pathways that different countries or risk communities may pursue in dealing with risk. Pre-assessment builds on the observation that collective decisions about risks are the outcome of a mosaic of interactions between governmental or administrative actors, science communities, corporate actors and actors from civil society at large. Many interactions are relevant to only some parts of the process. The interplay of these actors includes public participation, stakeholder involvement and the formal (horizontal and vertical) structures within which it occurs.

Figure 5: Strategies as a Function of the Generation of Nanoproducts: Application to Frame 1 and Frame 2

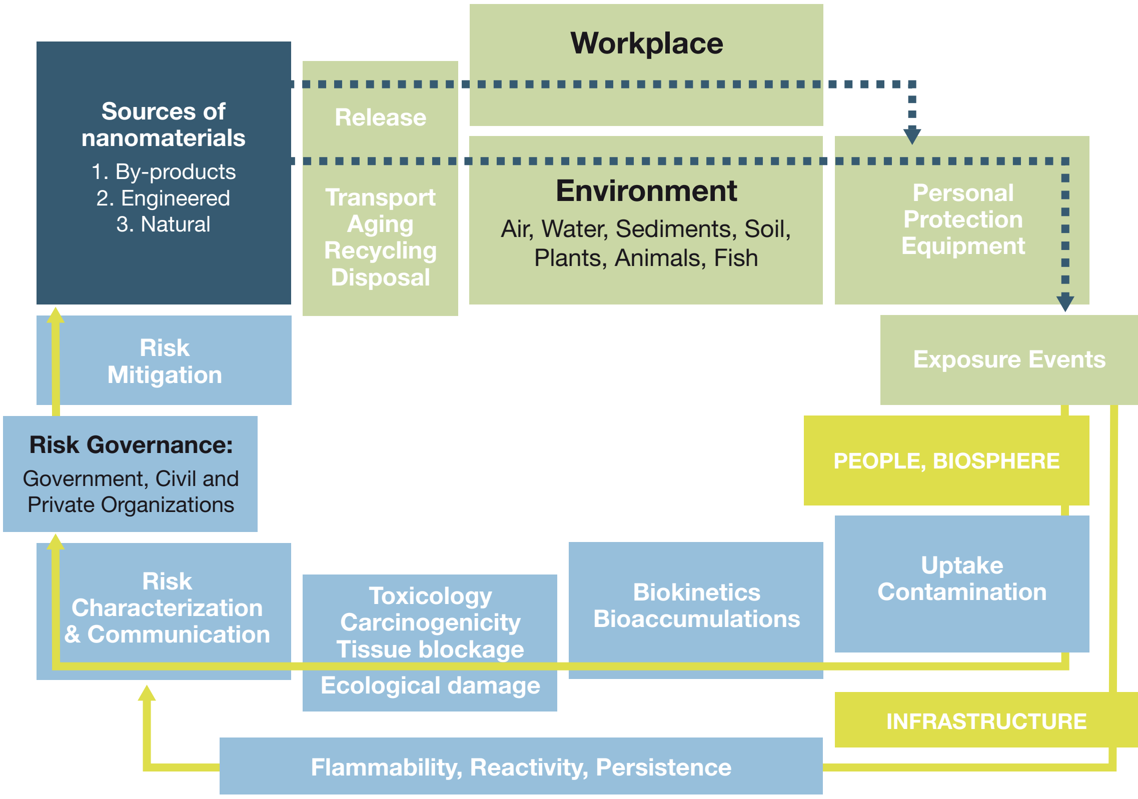


A systematic review of the potential benefits and risks for an emerging technology needs to start with an analysis of what major societal actors (such as governments, companies, the scientific community, NGOs and the general public) define as areas of concern or impacts that they will label as risk problems (rather than opportunities or innovation potentials, etc.). In technical terms this is called framing. Framing in this context encompasses the selection and interpretation of phenomena as relevant risk topics (Tversky and Kahneman 1981; van der Sluijs et al. 2003; Goodwin and Wright 2004). For nanotechnology we have identified two major frames which capture how the risks have so far been discussed:

- **Frame 1**. The context of classic technology assessment looking into the impacts derived from the application of nanoparticles and other relatively simple, passive or merely reactive nanostructured materials with steady behaviour in different areas of application (e.g. paint, cosmetics, food, and coatings). This frame is most suitable for issues related to the first generation of nanoproducts (passive nanostructures, Figure 5). The property or behaviour of some passive nanostructures may be complex - typically for system components – and, depending on application, there will also be more or less uncertainty when predicting positive or negative impacts for the economy, environment and society.
- **Frame 2**. This frame is not directed towards anticipating complex and still unknown impacts of different nanotechnology applications. It addresses the context of social desirability of innovations looking into processes of technical modernisation, changes in the interface between humans and machines/products and ethical issues concerned with the boundaries of intervention into the environment and the human body. This frame addresses the issues related to the future generations of nanoproducts (active nanostructures and nanosystems, Figure 5) and long-term implications of

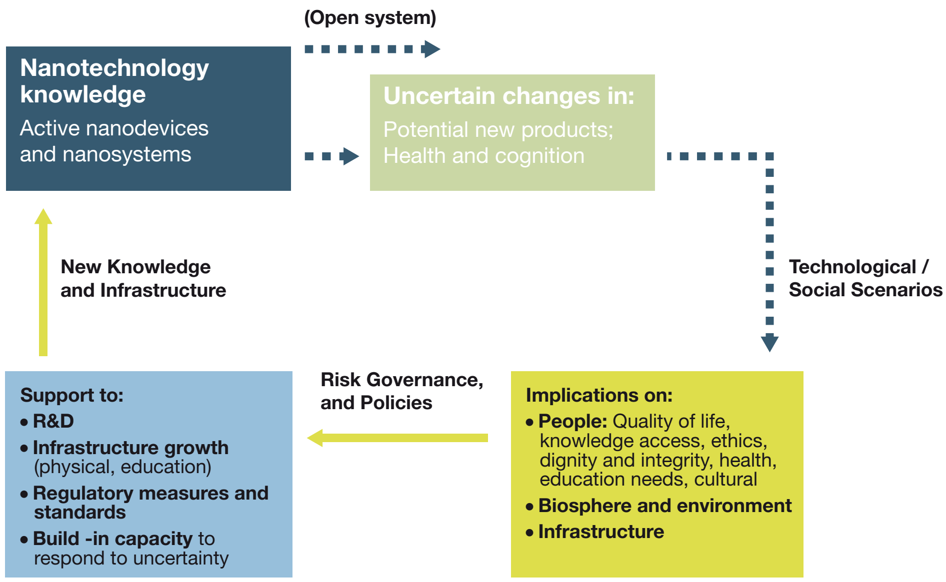
nanotechnology (Roco 2004a). Frame 2 concerns are related to more complex and/or evolving nanostructures and nanosystems than Frame 1, some of which may utilise fundamental molecular elements or nano-bio-structures as their building blocks. The behaviour of active nanostructures and systems typically changes over time and is therefore complex. It may be uncertain for system components and also tends to be uncertain for the system as a whole (at least from today's perspective). Frame 2 is more likely to be associated with higher degrees of ambiguity when considering current knowledge and perspectives on nanotechnology.

Figure 6: Environmental, Health and Safety (EHS) Research and Regulation for Nanomaterials (Frame 1): Key Physico-Biological Processes and Decision Steps during the Life-Cycle of Nanomaterials released either in the Environment or at the Workplace (modified from Roco (2005b))



The context for Frame 1 (see Figure 6) expresses the complexity of processes and decisions steps that ensue when passive nanostructures are applied within system components. Risk governance is focused on a scientific debate about the implications of novel aspects of nanoparticles on human health and environment, with the goal being to understand and recognise potential health and environmental risks before they materialise in larger quantity. This goal requires the establishment of a body of evidence related to toxicological and ecotoxicological experiments, and simulation and monitoring of actual exposure. The major actors here are scientific communities, product and process developers, governmental bodies and local institutions which include regulatory agencies, NGOs, ad hoc commissions and technology assessment institutes. A major conflict lies in the question of how much precaution is necessary when producing the nanostructures and over their use in potential applications. Several NGOs advocate a very precautionary approach where applications are restricted to highly investigated products. Other organisations, such as most industries, favour a slow penetration approach including plausibility checks (do we expect anything more serious than what we have already?) and constant monitoring. The flowchart in Figure 6 suggests the main steps in the research and regulation of nanomaterials once released either into the environment or in the work place (dashed line). The implications after exposure (solid line) are shown to affect people, the biosphere and the surrounding infrastructure. Risk governance should ensure safety in all those areas within the outlined closed loop.

Figure 7: Risk Governance for Active Nanostructures and Nanosystems (Frame 2): Key Decision Processes in the Open Loop Approach (modified from Roco (2005b))



The context for Frame 2 (see Figure 7) is more complicated and multi-faceted than that of Frame 1. Component complexity is increasing and the dynamic behaviour and multifunctionality of the nanostructures may lead to uncertainty within their respective systems. It is also directed towards a higher degree of ambiguity. The main argument is that nanotechnology represents a new class of processes and applications that may threaten human identity, speed up the pace of modernisation beyond that with which human societies can cope, and transform our environment in directions that nobody can realistically predict. This debate, focusing on what is desirable, leads different actors to assess technological trajectories on criteria that have not been previously considered. Inversely, discussions about what can be technologically possible can steer the formation of judgements about desirable societal changes (Grin et al. 1997; Grin and Grunwald 1999; Grin 2004; Goorden 2003). The debate on nanotechnology seems to pursue both directions: on one hand, new applications and future visions of the technology provoke new ideas and reflections about human identity and the mind; on the other hand new ethical considerations about sustainability direct nanotechnology research into applications that were not originally pursued by the engineering community.

The flowchart in Figure 7 suggests that the open system loop begins with nanotechnology knowledge creation leading to new products, health and cognition developments. By using scientific, technological and social scenarios one may estimate the long-term potential implications on people, the biosphere and the surrounding infrastructure. On this basis, risk governance and public policies could be formulated which address the further development of nanotechnology and evaluate its risks. In turn, this may lead to new R&D programmes, infrastructure growth, suitable regulatory measures and standards and build the institutional capacity to respond to uncertainty. The new knowledge created by each cycle may lead to new outcomes which are generally different from the previous cycle. The ethical implications of nanotechnology development on risk governance are particularly important for Frame 2: stakeholders must achieve understanding and engage in discussion about ethical and social responsibility for individuals and affected institutions. The societal implications of inequitable distribution of benefits and any unexpected consequences of the new technology may create tensions if not properly addressed (Weil 2003; Baumgartner et al. 2003).

The primary concern of Frame 2 is therefore characterised by a mixture of beliefs, values and visions that are not exclusively linked to nanotechnology but are, at least partially, associated with it. This frame is shared by many cultural opinion leaders, religious groups, and often individuals who are disappointed with the direction of technological and social change. To study these concerns and visions and to provide meaning to the often fragmented public voices is the domain of the social sciences and the humanities: traditional impact assessment or risk analysis will have no bearing on the arguments that are exchanged in this debate (Tait 2001). The evidence that is required for this debate is narratives that show plausible (or implausible) links between social and perception threats and a combination of technologies including nanotechnology. Examples are neurochips to be implanted in the human brain, nanomachines used in warfare, plants with biochips, and other futuristic applications. The main message is: Stop this process before it is too late.

Pre-assessment of the Two Frames

It is important in the pre-assessment phase and beyond to distinguish these two very different frames and understand the linkages between them. Each frame demands significantly different forms of handling and appraisal. In particular, the selection of management strategies needs to be adapted to the characteristics of the frame. At the same time, an incident in Frame 1 (for example, accidental exposure leading to a visible health impact) may serve as a catalyst for transmitting concerns to Frame 2 (the same may be true from Frame 2 to Frame 1) assuring the attention of a larger audience. It may trigger a chain reaction starting with a given health event, leading further to the image that modern societies cannot even deal with simple health hazards, and result in the conviction that humans should refrain from such complex technologies since they cannot control them. An additional risk challenge is the effect of randomly occurring hazards. The distinction between Frame 1 and 2 provides analytical clarity and focus although, in reality, the frames shade into each other. Public concerns may be driven by visions of Frame-2-applications, yet they may be associated or fuelled by experiencing Frame-1-applications. Furthermore, with the improvement of knowledge and more concrete experience with nanotechnology applications, some of the Frame 2 examples may be treated with approaches conceived for Frame 1. It is important to understand the need for an analytic distinction into two frames: first as a heuristic for identifying risks and concerns; secondly, as a tool to design the appropriate risk management, communication and education programs; and thirdly, as a reference for observing the dynamic process of development and application within and between the two frames.

The other areas of pre-assessment are closely related to the issue of framing. Early warning signals can be assigned to watch for the potential impacts of nanoparticles and/or to monitor the societal debate and evolution of concerns related to the ambiguity of nanotechnology applications. Depending on the dominant frame, the third step, pre-screening, is also affected. In the first frame, the risks of nanoparticles will be allocated to the classic risk assessment and management route. However, the second frame requires risk analysts to focus on the concern assessment route with a strong participatory element, giving greater consideration to the societal and ethical implications and nanotechnology's role in a technological culture. Evaluating the acceptability of nanotechnology as a promoter of modernisation cannot be based on technical, medical and ecological criteria alone. Here social, cultural, religious and ethical views need to be included and integrated. Finally, scientific conventions (the fourth step in pre-assessment) also depend on the respective reference frame. The usual toxicological and epidemiological methods need to be applied in the first frame; scientific methods of concern analysis, empirical attitude and value research and ethical reasoning are more appropriate to the second frame (Roco and Bainbridge 2003 and 2005; EC 2004).

Structuring risk governance into two frames is important in enabling the development of critical knowledge for effective risk management. If they are not decoupled it will impede the generation of targeted data for improved risk management of Frame 1 nanomaterials. Meeting the research needs required for Frame 1 necessitates an approach that is based on classic and modified research instruments and requires cooperation among technical, medical and ecological disciplines. The need for further research and assessments does not interfere with the present speed of diffusion as the research scope can be contained within established technology assessment procedures, so that timely and reliable results can be expected. Research for Frame 2 questions, however, requires a more holistic and transdisciplinary approach. This should include a strong involvement of the social sciences and the humanities, the incorporation of stakeholder preferences and intense reflections by legal and ethical scholars. The two frames should not be mixed because they rely on such different research and decision-making pathways.

Risk Assessment

The appraisal process in the IRGC framework (see figure 4) consists of two parts: risk assessment and concern assessment. They fit well the dualism of Frame 1 and Frame 2 that has been discussed above. The risk assessment phase covers the usual steps of hazard identification and estimation, exposure and vulnerability assessment, and, risk estimation and conclusion on the major challenges for nanotechnology risk assessment (categorisation of risk with regard to degree and cause of complexity, uncertainty and/or ambiguity). As explained earlier in this paper, nanostructures and, particularly, nanoparticles not only exhibit new properties which one can make use of in many consumer, industrial, environmental and pharmaceutical applications, but also there is already evidence that these chemical, physical, and biological properties may have possible harmful consequences for human health, nature and the environment. The existence of anthropogenic and natural nanoparticles has been known to science for a long time and certain nanoparticles have been characterised and their effects are well established in the scientific literature. Even though this knowledge is limited, one can predict that the development and use of the first generation of nanoproducts will largely increase the variety of types of nanoparticles, their density in our human and natural environment and the probability for human beings to have physical contact with them or to incorporate them.

Many scientific studies have experimentally investigated potential nanotechnology risks to environment, health and safety (EHS) (e.g. Jani et al. 1990; Li et al. 1999; Bennat and Müller-Goymann 2000; Alyaudtin et al. 2001; Oberdörster et al. 2002; Dick et al. 2003; Kreuter 2003; Service 2003; Hoet et al. 2004; Warhheit et al. 2004; Oberdörster et al. 2005). These studies are mostly taken from the fields of medicine, pharmaceutics and toxicology and focus on the possible uptake of nanoparticles within the human organism and on the consequences for the concerned organs. Scientific concerns have been voiced about the differences between micro- and nano- particles (e.g. Zhang et al. 2005), the easier penetration by nanoparticles into human tissue (e.g. Geiser et al. 2005; Oberdörster et al. 2004), and the potentially carcinogenic effects of nanotubes and nanoparticles (Nature 2003). Further studies have analysed the possible damage to ecosystems from nanotechnology (e.g. Colvin 2003) and the potential harm caused by explosion and high chemical reactivity, while others have focused on a recapitulating analysis of the experimental studies in meta-analyses (e.g. Baumgartner et al. 2003; Paschen et al. 2003; Hett 2004).

The routes for human and environmental exposure include oral, cutaneous and inhalative uptakes of nanomaterials during their production, transport (in air, water, soil and biosystems), ageing and waste disposal. Risk analysis surrounding fabrication of nanomaterials (at the workplace) is an important aspect of interest to process and insurance industries (Robichaud et al. 2005), although the risk of producing some nanomaterials (carbon nanotubes, quantum dots, etc.) may be similar to other common manufacturing processes. Key hazard factors (e.g. toxicity, carcinogenicity, volatility, flammability, and persistence) and their potential for exposure (e.g. transport characteristics from source to human tissue, water solubility and bioaccumulation) have also been considered. In addition, further studies reflect on the use of nanotechnology itself (e.g. Regis 1995; Jopp 2003; Boeing 2004). It has been argued that EHS analysis be extended for the product life-cycle but that, provided the hazard identification and exposure data of nanomaterials is determined and product pre-market testing is considered, the existing general chemical frameworks of the US EPA (2004) and OECD (2002) would be largely applicable.

The following section summarises the current level of knowledge in different risk categories:

- **Health Risks.** From the beginning of the debate on nanotechnology there has been an intense discussion of the potential risks (Wolfson 2003). This subject has been debated not only by nanoscientists but also increasingly by representatives of the social sciences and humanities (see e.g. Roco and Bainbridge 2001 and 2005; Fogelberg and Glimell 2003; and Johansson 2003), by NGOs and by social and political institutions. In general, free nanoparticles and other nanostructures do raise health and safety concerns. One reason is that these smaller particles have a much larger surface-to-mass ratio than larger particles and are more likely to penetrate cells in the body and take on different structures than they would have at their larger scale. Their chemical reactivity and bio-activity may also vary with particle size. In general, the risk of accumulation in cells and their level of toxicity depends on the exposure route, material and size of the nanostructure (Maynard and Kuempel 2005). Since the scope of potential complex relationships is not well-known, it is difficult to evaluate the toxicity of novel nanoparticles arising from these new technologies and most of the assumptions on adverse health impacts come from the emergence of evidence of air pollution, in effects from the inhalation of welding fumes and in extrapolation from the extensive body of knowledge on the health effects of existing micrometer sized particles.

  There are, however, a number of long-term studies underway which should clarify the current assumptions. One theory suggests that the finer particulates in air pollution, those in the nanoscale range, may be responsible for increasing blood coagulation leading to increased blood viscosity and causing cardiac ischaemia. Other hypotheses include an effect on neutrophil deformity and atherosclerotic plaque progression and destabilisation. There is also a general picture that is emerging from animal studies – that, on a mass dose basis, pulmonary toxicity is enhanced when particle size is reduced from the micrometer to the nanometer range. The increase in toxicity appears to be partly linked to the increase in the particle surface area (causing a catalytic effect and generating free radicals). However, it also seems that there is a difference in toxicity, depending on the materials: that is, some materials in the nanometer range are more toxic, leaving the final verdict on a material's toxicity to a case-by-case basis - for example, single high exposure to non-fibrous, non-cytotoxic particles such as carbon black, titanium dioxide and talc, can produce transient pulmonary inflammation. Following repeated exposure, there appears to be a risk of sustained inflammation, lung damage with hypertrophy, epithelia hyperplasia and interstitial fibrosis due to overload (exceeding alveolar macrophage's capacity for phagocytosis, leading to the secretion of inflammatory mediators). Exposure to non-fibrous, cytotoxic particles such as silica is more likely to directly affect the alveolar macrophages due to its surface chemistry and free radical generation potential (production of oxidative stress). For example, toxicological studies have shown that low exposure to micrometer-sized particles of quartz causes severe lung inflammation, cell death, and fibrosis (IARC, 1997). Studies have also been shown to cause tumours in rat (Seiler et al. 2001). Current thinking suggests that these effects are related to the surface of the quartz, which is reactive and generates free radicals leading to oxidative damage. Studies on exposure to coal and silicates have found that similar effects can be expected if the dose is sufficiently high, causing overload, and that this relates to the total surface area of the particles inhaled. In essence, cells and organs may demonstrate toxic response, even to substances generally known as non-toxic, when they are exposed in high enough doses to the nano-sized range. As a result, irreversible changes may occur in living tissues. Concern relating to exposure to nanosized fibrous particles is similar to those for non-fibrous particles, in this case pulmonary toxicity and/or cytotoxicity.

The history of asbestos is still fresh in our mind and there is a fear that nanosized fibres may introduce similar problems. Fibres such as those coming from carbon nanotubes could also cause a problem, not only due to their shape and dimension, but also because of their potential to be combined with iron or other metals. The addition of these metals could cause catalytic effects with free-radical-releasing pro-inflammatory properties. Current animal studies using nanosized particles such as titanium dioxide, barium sulphate, metallic cobalt and metallic nickel, found that metallic nickel demonstrated statistically more significant inflammation responses than either cobalt or titanium dioxide and that cobalt was more inflammogenic than titanium dioxide. Nickel and cobalt, but not titanium dioxide, caused lipid peroxidation. There has also been some concern voiced about the potential for nanosized particles to translocate to the liver and other organs, although this may be dependent on the differences in exposure conditions, chemical composition and particle size. A recent study has even suggested that nanoparticles generated by manufacturing processes may penetrate and pass along nerve axons and into the brain. In addition to exposure through lung tissue, there has been some fear that nanosized particles may also penetrate broken skin, adding to the overall body burden and potentially generating free radicals that could damage DNA. However, there has been little evidence to confirm this yet (HSE 2004).

- **Risk of changing human condition and human development.** The development of active nanostructures, nanosystems and hybrid bio-nanostructures has raised concerns about human development risks. These include devices which interface with human tissue and nervous system, artificial organs, genetic modification, brain and body control, hybrid viruses and bacteria, as well as economic and cultural development.
- **Risk of explosion.** Traditionally, it is known that dust explosions can occur in manufacturing sites that use fine particles of sugar, flour and animal feed and in operations that produce sawdust, organic chemicals, plastics, metal powders and coal. The major factor influencing the ignition sensitivity and explosion violence of the dust cloud is the size of the particle or the total surface area per unit volume. Generally, as the particle size decreases the specific surface area increases and the dust explosion and the ease of ignition also increases, although this effect is not linear and for some materials the effect plateaus at the smaller size range. There seems to be no lower particle size limits below which dust explosions could not occur. It may be possible that the increased surface area of nanoparticles could also increase the likelihood that they become self-charged and ignite. Nanopowders, again because of their large specific surface area, may become highly charged in use. There is also concern that they may remain airborne for longer than larger particles and be harder to detect. Unfortunately, for now there appears to be no data on the explosion characteristics of nanopowders, and the UK's Health and Safety Executive (Pritchard 2004) suggests that extrapolation of the data for larger particles to the nanosize range cannot be done accurately due to the changes in both the chemical and physical properties. The law of quantum physics comes into play at the smaller particle size and the behaviour of the surface starts to dominate the bulk behaviour of the material. For example, some materials that are conductors of electricity become insulators at the nanosize range.

- **Ecological risk.** Nanomaterials may affect ecosystems through the activities surrounding their fabrication or their release into the environment during production, use or disposal. Their impact may be important because of their size, reactivity, bioaccumulation and persistence. However, one must analyse each type of application individually. Robichaud et al. (2005) have shown that the relative environmental risk during fabrication of single-walled nanotubes, buckyballs (a variety of quantum dots), alumoxane, and titanium dioxide nanoparticles was comparatively low in relation to other common manufacturing processes now in use. In another example, Oberdörster et al. (2004; 2005) found situations where nanoparticles reached the brain of living organisms. Colvin (2003) has shown that surface treatment of nanoparticles may reduce or eliminate the toxic effect of some engineered nanoparticles.
- **Educational gap risk.** A gap may develop between the need to handle emerging nanotechnology issues and the ability of public understanding and professional development to responsibly take advantage of the new technology. The major risk here is the loss of opportunities due to a political paralysis caused by a growing gap between professional knowledge and public perception. If such a gap is a consequence of divergent values and visions about future developments, a more cautious approach to seeking opportunities is justified. If such a gap is based on misunderstanding and misrepresentation of the likely impacts of nanotechnologies outside the boundaries of uncertainty intervals, society may choose not to take advantage of the potential benefits due to unjustified fears of imagined risks.
- **Political and security risks.** Technological development may impact on investment policies and economic development, be used for criminal or terrorist activities or create an uneven distribution of nanotechnology benefits among countries (North-South and East-West). Equally, it could trigger a new military technological race. These risks are not exclusive to nanotechnology but, due to the wide range of applications, are particularly important for this technology.

What does that mean for risk assessment? Although the steps of risk assessment will follow the traditional path of hazard identification and estimation, exposure and vulnerability assessment and risk estimation, the specific methods for conducting these analyses might be different from those appropriate to normal toxicological routines. For example, the traditional filter and gravimetric methods used for particulates cannot be used for particles at this range and the currently available technology is expensive. One method used to sample for nanoparticles is the low-pressure nano-cascade impactor which uses five impactor plates with sizes between 10 to 100 nm. Another method uses a filter and passive sampler; but the sample has to be sized and counted by transmission electron microscope which makes the laboratory analysis expensive. For further reading on this topic see Brouwer et al. (2004).

Concern Assessment

In addition to risk assessment, the IRGC model includes a concern assessment. This is particularly important for dealing with Frame 2. What do we know about public concerns when it comes to nanotechnology? Although nanotechnology is still an emerging field, the battle lines being drawn up around it are analogous to those involved in earlier controversies over nuclear power, GM crops, biotechnology and mobile phone masts. These concerns are also likely to change rapidly in response to particular developments (Lyall and Tait 2005). On one side of the argument are those who see nanotechnology as an area of exciting potential for the economy, society and the environment. Challenging them are those who remain sceptical about the possible vested interests lying behind the science, the questionable nature of the commitments bound up in R&D processes, and the known and unknown risks that could be unleashed by its application. Since many new technologies experienced a strong public opposition after their often euphoric introduction, it is important to understand in advance the potential public reactions and potential mobilisation efforts of relevant social groups.

Nanotechnology and its implications has also been analysed for ethical, legal and other social issues (ELSI), from a societal perspective (Roco and Bainbridge 2001 and 2005, Nanoforum 2005), and from an NGO perspective (ETC 2003; Arnall 2003; Komm-passion Group 2004; Environmental Defense 2005). Furthermore, governmental organisations have established and/or funded technology assessments of nanotechnology. For example, the Office for Technology Assessment of the German Government (Paschen et al. 2003) and the German Enquête Commission for ethical and legal implications of modern medicine (Maasen 2003). In the US, the World Technology Evaluation Center (WTEC) has prepared a series of reports evaluating nanotechnology. In Switzerland, the Centre for Technology Assessment has analysed the impacts of nanotechnology on medicine (Baumgartner et al. 2003). Key society structural risks include the regulatory environment (risks may be raised by gaps in the regulatory system) and the portfolio of processes and products used in industry and waste handling policies. Several wildcard risks include accidents, terrorist attacks, the use of military nanoproducts (Altmann 2005), and the impact of mass media products (movies, books, etc.). One of the more notable contributions to the social risk debate is a report by the ETC Group, a Canadian NGO, which hit the headlines in February 2003 with its assessment of the potential dangers of nanotechnology. Demanding a moratorium on commercialisation, the report warns of a Pandora's Box of potential hazards, ranging from nanoparticle contamination through grey goo and cyborgs, to the amplification of weapons of mass destruction (ETC Group 2003). In the same month, the UK Government's Better Regulation Task Force called for the development of a new regulatory framework for nanotechnology and for an early and informed dialogue between scientists and the general public about its impacts (Better Regulation Task Force 2003).

For improving our understanding of the likely responses of the population and particularly major NGOs, concern assessment is linked to risk perception and stakeholders' concerns. It is necessary to investigate the evolving socio-cultural and political context in which research at the nanoscale is conducted, the societal needs that nanotechnology may satisfy and the popular images that experts, politicians and representatives of the various publics associate with nanoscience and nanotechnology. The past research on public attitudes and political mobilisation has demonstrated that the effectiveness of public protest does not depend so much on the number of people concerned about a technology but, rather on the composition of the groups that are willing to act publicly in favour of or against the implementation of such technologies (Hampel et al. 2000). Public perception of technological risks depends on two sets of variables. The first set includes the well-known psychological factors such as perceived threat, familiarity, personal control options, and positive risk-benefit ratio (Slovic 1992; Boholm 1998). The second set includes political and cultural factors such as perceived equity and justice, visions about future developments, and effects on personal interests and values (Wynne 1984; Tait 2001; Renn 2004a). While the first set of components can be predicted to some degree on the basis of the properties of the technology itself and the situation of its introduction, the second set is almost impossible to predict. The social, political and cultural embedding of a new technology is always contingent on situational and randomly assorted combinations of circumstances that impede any systematic approach for anticipation. Within the second evolving frame, the symbolic nature of nanotechnology representing fast modernisation, efficiency and artificiality, provides us with some hints of where the debate might go in the future.

Comparative qualitative studies have been conducted to investigate the public perception of nanotechnology (e.g. Gaskell et al. 2004), and several approaches from a broader Science, Technology and Society (STS) perspective analyse the potential social concerns and societal impacts of nanotechnology applications (e.g. Bainbridge 2002; Fogelberg and Glimell 2003; Johansson 2003; Sweeney et al. 2003; Wolfson 2003; Cobb and Macoubrie 2004; Spinardi and Williams 2005). Looking at the empirical results in the United States and Europe so far, it is interesting to note that the concern linked to the second frame (about the science fiction notion of self-reproducing nano-robots or other more exotic applications of nanotechnology that could harm humans directly) has been rarely found in the few surveys conducted until today (the theses of Joy (2000) and others have found little resonance in the public). Rather, critical remarks centre on the concern that nanotechnology would be misused by some people to harm other people thus exacerbating existing social inequalities and conflicts. In contrast, most respondents associated with quite a number of direct but non-specific benefits and found a number of ways to express confidence that nanotechnology would help human beings achieve legitimate goals (Bainbridge 2002).

In order to understand the risk perception side of nanotechnology, large opinion surveys are only of limited value. The main problem here is that for more than 90 percent of the respondents in both European and US surveys the term nanotechnology has no meaning or has weak meaning and evokes educated guesses at best (Roco and Bainbridge 2001). Even if the term is explained to the interviewees, the response is a direct reaction to the verbal stimulus and thus more an artefact of the questionnaire than a valid representation of a person's attitude. A more promising method would be to conduct focus groups in which proponents and opponents of nanotechnology would be given the opportunity to develop their arguments in front of representatives of the general public or selected groups, with the observers being asked to share their impressions and evaluations. Several of these studies are underway, partially combined with citizen juries or citizen panels, which are asked to investigate the public's preferences for regulatory actions after they have been informed about the likely impacts of nanotechnology. Nevertheless, empirical studies about public risk perception can provide data that is relevant to nanotechnology risk perceptions. They provide information about the direction of public opinion and attitudes in a situation which is still characterised by a high degree of uncertainty and by knowledge gaps. Table 1 lists the main results of one of these studies conducted in the United States.

In addition to the percentages of respondents who agreed, Table 1 also establishes correlations between items using Pearson's r product-moment correlation coefficients, limited mathematically in the range from -1.00 through 0.00 to +1.00. The -0.68 correlation for two of the listed items shows that people who have a tendency to agree with one of these items (e.g. the statement "Our most powerful 21st-century technologies - robotics, genetic engineering, and nanotechnology - are threatening to make humans an endangered species") will also have a tendency to disagree with the other (e.g. the statement "Human beings will benefit greatly from nanotechnology, which works at the molecular level atom by atom to build new structures, materials, and machines"). According to Bainbridge (2002 p.564), "In an attitudinal survey research one seldom sees a correlation with an absolute value this large, except of course in the substantively uninteresting case of correlating an item". Many of the respondents were aware of nanotechnology, and others reacted intelligibly to a brief description of the field. However, the response to some items suggests that enthusiasm for nanotechnology is slightly stronger at the right wing of the political spectrum as some respondents saw the benefits of nanotechnology primarily as profit for industry favouring the rich and powerful in society. This report recommends that, under the present situation of low trust, industry and regulators need to make a special effort to improve transparency and include the public in regulatory decision-making. In the comparable field of information technology this has been expressed as the digital divide (Department of Commerce 1999): the concern that disadvantaged and powerless groups will not benefit from information and communication technology. Such concerns may be reduced if government takes a role in ensuring that benefits are widely shared, or they may, perhaps evaporate as the benefits become more apparent. The chief finding of this initial, exploratory study is that science-attentive members of the general public are more enthusiastic about nanotechnology than individuals who expressed more indifference vis-à-vis scientific and technological developments.

Table 1: Attitudes toward Nanotechnology (N = 3909 Respondents) (Bainbridge 2002)

Statement	Percent who AGREE	Correlation (r) with item about:	
		Nanotechnology	Antitechnology
Human beings will benefit greatly from nanotechnology, which works at the molecular level atom by atom to build new structures, materials, and machines	57.5	1.00**	-0.68*
Our most powerful 21st-century technologies - robotics, genetic engineering, and nanotechnology - are threatening to make humans an endangered species	9.0	-0.68*	1.00**
Funding for the space programme should be increased	47.5	0.38*	-0.22*
Space exploration should be delayed until we have solved more of our problems on Earth	34.8	-0.35*	0.30*
Development of nuclear power should continue, because the benefits strongly outweigh the harmful results	34.2	0.31*	-0.31*
All nuclear power plants should be shut down or converted to safer fuels	32.1	-0.28*	0.33*
Research on human cloning should be encouraged, because it will greatly benefit science and medicine	31.7	0.37*	-0.29*
There should be a law against cloning human beings	52.3	-0.26*	0.22*
Some scientific instruments (e.g., e-meters, psionic machines, and aura cameras) can measure the human spirit	9.1	-0.02	0.05
Perpetual motion machines, anti-gravity devices, and time travel machines are physically impossible	29.3	-0.02	-0.03

*Statistically significant beyond the 0.001 level; significance can be conceptualized in terms of the likelihood that the coefficients could be reproduced by randomly reassigning responses across respondents, if the conventional interpretation in terms of a random sample of the population is considered inapplicable rather than merely approximate. **Autocorrelation of one item with itself.

Another recent survey of the US public, also using the method of informing the participants before asking their opinion, supports the general impression of an attentive public that welcomes nanotechnology as a means of helping the economy to prosper but also has deep suspicion about industry and distrust in government (Macoubrie 2005). The study concludes with some significant findings:

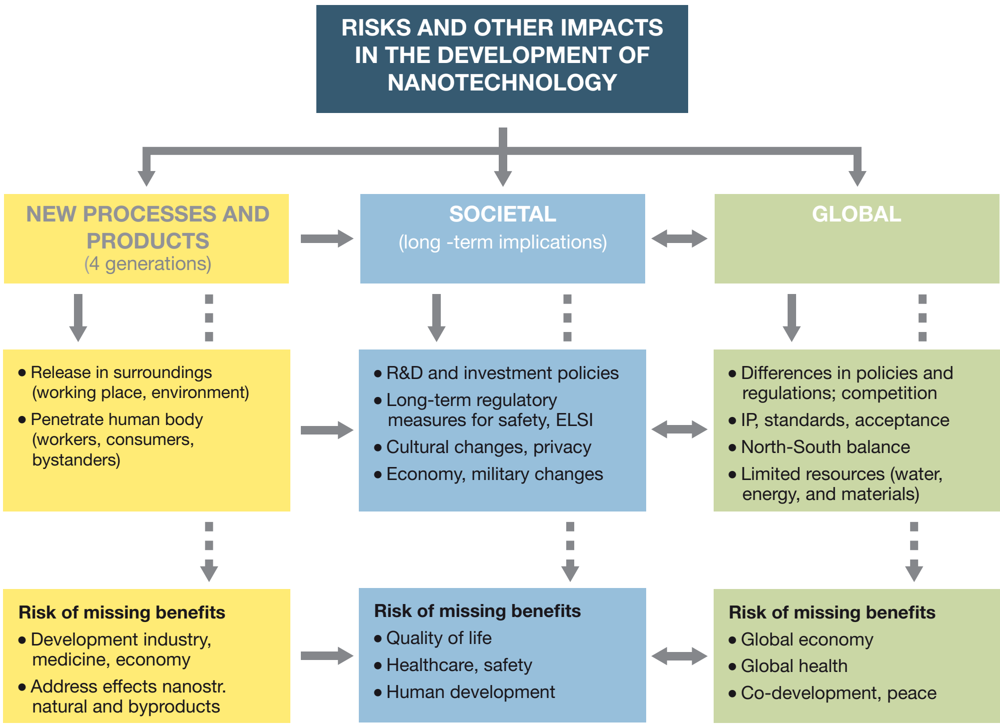
- Major benefits are anticipated by the public and are welcomed.
- The public wants to be included in the regulatory process.
- There is a lack of support for a ban on nanotechnology, but there is a high demand for effective regulation.
- There is low public trust in government. Participants believed the trust situation could be improved by more testing before products are approved for free distribution and by providing more unbiased information to the public.

- The influence of the media on public attitude formation is still low; most people have not heard about nanotechnology before.
- Industry is viewed with a high degree of suspicion.

A rather large number of ideas about nanotechnology's benefits but also about its risks have already entered popular culture. Over the coming years social scientists in a variety of fields would be well-advised to employ a diversity of research methods and analytical theories to chart and understand the growing significance of nanotechnology for modern civilisation. It is not clear whether the US results represent a general tendency in all OECD countries or the more commonly techno-optimistic attitude of US citizens. Large scale surveys have not been conducted in most European countries although preliminary studies suggest that the population is more sceptical in Europe than in the US. However, as yet there is no fundamental opposition or even outrage associated with the applications of nanotechnology.

An overview of the various potential risks and other impacts in the development of nanotechnology is summarised in Figure 8. The potential risks may be caused either by new processes and products (marked with yellow in Figure 8), by societal implications, and/or global interactions. The negative consequences may be directly related to harm by unintended effects (first row in Figure 8) or by the risk of missing the benefits (bottom row).

Figure 8: Risks and other Impacts in the Development of Nanotechnology (negative implications, including not taking advantage of the benefits)



Based on Environmental S&T, March 1, 2005, 107-112A, M.R.

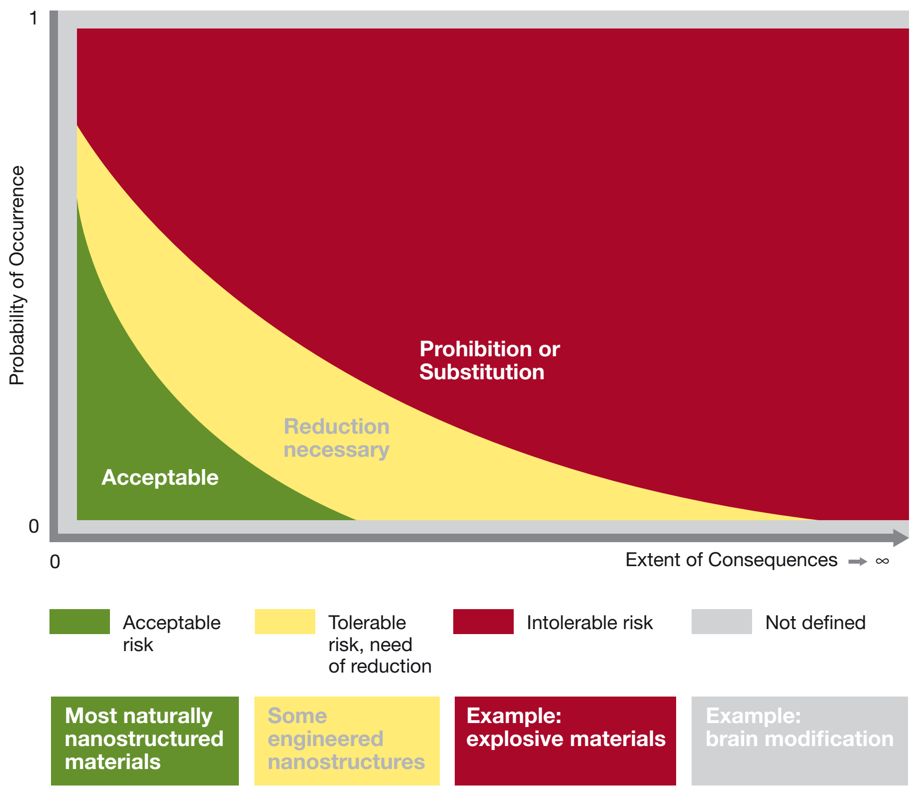
Risk Characterisation and Evaluation

Risk characterisation (see also Table 2 for knowledge characterisation) and evaluation comprises three major steps for both Frame 1 and 2:

1. Scientific (evidence-based) risk profile focused on risk assessment and concern assessment
2. Societal (value-based) balancing of benefits and risks (including societal needs, contribution to quality of life, contribution to sustainability, potential for substitution and compensation, policy imperatives, choice of technology and overall risk-benefits balance)
3. Conclusion on whether risk is acceptable, tolerable, unacceptable or not defined.

Corporate risk managers as well as regulatory agencies have the task of collecting information from the assessment processes and making a judgement about the balance between the potential negative and positive impacts. Such a judgement cannot be made for nanotechnology as a whole although some advocates of the second frame would like governments to make such sweeping generalisations. It is, rather, necessary to look at each application, collect what is known about its impacts and then delineate a judgement of acceptability or tolerability, such as by conducting case-by-case examples. It is also essential to distinguish between risk evaluation by the corporate sector and by regulatory agencies. Corporate decision-making is limited to balancing the positive and negative impacts with respect to the activities of the specific company (down-stream and up-stream), whereas regulatory agencies need to consider the cumulative effects of all similar or related activities and the interactive effects with other technological, economic or social developments. For both cases, corporate and public risk evaluation, it is advisable to make a distinction between tolerable and acceptable risks.

Figure 9: Acceptable, Tolerable, Intolerable and Undefined Risks relative to Benefits (Traffic Light Model, a Stakeholder Perspective)



The term tolerable refers to an activity that is seen as worth pursuing (for the benefit it carries) yet requires additional efforts for risk reduction or other risk management options 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. If tolerability and acceptability are located in a risk diagram (with probabilities on the y-axis and extent of consequences on the x-axis), the well-known traffic light model emerges (Figure 9). In this variant of the model, the red zone signifies intolerable risk, the yellow one indicates tolerable risk in need of further management actions (in accordance with the as low as reasonably possible – ALARP – principle) and the green zone shows acceptable or even negligible risk. The grey area illustrates the border lines, the first border identifying the area where one gets close to certainty (probability = 1) and the second where one gets close to indefinite losses. In the first case most legal documents and ethical schools prohibit the tolerance of risks that will lead to certain losses of life. However, certain losses of artefacts, money or other material assets may be tolerable. The same is true for indefinite losses. Many ethicists would not accept the possibility of an indefinite loss of human life even if the probability were extremely small. This is not true for other types of losses. Therefore we leave these boundary areas undefined.

To establish the boundaries between intolerable and tolerable as well as tolerable and acceptable is one of the most difficult tasks of risk governance. The UK Health and Safety Executive has developed a procedure for chemical risks based on risk-risk comparisons (Löfstedt 1997). Some Swiss cantons such as Basel County experimented with Round Tables as a means to reach consensus on the boundaries, whereby participants in the Round Table represented industry, administrators, county officials, environmentalists, and neighbourhood groups (RISKO 2000). Andrew Stirling suggested a combination of opening-up (for collecting arguments and weighing pros and cons) and closing-down procedures for deriving a normative judgement on risk tolerability and acceptability (Stirling 2004). Irrespective of the means selected to support this task, the judgement on acceptability or tolerability is contingent on making use of a variety of different knowledge sources. One needs to include the risk estimates derived from the risk assessment stage, and additional assessment data from the concern assessment. Both frames need to be represented at this stage.

Arriving at a balanced judgement means that nanotechnology will deliver sustainable added value for society, economy and industry only if it is possible to control and manage the unintended impact and risks in the sense of a societally accepted balance. It is not sufficient to include the physical-risk approach, although undoubtedly important, because it addresses only part of what is at stake within culturally plural, morally concerned and educated societies (AEBC 2001; Grove-White et al. 2000). Stakeholders play an important role in defining acceptable to intolerable by considering among other factors the balance between risk and benefits and the probability of extreme events.

Risk Management

The task of managing risks once the judgement on tolerability or acceptability has been made can be described in terms of classic decision theory in the following steps (Morgan 1990; Keeney 1992; Hammond et al. 1999):

- **Identification and generation of risk management options:** Generic risk management options include risk avoidance, risk prevention, risk reduction, risk transfer and – also an option to take into account – self retention. Risk management by means of risk reduction can be accomplished by many different means including the reduction of pollution at source via environmentally benign manufacturing and measures for cleaning polluted areas. Among them are:

- o technological and chemical processes such as clean air requirements in production halls or special furnace temperatures for melting metals;
- o technical prescriptions referring to the blockage of exposure (e.g. via protective clothing) or the improvement of resilience (e.g. via immunisation or vaccination);
- o governmental economic incentives including taxation, duties, subsidies and certification schemes;
- o third party incentives, i.e. private monetary or in kind incentives;
- o compensation schemes (monetary or in kind);
- o insurance and liability;
- o protective actions, including through regulations or policy decisions;
- o statistical studies to inform workers, consumers and public; and
- o cooperative and informative options ranging from voluntary agreements to labelling and education programmes.

All these options can be used individually or in combination to accomplish even more effective risk reduction. Options to manage risks can be initiated by private and public actors or both together. Among the potential technical options, protection technology and personal protective equipment may be used for protecting oneself against nanoparticles in the air. It is, for example, assumed that traditional aerosol control measures could work for nanoparticles if the collection devices used match the size of the particles. It should be stressed, however, that filter effectiveness for particles smaller than 15 nm is still uncertain. Traditional respiratory protection should work for particles over 15 nm, but it is critical that the facemask fits. It is also important to note that even the most efficient respirators (99.97% efficiency, labelled as N-, R- or P-100) have not been tested with nanoscale particulates. Additionally, it is recommended that impervious gloves and clothing be used to minimise dermal exposure.

- **Assessment of risk management options with respect to predefined criteria:** Each risk management option will have desired and unintended consequences which relate to the risks that they are supposed to reduce. In most instances, an assessment should be done according to the following criteria:
  - o Effectiveness: Does the option achieve the desired effect?
  - o Efficiency: Does the option achieve the desired effect with the least resource consumption?
  - o Minimisation of external side effects: Does the option infringe on other valuable goods, benefits or services such as competitiveness, public health, environmental quality, social cohesion, etc.? Does it impair the efficiency and acceptance of the governance system itself?
  - o Sustainability: Does the option contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
  - o Fairness: Does the option burden the subjects of regulation in a fair and equitable manner?
  - o Political and legal implementability: Is the option compatible with legal requirements and political programmes?
  - o Ethical acceptability: Is the option morally acceptable?
  - o Public acceptance: Will the option be accepted by those individuals who are affected by it? Are there cultural preferences or symbolic connotations that have a strong influence on how the risks are perceived?

  Measuring management options against these criteria may create conflicting messages and results. Many measures that appear initially to be effective may turn out to be inefficient or unfair to those who will be burdened. Other measures may be sustainable but not accepted by the public or important stakeholders. In addition, finding the most acceptable solution may impair or compromise the risk governance system itself. These problems are aggravated when dealing with global risks. What appears to be efficient in one country may not work at all in another country. Risk managers are therefore well advised to make use of the many excellent guidance documents on how to handle risk trade-offs and how to employ decision analytic tools for dealing with conflicting evidence and values (e.g. Viscusi 1994; Wiener 1998; van der Sluijs et al. 2003; Goodwin and Wright 2004).

- **Evaluation of risk management options:** Similar to risk evaluation, this step integrates the evidence on how the options perform using evaluation criteria with a value judgement about the relative weight each criterion should be assigned. Ideally, the evidence should come from experts and the relative weights from politically legitimate decision-makers. In practical risk management, the evaluation of options involves close cooperation between experts and decision-makers. As pointed out later, this is the step in which direct stakeholder involvement and public participation is particularly important and is therefore best assured by making use of a variety of methods (Rowe and Frewer 2000; OECD 2002).
- **Selection of risk management options:** Once the different options are evaluated, a decision has to be made as to which options are selected and which rejected. This decision is obvious if one or more options turn out to be dominant (relatively better on all criteria). Otherwise, trade-offs have to be made that need legitimisation (Graham and Wiener 1995). A legitimate decision can be made on the basis of formal balancing tools (such as cost-benefit or multi-criteria-decision analysis) by the respective decision-makers (given that his decision is informed by a holistic view of the problem), or in conjunction with participatory procedures.
- **Implementation of risk management options:** It is the task of risk management to oversee and control the implementation process. In many instances implementation is delegated, as when governments take decisions but leave their implementation to other public or private bodies or to the general public. However, the risk management team has at least the implicit mandate to supervise the implementation process or to monitor its outcome.
- **Monitoring of option performance:** The last step refers to the systematic observation of the effects of the options once they are implemented. The monitoring system should be designed to assess intended as well as unintended consequences. Often, a formal policy assessment study is issued in order to explore the consequences of a given set of risk management measures on different dimensions of what humans' value. In addition to generating feedback for the effectiveness of the options taken to reduce and mitigate the risks, the monitoring phase should also provide new information on early warning signals for both new risks and old risks viewed from a new perspective. It is advisable to have the institutions performing the risk and concern assessments also participate in monitoring and supervision so that their analytic skills and experience can be utilised in evaluating the performance of the selected management options.

For nanotechnology, options should be embedded in a set of scenarios. With respect to Frame 1 these scenarios should reflect different societal developments such as demographic changes, age distribution, globalised economies, and trends towards individualisation. With respect to Frame 2, public responses to this new technology could be used as the main structuring principle for designing such scenarios. Those scenarios could be labelled as follows:

- *Fears were groundless* – no significant additional hazard emerges, people start to get used to products based on nanotechnology. Negative health hazards do not show up and the concerns about social and ethical issues lose ground. Public attention moves to other issues. If this scenario materialises, the normal methods of risk management such as risk-benefit balancing will be sufficient.
- *Innocent until proven otherwise* – the only way of testing is to approve release of products then await signal symptoms. This scenario is based on a trial-and-error approach. The main management tool here is monitoring and some containment in order to avoid irreversible damage.
- *Cautious progressing* – effects are highly latent and the problem affects only future generations. Na-

notechnology is applied in many areas without any visible impact on health or the environment, but unintended and unexpected effects show up after a long time period. If this scenario is considered realistic, risk management tools such as containment (limiting application in space and time so that it can be withdrawn once the negative impacts become visible) and strict monitoring are most appropriate.

- *Ends justified by means* – realisable benefits (medical, water filtration, energy conversion, food resources) can outweigh adverse effects. This scenario implies that some applications are regarded as legitimate and others not. This scenario is likely to become realistic if the second discourse on ethical and societal issues becomes a dominant theme in society. Managing agencies are required to distinguish between different applications and conduct an extensive social benefit (or social need) and risk comparison to distinguish between legitimate and illegitimate applications.
- *Too hot to handle* – Insurers introduce exclusions to product liability insurance policies for specific nanotechnology applications. This scenario implies that the uncertainties drive insurance companies to withdraw liability policies from the market. Potential producers will refrain from marketing products with nanotechnology because of fear of liability. Risk management institutions may change the rules of liability and work together with insurance companies to share the financial risks.
- *Better safe than sorry* – sceptics of the technology invoke precautionary principle or other barriers and succeed in imposing a de facto moratorium on all major applications. The result is that the respective industry moves out and only the final products may be imported into the country. This scenario will restrict the action of regulators and promoters of this technology. The only risk management option is to control imported products.
- *No, thanks* – consumers follow lead of anti-technology NGOs and boycott products with nanotechnology. This scenario assumes that some actors in society succeed in convincing consumers to refrain from buying these products. Industry responds with restricted production. Risk management agencies are not successful in assuring the consumer that the regulation offers an adequate level of protection.

There may be other scenarios to consider. The main point here is to acknowledge that the choice of risk management measures depends on the scenarios that are taken into consideration. Prudent risk management should include contingency plans for dealing with a whole variety of scenarios in order to be well prepared for changes in economy, society and politics. Based on the distinction between simple risk, component and system complexity, uncertainty, and ambiguity it is possible to design generic strategies of risk management to be applied to classes of risks, thus simplifying the risk management process as outlined above. Table 2 provides an application of this management tool for nanotechnology that has been described in more detail by IRGC (2005).

Stakeholder Participation

Although there have been various attempts in recent years to engage business and policymakers in anticipatory debates about emerging technologies – for example the Digital Futures project on e-commerce (Wilsdon 2001) – methods for this type of upstream engagement are not well developed. A central aim of applying the IRGC model will be to stimulate participatory innovation in this area, and generate better platforms for stakeholder involvement. How can stakeholder involvement be implemented? It is again helpful to distinguish between simple, complex, high uncertainty and high ambiguity risk problems (Renn 2004b). How to deal with these different risk categories is explained in the last column of Table 2 and more specifically in Figure 10. Stakeholder participation is important for both Frames 1 and 2 and there are four cases in which different forms of stakeholder involvement in nanotechnology governance should be considered:

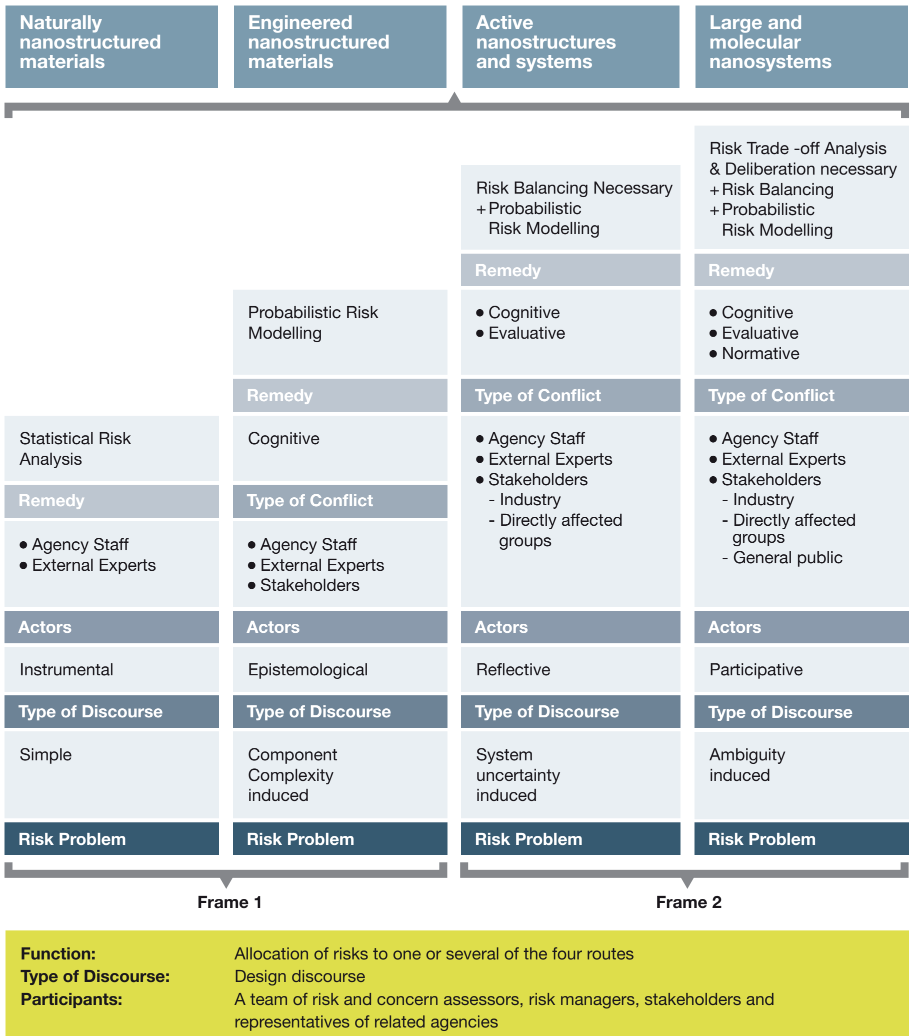
Table 2: Risk Characteristics and their Implications for Risk Management with Reference to Nanotechnology

Knowledge Characterisation	Management Strategy	Appropriate Instruments	Stakeholder Participation
1 'Simple' risk problems ***Frame 1:*** *Naturally nanostructured materials, where chemical composition determines properties*	*Routine-based:* (tolerability/ acceptability judgement)	➔ Applying 'traditional' decision-making • Risk-benefit analysis • Risk-risk trade-offs	Instrumental discourse
	(risk reduction)	• Trial and error • Technical standards • Economic incentives • Education, labelling, information • Voluntary agreements	
2 Component complexity-induced risk problems ***Frame 1:*** *Passive nanostructures with new properties and functions for same chemical composition; 1st generation of nanoproducts*	*Risk-informed:* (risk agent and causal chain)	➔ Characterising the available evidence • Expert consensus seeking tools: o Delphi or consensus conferencing o Meta analysis o Scenario construction, etc. • Results fed into routine operation	Epistemological discourse
	Robustness-focussed: (risk absorbing system)	➔ Improving buffer capacity of risk target through: • Additional safety factors • Redundancy and diversity in designing safety devices • Improving coping capacity • Establishing high reliability organisations	
3 System uncertainty induced risk problems ***Frame 2:*** *Active nanostructures and nanosystems*	*Precaution-based:* (risk agent)	➔ Using hazard characteristics such as persistence, ubiquity etc. as proxies for risk estimates Tools include: • Containment • ALARA (as low as reasonably achievable) and ALARP (as low as reasonably possible) • BACT (best available control technology), etc.	Reflective discourse
	Resilience-focussed: (risk absorbing system)	➔ Improving capability to cope with surprises • Diversity of means to accomplish desired benefits • Avoiding high vulnerability • Allowing for flexible responses • Preparedness for adaptation	
4 Unknown; Higher ambiguity-induced risk problems ***Frame 2:*** *Large nanosystems and molecular nanosystems*	*Discourse-based:*	➔ Application of conflict resolution methods for reaching consensus or tolerance for risk evaluation results and management option selection • Integration of stakeholder involvement in reaching closure • Emphasis on communication and social discourse	Participative discourse

- **Simple risk problems:** For making judgements about simple risk problems a sophisticated approach to involve all potentially affected parties is not necessary. Most actors would not even seek to participate since the expected results are more or less obvious. In terms of cooperative strategies, an instrumental discourse among agency staff, directly affected groups (such as product or activity providers and immediately exposed individuals) as well as enforcement personnel is advisable. One should be aware, however, that risks that appear simple often turn out to be more complex, uncertain or ambiguous than originally assessed. It is therefore essential to revisit these risks regularly and monitor the outcomes carefully.
- **Complex risk problems associated with components:** The proper handling of complexity in risk appraisal and risk management requires transparency over the subjective judgements and the inclusion of knowledge elements that have shaped the parameters on both sides of the cost-benefit equation. In nanotechnology complexity often refers to each component, although the whole system itself may be well defined. Resolving complexity necessitates a discursive procedure during the appraisal phase with a direct link to tolerability and acceptability judgement and risk management. Input for handling complexity could be provided by an epistemological discourse aimed at finding the best estimates for characterising the risks under consideration. This discourse should be inspired by different science camps and the participation of experts and knowledge carriers. They may come from academia, government, industry or civil society but their legitimacy to participate is that they can bring new or additional knowledge to the negotiating table. The goal is to resolve cognitive conflicts. Exercises such as Delphi, Group Delphi and consensus workshops would be most advisable to serve the goals of an epistemological discourse (Webler et al. 1991; Gregory et al. 2001).
- **Risk problems due to high unresolved system uncertainty:** Characterising risks, evaluating risks and designing options for risk reduction pose special challenges in situations of high uncertainty about the risk estimates. How can one judge the severity of a situation when the potential damage and its probability are unknown or highly uncertain? In this dilemma, risk managers are well advised to include the main stakeholders in the evaluation process and ask them to find a consensus on the extra margin of safety in which they would be willing to invest in exchange for avoiding potentially catastrophic consequences. This type of deliberation called reflective discourse relies on a collective deliberation about balancing the possibilities for over- and under-protection. If too much protection is sought, innovations may be prevented or stalled; if society goes for too little protection, it may experience unpleasant surprises. The classic question of how safe is safe enough is replaced by the question of how much uncertainty and ignorance are the main actors willing to accept in exchange for some given benefit? It is recommended that policy makers, representatives of major stakeholder groups, and scientists take part in this type of discourse. The reflective discourse can take different forms: round tables, open space forums, negotiated rule-making exercises, mediation or mixed advisory committees including scientists and other stakeholders (Amy 1983; Perritt 1986; Rowe and Frewer 2000).
- **Risk problems relating to high ambiguity in society due to unknown future developments and differences in value judgements:** If major ambiguities are associated with a risk problem it is insufficient to demonstrate that risk regulators are open to public concerns and to addressing the issues that many people wish them to take care of. In cases of high ambiguity the process of risk evaluation needs to be open to public input and new forms of deliberation. This starts with revisiting the question of proper framing. Is the issue really a risk problem or is it in fact an issue of lifestyle and future vision? The aim is to find consensus on the dimensions of ambiguity that need to be addressed in comparing risks and benefits and balancing the pros and cons. High ambiguities require the most inclusive strategy for participation since not only directly affected groups but also those indirectly affected have something to contribute to this debate. Resolving ambiguities in risk debates requires a participative discourse, a platform where competing arguments, beliefs and values are openly dis-

cussed. A further need is to resolve the classic commoners' dilemma: how to allocate common resources and to activate institutional means for reaching common welfare so that all can reap the collective benefits, rather than the few. The opportunity for resolving these conflicting expectations lies in the process of identifying common values, defining options that allow people to live their own vision of a good life without compromising the vision of others to find equitable and just distribution rules. Available sets of deliberative processes include citizen panels, citizen juries, consensus conferences, ombudspersons, citizen advisory commissions, and similar participatory instruments (Dienel 1989; Fiorino 1990; Durant and Joss 1995; Armour 1995; Applegate 1998).

Figure 10: The Risk Management Escalator and Stakeholder Involvement (from Simple via Complex and Uncertain to Ambiguous Phenomena) with reference to Nanotechnology



Categorising risks according to the quality and nature of available information on risk may, of course, be contested among the stakeholders. Who should decide whether a risk issue can be categorised as simple, complex, uncertain or ambiguous? It is possible that no consensus may be reached. In such cases, a detailed (worst-case) analysis of the possibilities for monitoring and surveillance may constitute the only achievable compromise (reversible removal of risk sources etc., timely detection of adverse effects, and strength of surveillance systems). The best means, however, to deal with this conflict is to provide for stakeholder involvement when allocating the different risks into these four categories. This task can be undertaken as part of the screening phase, the third component of pre-assessment. It seems prudent to have a multi-actor screening board perform this challenging task. This board should consist of members of the risk and concern assessment team, of risk managers and key stakeholders (such as industry, NGOs and representatives of related regulatory or governmental agencies). Allocating risks to the four categories needs to be done before the assessment procedures start. However, over the course of further analysis of risks and concerns the categorisation may change, since new data and information is being collected that may necessitate a re-categorisation of the risk. Yet the risk governance system that is proposed in this document builds upon the need to classify risks at the beginning and allocate them to different routes of appraisal, characterisation, evaluation and management. The type of discourse required for this task is called design discourse. It is aimed at selecting the appropriate risk and concern assessment policy, defining priorities in handling risks, organising the appropriate participation procedures and specifying the conditions under which the further steps of the risk handling process will be conducted. Figure 10 provides an overview of the different requirements for participation and stakeholder involvement for the four classes of risk problems and the design discourse.

Risk Communication

Risk communication is needed throughout the whole risk handling chain, from the framing of the issue to the monitoring of risk management impacts. In the risk governance framework for nanotechnology, risk communication is equally important in all four generations of development and within both Frame 1 and Frame 2. Communication has to be a means to ensure that (Lundgren 1994; OECD 2002):

- those who are central to risk framing, risk and concern assessment or risk management understand what is happening, how they are to be involved and, where appropriate, what their responsibilities are; and
- others outside the immediate risk appraisal or risk management process are informed and engaged.

The first task of risk communication, i.e. facilitating an exchange of information among risk professionals, has often been underestimated in the literature. A close communication link between risk and concern assessors and risk managers, particularly in the phases of pre-assessment and tolerability/acceptability judgement, is crucial for improving overall governance. Similarly, co-operation among natural and social scientists, close teamwork between legal and technical staff and continuous communication between policy makers and scientists are all important prerequisites for enhancing risk management performance. This is particularly important for the initial screening phase where the allocation of risks is performed.

The second task, i.e. communicating risk appropriately to the outside world is also a very challenging endeavour. Many representatives of stakeholder groups and particularly members of the affected and non-affected public are often unfamiliar with the approaches used to assess and manage risks and/or they pursue a specific agenda, trying to achieve extensive consideration of their own viewpoints. They face difficulties when asked to differentiate between the potentially harmful properties of a substance (hazards) and the risk estimates that depend on a combination of the properties of the substance, the exposure to humans, and the scenario of its uses (Morgan et al. 2002).

After diagnosing the needs of the two major audiences the form of communication must be chosen. Basically it consists of four elements:

- *documentation:* this serves transparency. In a democratic society it is absolutely essential that the public(s) not participating in the regulating process learn(s) of the reasons why the regulators opted for one policy and against another. Here it is of secondary importance whether this information can be intuitively grasped or understood by all. This situation is analogous to the information slips packaged with medicaments. Almost no-one is able to understand them, save a few medically trained people. Nevertheless these slips have important messages for the average patient, too. They illustrate that nothing is being withheld here. Considering this, documentation in the field of nanotechnology products marketed to the consumers (such as sunscreens) should more accurately reflect risk in a timely manner and it should show how and why decisions in risk management were made, which arguments were considered and what scientific bases were used. A good medium for this purpose would be the internet.

- *information:* information serves to enlighten the communication partner. Information should be prepared and compiled in such a way that the target group can grasp, realise and comprehend it, and can integrate its message into their everyday life. Here it is important that the concerns of those informed are adequately taken up.
- *two-way communication or dialogue.* This form of communication is aimed at two-way learning. Here the issue is not a one-way street of learning but an exchange of arguments, experiences, impressions and judgements. When someone comes along and says he'll teach you something but doesn't want to learn anything him- or herself, then there won't be a dialogue, but an instruction at best. In such a case no-one will be surprised that the instructed will break off the dialogue as fast as possible. There must be willingness on both sides to listen to and learn from the other.
- *participation in risk analyses and management decisions.* In a pluralistic society people expect to be included adequately, directly or indirectly, in decisions which concern their lives. Not all affected people can participate in risk governance, but it must be ensured that the concerns of the stakeholders will be represented in the decision-making process and that the interests and values of those who will later have to live with the risk effects will be taken up appropriately and integrated into the decision-making process. The previous section on stakeholder participation provided some insights into this aspect of risk communication.

Effective risk communication implements all four forms of communication in parallel. These four forms meet the various needs of diverse publics which cannot be satisfied by one communication instrument alone. The process of risk communication should not aim at convincing the other side that a risk is tolerable or intolerable. Communication in all four aspects has the principal function of enabling concerned citizens to make their own balanced risk-judgement. Based on the knowledge of factually provable consequences of risk-related events or activities as well as of the remaining uncertainties and ambiguities, this means that any person or social group affected by risks should be sufficiently well informed to make a personal judgement of the risks in question, a judgement which meets their own criteria or which is considered ethically imperative for society. Of equal significance to a successful communication is how the assessment of risks by politicians and experts is carried out, and the best form and most suitable structure or type of communication process that is used. Packaging is important, but the best packaging is of no use if the contents do not live up to the wrapping.

In this respect, extensive advice on an effective communication strategy is helpful and useful. In the meantime it is common sense to implement communication early, tailored to the target group, comprehensibly and, above all, emphatically. At all times the main focus should be on the contents of the communication and not on its form. As with all critical technologies, successful communication starts with a scientifically sound, subject-oriented process of risk assessment appropriate to the value concepts of its society. For this reason, special attention must be paid to understandable methods of risk assessment which take full account of the concerns of people. Above all, it is crucial to ensure that the ever necessary inclusion of value judgements is made transparent and is politically and/or ethically legitimised. This is particularly necessary for issues pertaining to Frame 2. Within the framework of communication it is moreover imperative to address directly the three challenges of risk governance, i.e. complexity, uncertainty and ambiguity. They must be central elements of the message, as these are three problematic areas which time and again give rise to irritation, misunderstanding and confusion. Many special manuals for risk communication have been developed which show how these three challenges can be best met (e.g. OECD 2002; Lundgren 1994).

5 RECOMMENDATIONS

General Risk Governance Strategy

There are several general strategies for technological risk governance which should also be respected in the case of nanotechnology. These include the development of an inclusive, globally focused, risk governance framework that addresses both short and long-term applications, the adoption of strategies that ensure the interests of all potentially affected parties are addressed, understood and respected by decision-makers and the assimilation of adopted strategies with other global governance systems. More specifically the adoption of a strategy for the risk governance of nanotechnology requires that decision-makers distinguish between Frame 1 and Frame 2, designing risk management and communication programmes that promise adequate and effective strategies for each frame. The following sections provide initial recommendations for the risk governance of nanotechnology and wherever possible recommendations are identified individually for Frame 1 and Frame 2. Some of the recommendations could also apply to many technologies and should also be taken into account when designing an appropriate and effective risk governance framework for nanotechnology.

Technical and Organisational Recommendations

Key technical and organisational needs for each of Frame 1 and Frame 2 are identified in Table 3:

Table 3: Key Technical and Organisational Needs for the Two Nanotechnology Risk Frames

Risk Frames	Hazard	Exposure	Risk
Frame 1	• Testing strategies for assessing toxicity and eco-toxicity; • Best metrics for assessing particle toxicity and eco-toxicity; • A nomenclature which includes novel attributes, such as surface area; • Pre-market testing, full lifecycle assessment and consideration of secondary risks; • Disposal and dispersion methods for nano-engineered materials; • Development of waste treatment strategies; • Collection of best available data.	• Exposure monitoring methodologies; • Methods for reducing exposure and protective equipment; • Collection of best available data.	• Risk assessment methodologies; • Guidelines and best practices made available internationally; • Evaluation of the probability and severity of risks, including loss of benefits; • Balanced knowledge-based communication and education of EHS and ELSI, including uncertainties and ambiguities; • Collection of best available data.

Risk Frames	Hazard	Exposure	Risk
Frame 2	• Identifying the hazards using scenarios, such as those developed at the Nano Frontiers workshop (2006); • Matrix for assessing the identified hazards.	• Estimation of exposure for events with great uncertainties using methods such as casual chain.	• Identifying, communicating and educating others on EHS, ELSI, Human Development Implications and Political and Security Issues; • Developing capacity to address uncertain/ unknown and ambiguous developments at national and global levels; • Identifying and analysing highly controversial developments.

Institutional Recommendations

Significant transformations are needed to address the institutional gaps which may emerge because of national and international institutional interconnections. The following recommendations apply to both Frame 1 and Frame 2.

- Systematic liaisons between government and industry to share risk information and promote socially responsible outcomes.
- Sufficient resources and capabilities for conducting concern assessments along with risk assessments to identify concerns in a timely and early manner.
- Information for consumers enabling them to make informed choices with respect to the products that they purchase.
- Transparent decision-making processes for nanotechnology R&D and investment, so that stakeholders and the public are aware of how decisions are made and what evidence they are based on.
- All non-proprietary information on test results, impact assessments and their interpretations published transparently on the internet.
- Appropriate communication platforms that help address the purposes for which society and different actors in society want future technologies to be developed. Such discourse activities should be conducted prior to development of the new technologies or their applications.
- National governments and international communities need to get involved in common scenario development exercises for future applications of nanotechnology, particularly referring to third and fourth generation products and processes. These scenarios could act as catalysts for public debate and consensus seeking exercises.
- National governments and international communities need to organise systematic feedback from their various constituencies, including samples of the general public. Such feedback rounds could provide valuable information about the concerns, hopes, worries, visions and preferences of the various actor groups and the public at large. Among the many instruments to perform such feedback rounds are Stakeholder Dialogues, Round Tables, and Citizen Juries (OECD 2002).
- International activities should be undertaken to establish common rules and standards for potentially high-impact, long-term projects for nanotechnology. Incentives should be provided for promoting

and sustaining international cooperation. This cooperation can also act as a driver for all participating countries to honour and enforce the common standards.

- The system whereby companies and individuals can stockpile intellectual property rights for basic natural processes and structures should be critically examined.
- Establishment of a process of periodic review of national and international institutional frameworks in order to address continuing changing nanotechnology applications; this recommendation is particularly important for Frame 2.

Risk Communication Recommendations

In order to design an effective risk communication programme it is essential to take into account the two frames of nanotechnology (for the first and second-fourth generations of nanotechnology products, respectively, as defined before) and, for each frame, to consider the differences between the risks associated with (a) human health and biosystems on one side, and (b) physical infrastructure (surrounding of the biological systems) on the other side. Risk communication should avoid the strategic mistake of grouping all applications of nanoscale technologies under the single descriptor "nanotechnology" because this would blur the distinction between the two frames and their subcategories and risks discrediting the whole of nanotechnology development if there is a singular incident or some other problems related to a specific application. The second major point is to have separate risk communication programmes for each of the two frames.

- The first communication strategy (for both frames 1 and 2) should be designed to enlighten the discussion about the benefits and non-intended side effects and the means to identify and quantify those effects. Communication tools here refer to internet-based documentation of scientific research, product labelling, press releases, consumer hot lines and similar activities.
- The second strategy (particularly for frame 2) should be directed towards a broader debate on the desirability of special applications of nanotechnology in the light of ethical and social issues. The main message here could be that it is not nanotechnology that creates the problem but, rather, the use of this technology in a controversial application. It is certainly legitimate to reject special applications (such as using neurochips in the human brain for control of its functions without a medical justification) without having to oppose the technology that makes such an application technically feasible.
- A third major strategy in risk communication is to provide public information on the principles and procedures used to test nanotechnology products, to assess potential health or ecological impacts and to monitor the effects, as well as to inform the public on investment policies in research, development and production. If people have the reassurance that public authorities take special care and attention to protect the population against unintended consequences of this new technology, they may be willing to invest some more trust than today in the capacity of society to control the risks and be aware of and responsive to remaining uncertainties. It should be emphasised, however, that communication cannot produce trust; trust evolves as a by-product of public satisfaction with the perceived performance of risk handling institutions (Webler et al. 1991). This is true for both the public and the private sector. There is special need for an international approach in which risk information is given by large transnational companies. Experiences of these companies with international and transboundary governance provisions should be shared without the need to disclose competitive information (see also recommendations to stakeholders).

It is notable that public engagement does not necessarily solve the problem; it does, however, enlighten the public debate and provide incentives for mutual learning and for gaining and sustaining trust. It also helps individuals to be more attentive to both benefits and risks. Scientists have a special role in risk communication. They are the key witnesses in all research questions and represent the state of the art in knowledge and system understanding. In spite of the loss of credibility for all major institutions over the last decades (including government, industry, science, and others), scientists are still the group with the highest credibility in most countries. They incorporate authenticity and to a large degree economic disinterestedness. They are, however, often poor communicators in public arenas. Risk communication training courses and exercises for scientists are therefore essential elements of an effective risk communication initiative. In addition, regulators, industrial developers, representatives of NGOs and other interested parties should be integrated in risk communication programmes, particularly those directed to the general public. The inclusion of media stakeholders in risk communication efforts may help to accelerate the public engagement efforts.

Recommendations to deal with Trans-Boundary Issues

In an interdependent world, the risks faced by any individual, company, region or country depend not only on their own choices but also on those of others. Nor do these entities face one risk at a time: they need to find strategies to deal with a series of interrelated risks that are often ill-defined or outside their control. In the context of nanotechnology, the risks faced in one country, for instance, may be affected by risk management failures in another country. For example, if due to lax risk regulation a major incident occurs in one country involving nanoparticles, this will have repercussions on the debate on nanotechnology in many other countries. In particular, in connection with the second frame, evidence that control mechanisms do not work in one place may fuel a fierce debate in other parts of the world about the acceptability of this technology in general. At the same time, poor enforcement of regulations in one country will not remain undetected if a working and effective international cooperation exists. Under this condition, there is a clear incentive for all countries to assure compliance.

The more interdependencies that exist within a particular setting (be this a set of organisational units, companies, a geographical area or a number of countries etc.) and the more that this setting's entities – or participants – decide not to invest in risk reduction, while being able to influence other entities, the less incentive each potentially affected participant will have to invest in protection. At the same time, however, each participant would have been better off had all the other participants invested in risk-reducing measures. In other words, weak links may lead to suboptimal behaviour by everyone. This is particularly a problem for countries with a record of effective and precautious regulatory actions since this positive record can become worthless if a major incident occurs in another country due to failure of regulatory oversight. Creating incentives for all countries to participate in risk governance is a key issue. This may be done by using cost benefit studies (to show that it is in their own interest), using better methods of communication, and designing insurance policies which take this into account.

- One issue is how to create incentives for all countries to participate in risk governance. Possible agents of change include policies by insurance companies, certification programmes, education programmes, R&D programmes, responses to disruptive technological and economical developments, and completing international studies on cost and benefit/risk analysis.
- The role of international organisations dealing with technical, economical and policy issues (OECD, UNIDO, ISO, ASTM and others), international industry and academic organisations (SRC International; International Electronics Manufacturing Initiative, ICON and others), and NGOs (ex: ETC Group, Greenpeace, Woodrow Wilson Center and others) needs to be further explored.
- For situations in which some participants are reluctant to adopt protective measures to reduce the chances of negative incidents, a solution might be found in a public-private partnership. This is particularly true if the risks to be dealt with are associated with competing interpretations (ambiguities)

about their acceptability as well as with conflicts about the rigour necessary to monitor and regulate side effects. Both conditions seem to apply to nanotechnology. Several countries see nanotechnology as an opportunity to gain a competitive advantage by developing the technologies and associated products faster than competing nations. This is certainly a major reason for proposing international regulation and common strategies for risk management.

- A way to structure a private-public partnership is to have government standards and regulations coupled with third party inspections and insurance to enforce these measures. Such a management-based regulatory strategy will encourage the addressees of the regulation, often the corporate sector, to reduce their risks from e.g. accidents and disasters. It also shifts the locus of decision-making from the government regulatory authority to private companies which are, as a result, required to do their own planning as to how they will meet a set of standards or regulations (Coglianese and Lazer 2003). This, in turn, can enable companies to choose those means and measures which are most fit for purpose within their specific environment and, eventually, may lead to a superior allocation of resources compared to more top-down forms of regulation. The combination of third party inspections in conjunction with private insurance is consequently a powerful combination of public oversight and market mechanisms that can convince many companies of the advantages of implementing the necessary measures to ensure product and workplace safety.
- It is critical that international standards and best practices be communicated globally. This will require special efforts by institutions to penetrate developing and developed countries in a reasonable time frame to help stakeholders understand the importance of regulatory actions and public-private cooperation to ensure that the opportunities are sought and the risks are either avoided or at least reduced. Mechanisms need to be established to maintain and communicate best practices, standards, and knowledge and to communicate these to governments, industry, entrepreneurs, and universities as quickly as possible.

Recommendations to Various Stakeholders

These general recommendations need to be implemented by social actors. The days are gone when regulatory actions were the sole responsibility of governments. The complexity of the subject, the different types of agency among and between the different actors, the scope of responsibilities and accountability, the trans-boundary nature of benefits and risks as well as the delicate balances of power and interests make it inevitable that governmental, economic, scientific and civil actors cooperate for the purpose of better regulation of nanotechnology. Many of the recommendations and suggestions developed above are directed towards governments, but national governments are often unable to operate effectively on the global level. They need the cooperation of industry and civil society actors who increasingly organise themselves on the global level.

The private sector is a major player in the development and diffusion of nanotechnology. It is in the best interest of private investors to assure that minimum standards for safety and health protection are established and enforced internationally and that potential risks are investigated and assessed before actual damage occurs. The international business community is well aware that the development of nanotechnology applications depends heavily on public confidence in the ability of industry and government to control risks and on the flexibility and creativity of the business sector to deal with new information and research results about potential impacts, be they positive or negative.

Due to the lack of global governance structures in dealing with nanotechnology regulation, one of the most promising routes for private actors is the establishment of voluntary codes or rules for assuring safety and risk control. One major incident in a remote country can trigger international reactions that might go far beyond the actual case. It is therefore important for internationally operating companies to make sure that, if actual practices may be formed according to local or regional traditions, all their facilities follow identical EHS-standards and requirements. Beyond the harmonisation of standards in multinational companies, voluntary agreements and codes for the entire industry may also help to reduce risks and sustain public trust and confidence. One possibility to consider is the establishment of a certification system that would force all companies to adhere to specific rules when applying for this certificate. Such a system could be modelled according to the Forest Stewardship Council or similar organisational settings. Another possibility may be the establishment and enforcement of international standards (for example ISO-standards) that require companies to follow predefined rules for safety and protection of public health. Demonstrating that private industry has done what it can to protect the public and the environment is the best guarantee that the benefits of this technology will unfold and thus improve living standards as well as public confidence.

Voluntary agreements, certificates or international standards are suitable instruments for dealing with potential risks of nanotechnology applications in the short term, until formal norms can be established. The second frame includes concerns about social disturbance and threats to human identity and cultural values. The ambiguity associated with these endpoints of risks demands a more discursive and participatory approach and private industry should be willing and prepared to engage in such a dialogue programme. For example public statements about the ethical implications of one's own research could include the promise not to engage in certain ethically problematic areas of application (even if they are legal). Another possibility is to initiate public forums or Round Tables amongst major stakeholders and concerned groups with the objectives of exploring potential social risks and designing barriers to prevent them from occurring. If industry can convey the message that it takes these concerns seriously, and is willing to shape and reshape its own policies in accordance with reasonable demands of precaution against such social risks, the struggle for more trust and confidence can lead to success. Both voluntary agreements and new forms of dialogue and public consultation are also attractive to non-governmental organisations as it is in their interest to make sure that environmental quality and public health are assured through the appropriate means. Often, NGOs also pursue secondary goals such as equity, social justice and assistance to the poor and these concerns can be integrated into the policies of voluntary agreements and public forums. The constructive processing of conflicts in suitable arenas is probably the most effective way to control the risks while still enjoying the benefits.

Table 4 lists more specific recommendations for the main societal actors in regulating nanotechnology. The list includes suggestions for private industry, academia, governments, civil society actors and international organisations. Risk managers and regulators should selectively focus on those aspects of the conceptual framework for risk governance of nanotechnology presented in this paper that are essential for the nanotechnology application(s) for which they have an interest or responsibility.

The Role of the IRGC

This paper has aimed to develop a conceptual framework for the global governance of risks associated with those technical areas and applications of nanotechnology for which there is an apparent need for improved approaches to risk and safety issues.

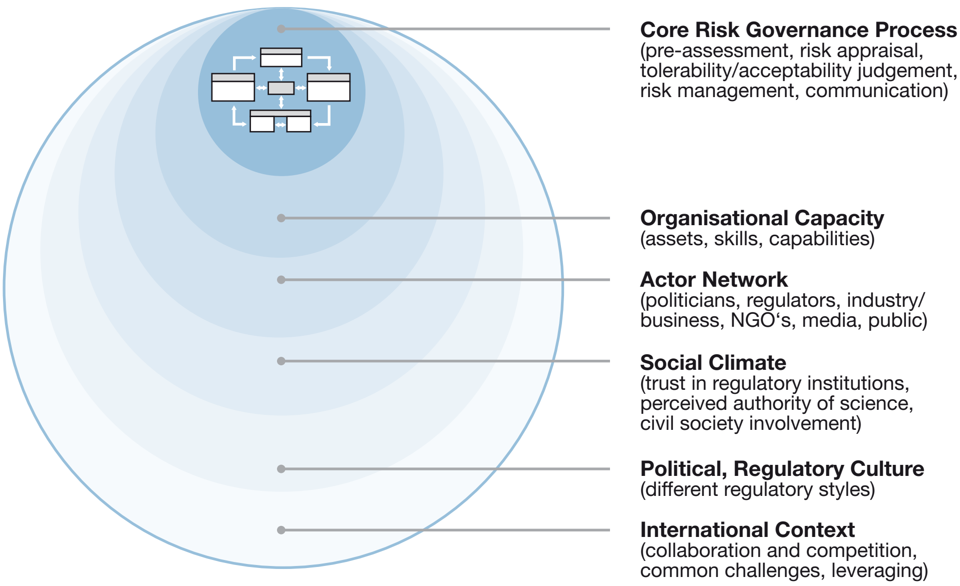
Nanotechnology is an important issue for the IRGC as it touches its main mission and relates to all the major elements of the IRGC risk governance model (IRGC 2005) (see Figures 4 and 11). Given the dominance of the two frames of the nanotechnology debate (for the first and second-fourth generations of nanotechnology products, respectively), there is a real danger that the response of national and international risk management agencies will not be adequate to address all the problems and challenges in both frames at the national and global levels, leading to a possible loss of trust and of perceived

Table 4: Potential Roles for All Actors Involved

Stakeholder	Recommendations
Academia	• Conduct research for physico-chemical knowledge, EHS, ELSI, and on new methods for risk analysis and management specific for individual nanotechnology applications. • Educate a new generation of nanotechnologists sensitive and knowledgeable about risk governance, in the context of converging technologies (nano, bio, info, cognitive) and international relations. • Conduct public outreach and engagement; participate in public debates on nanotechnology and its benefits and risks. • Engage impartially in risk related issues, without bias towards industry interests or pressure group values.
Industry	• Adopt self-regulations that can be implemented faster (in few years) than regulations (generally requiring about 10 years from genesis to application). A focus should be on best practices for risk governance. • Public disclosure of testing and possible risks of nanomaterials. • Assess potential implications and scenarios of nanotechnology development for potential response in the preparation of the workforce, investment needs, and measures for disposal of used products. Earlier in technology development, one should evaluate the risk to researchers, other workers, and waste handlers. • Develop mechanisms to exchange information with other industries, academia, public, and government.
Government	• Support R&D for EHS, education, ELSI, HDI and PSI and integrate the results into the planning of large R&D projects and planning for nanotechnology investments. • Prepare and implement a new risk governance approach based on adaptive corrections at the societal system level. In the short-term and when suitable, adapt existing legislation to nanotechnology development. • Build capacity to address accidents and other unexpected situations. • Provide incentives to reduce risks; for example, developing nanotechnology applications which replace polluting materials with green substitutes. • Prepare long-term plans and scenarios of nanotechnology development, and develop anticipatory measures in risk governance on this basis. Evaluate the relationship between regulations and innovation. • Support studies on the implications of nanotechnology on existing national legislation, professional codes, nomenclature and standards, human rights and international agreements. Support the use of metrology in risk governance decisions. • Address equal access to nanotechnology benefits and equity issues in society. • Prepare longitudinal surveys (of six to twenty four months) on public perception. • Develop a communication strategy to keep industry, end-users and civil organisations informed about representative developments and EHS aspects of the new technology. Consider establishing a clearing-house information role for government organisations. • Adopt transparent oversight processes with public input. • Encourage international collaborations in risk governance.
User, public, NGOs and civil organisations	• Serve a watchdog function for the impacts and effects of nanotechnology applications over research laboratories, industry production, consumer preferences, transportation, and environment. • Create user organisations to clearly articulate the needs of users and those potentially at risk with respect to applications, uncertainties and the implications of nanotechnology in both the short- and long-term. • Develop continuous channels of communications with industry, academia, and government • Facilitate public participation in addressing social impacts and ethical considerations.
International organisations	• Promote communication between government, business and non-government organisations in various countries • Encourage and support coherent policies and regulatory frameworks for nanotechnology. • Establish shared data bases for EHS/Education/ELSI results and develop programmes for periodical exchanges of information. • Support studies on macroeconomic trends, trade implications and avoiding possible international disruptions, particularly for developing countries that do not have the capacity to fully protect their interests. • Coordinate intellectual property issues for nanotechnology. • Establish certification programmes for risk governance in an organisation. • Connect risk management practices to international practices and standards (ISO).

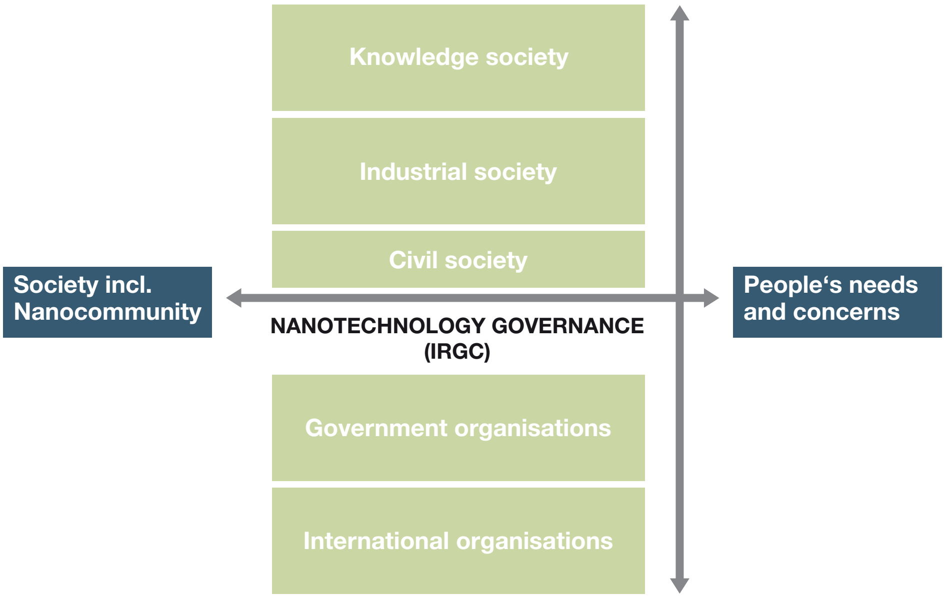
competence. It is important that risk management agencies are prepared to consider all the stages of the risk governance process and develop tools that address the challenges at each step in the process. This implies that sufficient resources are invested in risk governance and that the persons dealing with this issue are adequately trained and prepared for improving their performance. Beyond the national governments, IRGC is convinced that cooperation between governmental agencies, the private sector, civil society actors and science communities is crucial for a governance structure that is effective, efficient and fair. Cooperation can inspire processes which aim at developing internationally agreed standards and rules and promoting dialogue on the many still intangible implications of the second to fourth application of nanotechnology.

Figure 11: Risk Governance Overview (the IRGC core risk governance process is detailed in Figure 4)



International organisations could usefully facilitate such processes. Some can provide models, assistance and expertise in doing risk assessment and concern assessment. Others can provide checklists for an effective and efficient risk management plan and help to detect weak links in the system. IRGC itself could assist in developing frameworks for research plans or regulations or applying analytical techniques, and help to facilitate the necessary involvement and communication process. IRGC can also help in initiating and promoting international strategies and making suggestions for effective public-private partnerships. IRGC is, therefore, willing to continue to play an active role in the process of developing an effective, international risk governance strategy for nanotechnology.

Figure 12: Addressing People's Needs and Concerns through the Stakeholder Perspective: Knowledge, Industry, Civil Society, Government and Global. The Role of IRGC is noted in both Nanotechnology Governance and providing a bridge for Stakeholders.



The risk deficits identified and recommendations contained within this white paper will contribute towards developing models for risk governance policies for Frame 1 and Frame 2. These globally situated models should deal with disagreements and respond to changes in time and overall international interactions. In July 2006 IRGC will promote this process by organising an international conference at which key stakeholders will be able to debate the key needs for nanotechnology risk governance and influence the development and publication of globally distributed recommendations. Activities for increasing public awareness of nanotechnology and participation in making investment decisions will also be evaluated in this context as a method for reducing risk. With the publication of this white paper on nanotechnology risk governance and the results of surveys undertaken in 2005 of key stakeholders, IRGC has already made a significant contribution to nanotechnology risk communication (see schematic in Figure 11). The reports will be disseminated to key potential users and posted on the IRGC website. IRGC will also continue to provide a platform for different actors in this debate to exchange ideas, concerns, and insights, with the goal being to reach consensus on appropriate regulatory actions.

A Potential Future Role for International Bodies

Stakeholders can contribute to framing the issues related to the risks of nanotechnology by adopting a proactive approach. For example, it is more productive to focus on how one can engineer safe nanostructures and nanosystems rather than to merely observe that some nanostructures are not safe. In another example, collaboration should take place among various specialised organisations (such as the International Dialogue (2004) and the National Institute for Occupational Science and Health (US)) to create and maintain databases for knowledge on toxicity for nanomaterials, regulations, R&D needs and investment needs.

National or international exercises for constructing scenarios that appear relevant to the context of the diffusion of nanotechnology and the likely social reactions to it should also take place. The scenarios suggested in this report may serve as default options for designing more specific scenarios that relate to the specific situation and the contextual conditions of the countries selected for the analysis.

Academic researchers, developers, potential users and other important actors should be actively involved in this scenario building exercise in order to ensure the inclusion of an adequate representation of societal forces that ultimately shape the future of nanotechnology.

Last, but not least, a targeted and effective communication programme is necessary which should include suggestions for a special educational initiative in the context of the worldwide activities to enhance public understanding of sciences and humanities. One could imagine that an international expert organisation may help agencies, NGOs or companies to design specific communication and educational material such as internet presentations, brochures, press releases, consumer product labels and others. One should be aware, however, that those means only affect the first frame of the debate. For meeting the challenges of the second frame, other communication means are needed such as, for example, an open forum on the use and abuse of nanotechnology for medical, military or other controversial purposes. In addition, citizen panels or joint action committees (including consumer associations, unions, employers, etc,) could be convened to draft recommendations for regulatory provisions that would inhibit the potential misuse of nanotechnology. All these activities would be able to preserve or even restore trust in the risk managing agencies.

This paper presents for the first time a conceptual framework for nanotechnology risk governance at an international level for short and long term issues which are upstream of specific implementation policies. By considering the particularities of nanotechnology as an emerging technology, the proposed conceptual framework and guidelines on risk governance provide a step forward in assisting risk management agencies as well as private companies to integrate scientific assessments and concern assessments into one appraisal process and to select the appropriate risk management and stakeholder involvement strategies.

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  The Australian Research Council Nanotechnology Network, http://www.ausnano.net
- Japan
  National Institute of Advanced Industrial Science and Technology, http://www.aist.go.jp
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- Chinese Taipei
  National Science and Technology Program for Nanoscience and Nanotechnology, http://nano-taiwan.sinica.edu.tw/newsen.asp
- India
  Department of Science and Technology, http://www.dst.gov.in
- Israel National Nanotechnology initiative, events@nanoisrael.org
- Malaysia
  Department of Chemistry, Faculty of Science, Universiti Teknologi Malaysia, http://www.kimia.fs.utm.my
- People's Republic of China
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- German Federal Ministry of Research and Education (BMBF), http://www.bio-pro.de/en/life/meldungen/01920/index.html
- German Federal Institute for Risk Assessment, http://www.bfr.bund.de/cd/template/index_en
- Impart-Nanotox (EU funded projects), http://www.impart-nanotox.org/
- NanoJury website, http://www.nanojury.org/
- Nanologue (EU funded dialogue on the benefits, risks and social, ethical and legal implications), http://www.nanologue.net/
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- American National Standards Institute (ANSI), http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3
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- Environmental Protection Agency (EPA), http://es.epa.gov/ncer/nano/
- Food and Drug Administration, http://www.fda.gov/nanotechnology/
- NCI Nanotechnology Characterization Laboratory, http://nano.cancer.gov/about_alliance/nanotech_characterization_lab.asp
- National Science Foundation (NSF), http://www.nsf.gov/nano/; http://www.nsf.gov/crssprgm/nano/activities/nni01_03_env.jsp and http://www.nsf.gov/crssprgm/nano/7a_fy2005_env_nsfweb_06_0223.xls
- National Toxicology Program, 2000-NTP, http://ntp-server.niehs.nih.gov/index.cfm
- Nanoscale Informal Science Education Network (NISE), award by National Science Foundation, http://www.exploratorium.edu/nise

International Organisations (2006)

- Asia-Pacific Economic Cooperation (APEC), http://www.apecsec.org.sg/apec/apec_groups/working_groups/industrial_science_and_technology.html
- International Organization for Standardization (ISO), http://www.iso.ch/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932
- Organisation for Economic Co-operation and Development (OECD), http://www.oecd.org/department/0,2688,en_2649_34365_1_1_1_1_1,00.html
- United Nations Industrial Development Organisation (UNIDO) – International Centre for Science and Technology (ICST), http://www.ics.trieste.it/ActivityDetails.aspx?activity_id=387

Non-governmental organisations (2006)

- Center for Responsible Nanotechnology, http://www.crnano.org/
- Demos, http://www.demos.co.uk/
- Environmental Defense, http://www.environmentaldefense.org/home.cfm
- ETC Group, http://www.etcgroup.org/search.asp?theme=11
- Foresight Nanotech Institute
  http://www.foresight.org/
- Greenpeace Environmental Trust, http://www.greenpeace.org.uk/contentlookup.cfm?ucidparam=20031003120335&MenuPoint=A-L&CFID=3301994&CFTOKEN=42654233
- International Council on Nanotechnology (ICON), http://icon.rice.edu/
- Meridian Institute, http://www.nanoandthepoor.org and http://www.merid.org
- Woodrow Wilson Center, Project on Emerging Nanotechnologies, http://www.wilsoncenter.org/nano

7 GLOSSARY OF TERMS USED IN THIS WHITE PAPER

Acceptability: Risks are deemed to be acceptable if they are insignificant and adequately controlled. There is no pressure to reduce acceptable risks further, unless cost effective measures become available. In many ways, acceptable risks are equivalent to those everyday risks which people accept in their lives and take little action to avoid. (See also 'Intolerable Risks' and 'Tolerability'.)

Actuator: A piece of apparatus that produces movement when given a signal.

Agent: In the context of risk a substance, energy, human activity or psychological belief that can cause harm.

ALARA: As Low As Reasonably Achievable.

ALARP: As Low As Reasonably Practicable. (Note: There is little or no difference in practice between ALARA and ALARP. 'Reasonably practicable' is defined in some countries through case law which says that a reduction in risk is 'reasonably practicable' unless the improvement achieved is grossly disproportionate to the cost of achieving that improvement.)

Alveolar macrophage: A cell situated in air sacs in the lung the purpose of which is to remove waste products, harmful micro-organisms and foreign material.

Ambiguity: Giving rise to several meaningful and legitimate interpretations of accepted risk assessments results. See also 'Interpretative Ambiguity' and 'Normative Ambiguity'. ('Ambiguity' is one of three major challenges confronting risk assessment; the others are 'complexity' and 'uncertainty'.)

Atherosclerotic plaque progression: Accumulation of cholesterol deposits on the inner walls of the arteries.

Bio-accumulation: The transfer of pollutants from the environment to the food chain leading to an increase in the concentration of chemicals in a biological organism over time.

Bio-active: The stimulation and activation of the human body's natural healing abilities at the cellular level.

Blood viscosity: A tendency for blood to be 'sticky' with a low rate of flow leading to poor blood circulation. High blood viscosity can damage the walls of blood vessels and lead to the build up of plague.

Brain-machine interface: A direct communication between the brain and a computer. Neural signals are intercepted and read by a mechanical device in the brain allowing the direct control of an electronic device via thought.

Buckyballs: Known formally as a buckminsterfullerene a buckyball is a novel form of carbon molecule arrangement made up of 60 carbon atoms in the shape of a closed cage sphere. Important properties include rotational symmetry and strength.

Buffer Capacity: Capacity of a system to withstand a risk event (e.g. the failure of a component) through the incorporation of additional protective measures.

Carbon-nanotubes: Graphite layers seamlessly rolled to form nanoscale-sized cylinders. Important properties include strength, elasticity and thermal conductivity.

Cardiac ischaemia: Insufficient blood supply (and therefore, oxygen) to the heart. This condition is normally due to narrowed or blocked coronary arteries.

Catalytic effect: Use of a catalyst to increase the rate of a chemical reaction.

Cognitive processes: Physical, chemical and biological processes at the level of the neuron.

Complexity: Complexity refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects. ('Complexity' is one of three major challenges confronting risk assessment; the others are 'uncertainty' and 'ambiguity'.)

Complex systems: Systems that display adaptive and self-organising behaviour.

Confinement effects: Properties caused by the geometric confinement of a substance in contrast to those apparent in the bulk state.

Converging technologies: The convergence of nanotechnology, biotechnology, information technology and cognitive sciences to produce entirely new materials, devices and systems.

Coping Capacity: Building into systems, society, organisations or individuals measures to reduce the impact of a risk if it is realised. For example, measures to improve the ability of a building to resist earthquakes. (See also 'Resilience'.)

Cytotoxicity: the quality a substance holds which makes it toxic to cells.

Design discourse: A form of deliberation for defining and specifying the most appropriate route for assessment and management of a given risk.

Dose-Response Function: The relationship between the amount of exposure (dose) to a substance (or other hazard) and the resulting changes in health or body function. (Note: Usually applied to human beings but can be applied more widely in the environment.)

Early warning: Institutional arrangement for (systematically) looking for indicators of potentially damaging events or their precursors.

Ecotoxicity: The study of how chemicals impact on the environment and the biological organisms living in it.

Emerging behaviour robotics: The ability of robots to truly mimic biological behaviour.

Epistemological: Concerning the nature, origin and scope of knowledge. So an 'epistemological discourse' is about the scope and the quality (validity, reliability and relevance) of the information available and is aimed at finding the best estimates for characterising the risk.

Epithelia hyperplasia: A growth in tissue in the human body.

Exposure: Contact of a risk target (humans, ecosystems) with a hazard.

Fibrosis: Development of excess fibrous connective tissue in an organ or tissue as a reparative or reactive process.

Flexibility: One of the skills essential to tackling modern risk situations. The ability to look for new ways to make sense of a dynamic situation, if necessary to fight against traditional practices and institutional inertia, and to find novel solutions.

Framing: The initial analysis of a risk problem looking at what the major actors, e.g. governments, companies, the scientific community and the general public, select as risks and what types of problems they label as risk problems. This defines the scope of subsequent work.

Governance: At the national level, the structure and processes for collective decision making involving governmental and non-governmental actors (Nye and Donahue 2000). At the global level, governance embodies a horizontally organised structure of functional self-regulation encompassing state and non-state actors bringing about collectively binding decision without superior authority (c.f. Rosenau 1992; Wolf 1999).

Hazard: A source of potential harm or a situation with the potential to causes loss. (Australian/New Zealand risk management standard).

Heuristics: A technique of directing attention towards discoveries.

Hypertrophy: Increase in the size of an organ.

Instrumental [discourse]: Used in the case of 'simple risks'. It is aimed at finding the most cost-effective measures to make the risk acceptable or at least tolerable.

Intolerable Risks (alternatively 'Unacceptable Risks'): A risk that society deems to be unacceptable, no matter what benefits arise from the activity giving rise to the risk.

Justification: The case for undertaking an activity that carries an element of risk. In effect, some kind of risk/benefit analysis which demonstrates the case for the activity.

Lipid peroxidation: The oxidative degradation of lipids.

Metrology: The science of measurement.

Molecular recognition: Interactions between two molecules allowing them to form a complex bond.

Neuromorphic engineering: The creation of artificial neural systems whose design is based on that of the biological system.

Participative [decision making/discourse]: Open to public input; possibly including new forms of deliberation. Examples of participative discourse include citizens' juries, consensus conferences etc.

Reflective [discourse]: Collective reflection on the course of action to take, e.g. balancing possibilities of over- and under-protection in the case of large remaining uncertainties about probabilities and/or magnitude of damage(s). Examples of reflective discourse include round tables, open space forums and negotiated rule making.

Resilience: A protective strategy to build in defences to the whole system against the impact of the realisation of an unknown or highly uncertain risk. Instruments for resilience include strengthening the immune system, designing systems with flexible response options, improving emergency management etc.

Risk: An uncertain consequence of an event or an activity with respect to something that humans value (definition originally in: Kates et al. 1985: 21). Such consequences can be positive or negative, depending on the values that people associate with them.

Risk Analysis: Some organizations, e.g. Codex Alimentarius, use risk analysis as a collective term which covers risk assessment, risk management and risk communication.

Risk Appraisal: The process of bringing together all knowledge elements necessary for risk characterisation, evaluation and management. This includes not just the results of (scientific) risk assessment but also information about risk perceptions and economic and social implications of the risk consequences.

Risk Assessment: The task of identifying and exploring, preferably in quantified terms, the types, intensities and likelihood of the (normally undesired) consequences related to a risk. Risk assessment comprises hazard identification and estimation, exposure and vulnerability assessment and risk estimation.

Risk Characterisation: The process of determining the evidence based elements necessary for making judgements on the tolerability or acceptability of a risk. (See also 'Risk Evaluation'.)

Risk Estimation: The third component of risk assessment, following hazard identification and estimation, and exposure/vulnerability assessment. This can be quantitative (e.g. a probability distribution of adverse effects) or qualitative (e.g. a scenario construction).

Risk Evaluation: The process of determining the value-based components of making a judgement on risk. This includes risk-benefit balancing or incorporation of quality of life implications and may also involve looking at such issues as the potential for social mobilisation or at pre-risk issues such as choice of technology and the social need of the particular operation giving rise to the risk. (See 'Justification'.)

Risk Governance: Includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Encompassing the combined risk-relevant decisions and actions of both governmental and private actors, risk governance is of particular importance in, but not restricted to, situations where there is no single authority to take a binding risk management decision but where instead the nature of the risk requires the collaboration and co-ordination between a range of different stakeholders. Risk governance however not only includes a multifaceted, multi-actor risk process but also calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and co-ordination mechanisms such as markets, incentives or self-imposed norms) and political culture including different perceptions of risk.

Risk Management: The creation and evaluation of options for initiating or changing human activities or (natural and artificial) structures with the objective of increasing the net benefit to human society and preventing harm to humans and what they value; and the implementation of chosen options and the monitoring of their effectiveness.

Risk Perception: The outcome of the processing, assimilation and evaluation of personal experiences or information about risk by individuals or groups in society.

Risk Prevention: Measures to stop a risk being realised. This often means stopping the activity giving rise to the risk. But this, because of the need for substitution, can often give rise to other risks in the substituted activity.

Risk Reduction: Measures to reduce the level of risk, for example by reducing the likelihood of the risk being realised or reducing the impact of the risk.

Risk Trade-Offs (or Risk-Risk Trade-Offs): The phenomenon that interventions to reduce one risk can increase other risks, or shift risk to a new population.

Risk Transfer: Passing on some or all of the consequences of a risk to a third party. In some cases, this may be part of legitimate risk management e.g. to an insurance company; in other cases, for example, where those benefiting from the risk generating activity are not those who suffer from the risk (e.g. those suffering pollution down stream from a chemical plant), risk governance needs to ensure that such transfers are dealt with fully and equitably.

Robustness: This concerns primarily the insensitivity (or resistance) of parts of systems to small changes within well defined ranges of the risk consequences (contrast with ‘resilience‘ which more concerns whole systems).

Social Amplification of Risk: An overestimation or underestimation of the seriousness of a risk caused by public concern about the risk or an activity contributing to the risk.

Social Mobilisation: Social opposition or protest that feeds into collective actions (such as voting behaviour, demonstration or other forms of public protest).

Stakeholder: Socially organised groups that are or will be affected by the outcome of the event or the activity from which the risk originates and/or by the risk management options taken to counter the risk.

Tolerability: An activity that is seen as worth pursuing (for the benefit it carries) yet requires additional efforts for risk reduction within reasonable limits. (See also ’Acceptability’ and ’Intolerable Risks’/ ’Unacceptable Risks’.)

Toxic response: The type of adverse effect e.g. cancer, inflammation, irritation, neurotoxicity.

Toxicology: The science of poisons or the study of chemical or physical agents that produce adverse (harmful) effects in biological systems.

Toxin: Something that causes an adverse or toxic effect.

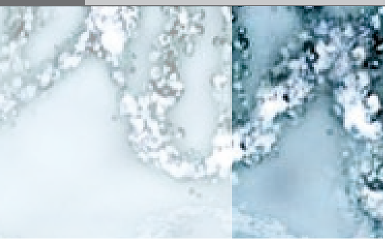
Ubiquity: In the context of risk, one for which the impact of the risk being realised is widespread, usually geographically.

Unacceptable Risks: See ’Intolerable Risks’.

Uncertainty: A state of knowledge in which, although the factors influencing the issues are identified, the likelihood of any adverse effect or the effects themselves cannot be precisely described. (Note: this is different from ignorance about the effects or their likelihood. ‘Uncertainty’ is one of three major challenges confronting risk assessment; the others are ‘complexity’ and ‘ambiguity’.)

Vertical Governance: This concerns the links between the various segments which may have an interest in an issue, e.g. between local, regional and state levels (whereas ‘horizontal governance’ concerns the links within those segments).

Vulnerability: The extent to which the target can experience harm or damage as a result of the exposure (for example: immune system of target population, vulnerable groups, structural deficiencies in buildings, etc.).



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ANNEXES

INTRODUCTION TO THE ANNEXES

The annexes comprise of summaries of surveys conducted between August and November 2005. These surveys, on the role of government (Volume A), industry (Volume B), risk research organisations (Volume C) and NGOs (Volume D) in nanotechnology risk governance, were undertaken by IRGC as part of the preparatory work for their project Nanotechnology Risk Governance ("Addressing the need for adequate risk governance approaches at the national and international levels in the development of nanotechnology and nanoscale products"). The survey summaries included in this white paper contain an overview of current governance strategies in nanotechnology and recommendations for appropriate risk governance structures and processes from the perspective of the survey respondents.

Findings from these surveys, together with the outcomes of two expert workshops held in May 2005 and January 2006, have been used to develop the high-level risk governance recommendations identified in this white paper on 'Nanotechnology Risk Governance'. The complete survey reports, including full responses, have been published as separate volumes on the IRGC website http://www.irgc.org/irgc/projects/nanotechnology/.

ANNEX A – SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME A. THE ROLE OF GOVERNMENTS

Background

This summary is an extract from a survey report on the role of government in nanotechnology risk governance. The surveys were originally sent to potential participants from 16 different economies (Australia, Brazil, Canada, Chinese Taipei, Egypt, France, Germany, India, Ireland, Italy, Japan, PR China, South Korea, South Africa, the UK and the US), as well as the European Commission, and during the relevant time period 12 responses were received: Canada, Chinese Taipei, France, Germany, Ireland, Italy, Japan (two separate responses), PR China, South Korea, the UK and the US. The full survey report also includes data on R&D from 15 additional economies and the European Commission which was collected in 2004 at the First International Dialogue on Responsible Nanotechnology.

Summary of current Governance Strategies

Nanotechnology R&D is a top science and engineering priority

The rapidly increasing government investment in nanotechnology R&D suggests that this area is an important part of national science and technology agendas particularly within the fields of materials, biotechnology, medicine, electronics, engineering, sensors, aerospace, food quality, environmental monitoring and metrology. Nanotechnology is increasingly being recognised as a top national R&D priority in both developed countries and countries in development. To date, less emphasis has been placed on risk governance, although projects which address environmental, health and safety (EHS), including toxicology, worker safety, and ecotoxicology, as well as standards, nomenclature and patenting have been initiated in the last few years. Information on this work is being compiled through international expert bodies, research institutes, industry representative groups, and public bodies. In several countries central research coordination bodies have been established and many existing research institutions and national ministries are prioritising nanotechnology. The national ministries involved in R&D are science and technology, education, defence, health, energy, environment and economic development. Nanotechnology-specific centres have been established in nearly all of the countries surveyed, the importance of nanotechnology education and training has been highlighted by several responders and the involvement of social scientist in large projects has been recommended.

A focus on partnerships

Strategies for encouraging collaboration between industry and academia include financial support for small business and start-ups, tax incentives, the establishment of nanotechnology networks and funding of collaborative projects. Internationally, cooperation is taking place within the fields of fundamental research and education, science and technology innovation, responsible development, development of standards and EHS. Methods of cooperation include, inter alia, networks, workshops, committees, dedicated internet sites, exchanges of personnel, and collaborative projects.

The role of government

At the national level some countries have established nanotechnology-specific inter-ministerial bodies to provide guidance for policy development, with members being drawn from within government and external experts. The majority of these bodies have been established within the national ministry for science and technology making this ministry the focal point for policy development. Other ministries involved in governance policy include those for the economy and the environment. In several countries (the US, Japan, PR China, Chinese Taipei, South Korea), there are interagency coordinating offices under the offices either of the prime minister or of the president. Strategic policy for risk governance is still underdeveloped although there is a clear acknowledgement that this needs to become a focal point. Some examples of current activity include, inter alia, a requirement for nanotechnology centres to address issues of risk, establishment of best practices and standards, and the funding of research programmes for both physical and social risks. Currently the main priority is to increase the knowledge base and monitor development so that efficient strategies can be put in place in the future.

Recommended Governance Strategies

Table 1: Risk governance recommendations (suggested in the survey)

Type of governance strategy	Recommendations, suggestions and ideas
Risk research recommendations	• Advance studies of hazard, exposure and risk of nanoproducts. • Categorisation and standardisation of materials. • Education and training for researchers and manufacturers. • Application of risk evaluation procedures tailored to nanotechnology applications. • Environmental, health and safety impacts required input to R&D projects. • Specific plans for environmental impact, chemical toxicity and pollution control. • Green design and green manufacturing. • Nanoproducts lifecycle approach. • Address questions of ownership, control and social ends. • Identification of stakeholder needs through engagement. • Investment in key areas for sustainable development.
Stakeholder engagement recommendations	• Regular workshops with stakeholders. • Dedicated public groups. • Social scientist participation at R&D stage. • Lowering of organisational barriers. • International dialogue between ethical advisory committees.

Type of governance strategy	Recommendations, suggestions and ideas
Risk communication recommendations	• Balanced disclosure of positive and negative evidence. • Information provided tailored to the knowledge levels of different stakeholders. • Channels for dissemination of information appropriate for accessibility by different stakeholder groups. • Encourage independent sources of information. • Communication of secondary unanticipated consequences. • Periodical re-evaluation of risk to be disseminated to the public. • Maintaining a minimum level of interaction with the public for a continuum message.
Governance approaches	***International expert bodies:*** • Joint projects of industry and scientific organisations. • International networks of excellence on risk governance of nanotechnology. • A supranational body to supervise international rules. • An issue specific expert advisory committee. • UN to coordinate conflicting national policies. • Focus on topics of global interest. • Sharing of materials and instrumentation. • Collaboration of national nanotechnology coordination bodies. • Coordinated planning for transporting nanomaterials across boundaries. • Technology-by-technology approach to ethical considerations. • Technical advice based on unified criteria. ***Self-regulation (by industry and research organisation's)*** • International standards on classification, terminology and nomenclature. • Guidelines for research and development. • Peer review of publications. • Voluntary peer reviews of decision processes. • Open-source software development model. ***Government*** • Labelling of consumer-sensible nano-related products. • Structured international agreement. • R&D channelled through national coordinating bodies. • Strengthened capacity of legislative institutions to respond to emerging technologies. • Development of compensation mechanisms. • Development of nomenclature and standards of risk for different categories or products. • National, international and supranational links on regulatory schemes, definitions and nomenclature, best practices, common assessment policies and testing protocols. ***Industry*** • Voluntary disclosure and product labelling. • Collaborate with governments, NGOs, researchers and public organisations.

ANNEX B – SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME B. THE ROLE OF INDUSTRY

Background

This summary is an extract from a survey report on the role of industry in nanotechnology risk governance. The survey was originally sent to 112 potential industry participants from 19 different economies and during the relevant time period 11 responses were received from: the Industrial Technology Research Institute (Chinese Taipei), Allianz and NanoBioNet (Germany), Ayanda Biosystems and Swiss Re (Switzerland), the Chair of the International Organization for Standardization Technical Committee 229 on Nanotechnologies (UK) and Canon, Environ, Intel, NanoDynamics Inc. and Pfizer (US). The respondents represented a selection of organisational types including: 2 nanotechnology start-ups, 3 multinationals, an industrial research institute, an international standardisation organisation, an insurance company, a reinsurance company, an environmental consulting firm and a nanotechnology network supporting companies in competitive development.

Summary of Current Governance Strategies

A strong focus on the commercialisation of R&D

The survey responses emphasised the importance being attached to the development of nanotechnology by certain sectors of industry. There was a strong focus on the commercialisation of the advances already made in research and development (R&D), and the need to gain a competitive advantage over the many other organisations in the market. Responses indicated that competition in nanotechnology was not just confined to certain nations and this was, for example, reflected in the global composition of the International Organization for Standardization (ISO) Technical Committee 229 on Nanotechnologies. One notes the willingness of some organisations to collaborate in an international dialogue and the awareness of some of the respondents that regulation may be needed to prevent irresponsible development globally in the race for competitive advantage. A consequential outcome of this level of competition was what seems to be a common approach of strategic investments and partnerships between multinationals, start-up companies, universities, national laboratories, trade associations and consultancy experts. In terms of industry-wide collaboration the main types commented on in the surveys were government funded centres, government-industry initiatives, industry-academia networks and industry consortia with a high level technical advisory board.

Industry is focused on EHS risks

With respect to consideration of risks, the responses indicated that industry was fully aware of the potential impact on levels of innovation that could be caused by inadequate risk governance of human health and the environment, and, the perception of the public. The major focus identified in the survey responses was on research for EHS and, in particular, the development of guidelines for worker health and safety and the establishment of an international metrology and nomenclature. No mention was made of specific programmes to investigate ethical, legal and social issues (ELSI), although some members of industry were taking part in collaborative efforts including discussion on these issues. No nationally or internationally agreed standards or best practices for nanotechnology were mentioned and any structures in place were seen to be voluntary and at organisational level. The majority of the respondents did agree that standards bodies and industry organisations should take a leading role in nanotechnology risk assessment and management. However, among the respondents there were differences in opinion as to whether nanotechnology-specific risk governance practices should be put in place within individual companies before industry wide measures are identified: some participants are taking a wait-and-see approach, whilst others were already putting in place precautionary measures.

A need to ensure responsible development

A common recognition of the respondents was the need to ensure responsible development, particularly in sectors where organisations might have opportunities to act irresponsibly in order to gain competitive advantage, or where current legislation is not designed to protect against unexpected risks, for example, in the cosmetics industry. An important method of addressing this was perceived by the respondents to be through collaboration with government and academia and within industry itself. For example, the Consultative Board for Advancing Nanotechnology (CBAN), a US government and industry collaboration, has an Environmental, Health and Safety Working Group. Differences of opinion between the respondents arose as to when collaboration should take place. On the one hand, some participants considered that without an adequate definition of what the risks actually are it would not be possible to have an effective dialogue. On the other hand, it was felt by several participants that in order to gauge potential technical and social risks collaboration should take place now. There was greater agreement regarding the inclusion of the public in dialogue, with a clear feeling that risks should be communicated to the public by an independent, 'trusted' source only once a rational assessment of risks and benefits has taken place. There was no mention by any respondent of the possible inclusion of the public in early dialogue.

The current state of knowledge is insufficient to set new regulations

Finally, there seemed to be three common perceptions among the participants regarding changes in legislation. The first being that the current state of knowledge is insufficient to set new regulations, the second that any changes which are made to regulatory policy should be designed to restrict irresponsible behaviour rather than restrict innovation, and the third that there should not be a long period of regulatory uncertainty. The majority of respondents considered that potential risks must be better understood, categorised and measured, and that effective risk governance processes needed to reflect the differences between these categories and the different types of risks which may result from them. It was recommended that government should be directive rather than restrictive, and again there was a difference in opinion between those who considered that changes should be made only if there are signs of irresponsible development, and those who considered that a precautionary but responsible approach was needed from the outset – with government basing any changes in policy on the work done by organisations such as ISO. There was, however, more of a general agreement that entirely new legislations would not be necessary, and that any changes which are needed should result in the adaptation of existing regulations which would be less disruptive for industry and more easily and rapidly achievable.

The following table provides a listing of the recommendations for risk governance made by the survey respondents:

Recommended Governance Strategies

Table 1: Risk governance recommendations (suggested in the survey)

Type of governance strategy	Recommendations, suggestions and ideas
Risk research recommendations	• Identify deficits in research capabilities so that potential risks can be better understood, categorised and measured. • Distinguish between nanotechnology applications in order to more efficiently assess risk. • Establish dedicated multidisciplinary risk research centres of excellence. • More aggressive risk training within R&D parameters.
Stakeholder engagement recommendations	• Collaboration between governments, industry, academia and NGOs on the establishment of best management practices. • Forums for international dialogue on EHS issues. • Forums for individual organisations to exchange good governance practices. • Attendance at meetings by those who use the technologies, such as engineers and clinicians.
Risk communication recommendations	• Inform public with detailed scientific basics (not just hype) supported by substantial evidence. • Ongoing surveys of public opinion to inform the public and other interested parties. • Provision of information by independent 'trusted' organisations, such as the Royal Society and Royal Academy of Engineering in the UK. • Coordinated risk communication by governments, academics and industry internationally on EHS impacts, societal impacts and overall benefits. • Provision of relevant and accessible communication through the media. • Serious consideration of public concerns and demonstration of an adequate response helps to gain credibility and trust.
Governance approaches	***International expert bodies:*** • Determine international standards and harmonise regulatory requirements. • Develop international trade agreements for certification of products and materials according to internationally established standards. • Develop approval mechanisms for nanoscale materials and products as a prerequisite for best practices. • Publish best practices for occupational safety. • Publish best practices for a lifecycle approach towards nanoproducts. • Collaboration between multinational organisations (such as the European Commission (EC), Organisation for Economic Co-operation and Development (OECD), World Health Organisation (WHO) and the United Nations (UN)) and consultation with national bodies. • Provide advice which is independent of national legal environments. ***Self-regulation (by industry, NGOs and research organizations)*** • Introduce voluntary programmes for best practices or guidelines in laboratories. • Treat free nanoparticles as potentially hazardous materials. • Invest in toxicological and ecotoxicological research. • Maintain awareness of current developments in risk. • Invest in responsible and sustainable nanotechnology and avoid hype. • Monitor particle emissions. • Clean work areas at the end of each shift using vacuum pickup and wet wiping methods.

Type of governance strategy	Recommendations, suggestions and ideas
	• Prevent the storage and consumption of food and beverages in workplaces where nanomaterials are handled. • Provide hand-washing facilities and encourage workers to use them before eating, smoking etc. • Provide facilities for showering and changing clothes to prevent contamination of external areas. • Transfer of material from primary containers to processing equipment in a fume cabinet. • The use of filter masks, goggles and silicon rubber gloves when transferring materials, and when cleaning equipment or accidental spills. • Implement risk management practices as early as possible and make them publicly available. • Establish rigorous quality controls and environmental testing procedures. • Provide guidelines to workers for understanding, measuring and managing risk at the product line. • Develop a nano-EHS programme to implement recommended guidelines. • Provide official support for nanoethics. • Obtain membership of industry organisations active in nanotechnology. • Standards bodies and industry organisations to take the lead in defining risk governance practices. • Industry and trade associations to lead self-regulation of different sectors and international cohesiveness. • Judge nanomaterials on a case-by-case basis rather than using a generic approach and characterise using multidisciplinary teams. • Develop best practices that screen new materials for potentially high risk nanotechnological properties and for approval procedures which take this information into account. • Develop training and certification schemes with respect to nanotechnological advice provided by consultancy agencies. • Document products in the process of being developed and those currently on the market to provide an information source for occupational and environmental safety agencies. • Develop informal approaches in areas of EHS and ELSI, for example, traditional cost-benefit analysis should also include the positive and negative consequences for society. • Shareholder oversight (through corporate charter) to prevent investment in technologies harmful to the environment or human health, and may lead to applications in warfare. ***Government*** • Steer research directions through funding of key strategic pre-commercial areas. • Support and guide independent research on nanotechnology related risks. • Provide transparent and open access to the results of government supported research. • Provide education, awareness, guidelines, and effective but not over restrictive legislation. • Standardise and harmonise risk assessment processes and regulations nationally. • Instigate a transparent review of existing legislation and assess risk governance gaps related to the specific properties of nanotechnology.

ANNEX C – SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME C. THE ROLE OF RISK RESEARCH ORGANISATIONS

Background

This summary is an extract from a survey report on the role of risk research organisations in nanotechnology risk governance. The survey was originally sent to 15 potential participants and during the relevant time period 5 responses were received from Ochanomizu University (Japan), the Institute for Occupational Health Sciences (IST) (Switzerland), the Centre for Nanotechnology in Society (University of California, US), the Center for Science Technology and Public Policy (University of Minnesota, US) and the Woodrow Wilson International Center for Scholars (US). These organisations research a range of nanotechnology-related topics and at a general level focus on: improvements to the regulatory system; occupational health; basic research and development (R&D); and the societal implications of nanotechnology in areas such as health, environment, agriculture and public perception. The majority of the survey respondents were individually involved in assessing the implications of nanotechnology on society rather than the technical issues and all of the organisations were based in developed countries, predominantly the US.

Summary of Current Governance Strategies

The research organisations were focused on societal risks and benefits

The responses to this survey on the role of risk research organisations had significant commonality of focus. The respondents were all involved in researching possible changes to risk assessment, risk management and policy frameworks, and the survey responses were all focused on the potential benefits that nanotechnology could bring for society, such as innovations in health, environment, energy and minimal impact production methods, rather than potential economic gains. This commonality of focus resulted in many similar answers but also a significant depth of response that allowed the issues to be investigated in some detail.

- **Environment, Health and Safety Issues (EHS).** The individuals surveyed were researching projects concerning the properties of ambient particles, the implications to human health of nanostructure toxicity and body penetration, the development of toxicity screening strategies and critical research needs, and the potential for developing 'green nanotechnologies'.
- **Ethical, Legal and Social issues (ELSI) in conjunction with policy issues** The individuals surveyed were assessing issues such as frameworks for agrifood nanotechnology, the improvement of risk evaluation and management of nanomaterials, the development of strategies for addressing critical societal issues and the impact of risk perception.

The organisations were concerned with both EHS and with ELSI, as well as with policy aspects. The initial phase of research generally encompassed the collation and dissemination of available EHS information, and the second phase developed recommendations to policymakers. Finally, both the short-term and long-term implications of nanotechnology development were considered to be important, although in all cases there was a clear emphasis on the shorter-term issues.

The primary concern of the respondents was the inability of current political and social frameworks to deal with potential nanotechnology risks. Efficient characterisation of risk was believed to be dependent on many unknown factors such as, toxicity, release and dispersion rates, exposure, dose-response relationships, and severity of the consequences. Nevertheless, the survey responses did include reference to specific risks and these were predominantly focused on ELSI and political risks such as new functions at the nanoscale, nanoscale structures in consumer products, loss of potential benefits, the potential pervasiveness of nanotechnology and international inequality. Health risks were also referred to, such as the ability to enter organs, tissues and cells.

Collaboration and communication is the key to reducing risk

The two most important factors in the respondents' ability to impact on risk reduction were highlighted as being co-operation with other sectors both nationally and internationally and communication of potential risks to the attention of policymakers and other interested parties. The survey respondents were collaborating with a wide range of individuals and organisations, primarily from government, industry, non-governmental organisations (NGOs) and other research organisations. Their ability to raise awareness about the possible impacts of risk was based predominantly on participation in advisory boards, forming partnerships with other like-minded organisations and informal networking through meetings such as workshops and conferences. The survey respondents also underlined the importance of openness and transparency in risk communication in particular when communicating with the general public. Key risk communication factors noted included the importance of the media in public perception, the impact of intellectual property rights on the ability of companies to share risk information and the need for communication to be multi-directional.

Regulation, standards and best practices

The most significant regulatory concern raised by the survey respondents was that current regulatory structures and practices may be insufficiently responsive and flexible to cope with the individual characteristics of nano-materials or products. One respondent felt that we have to be careful not to regulate science and technology, but to pay attention to the individual products and their applications. In the same context, another response considered that the usual regulatory practices for new chemical substances would be sufficient provided that nanostructures are treated as new substances.

Finally, the survey responses considered the ability for international governance regimes to address the social and economic risks and benefits as well as the technical EHS issues and, additionally, whether all nations would be able to act under a global risk governance framework. The respondents highlighted the important role to be played by international organisations in providing independent and effective advice, by national governments in adapting guidance to their own social and political contexts and by industry-led initiatives and self-regulation. Alongside of these roles the survey responses also highlighted the need for public access to information both about products, and their potential benefits and risks.

The following table provides a listing of the recommendations for risk governance made by the survey respondents. The list includes all of the recommendations proposed but does not imply that each suggestion is endorsed by all of the survey respondents.

Recommended Governance Strategies

Table 1: Risk governance recommendations from Risk Research Organisations. (suggested in the survey)

Type of governance strategy	Recommendations, suggestions and ideas
Risk research recommendations	• A 'Hippocratic Oath' setting out moral and ethical obligations for nanotechnology developers. • Institutional review boards (IRB) to assess the risks and benefits of the research undertaken. • Efforts should be made to coordinate research and prevention strategies. • Common understanding of important categories of nanomaterials. • Global consensus on broad issues regarding ES&H implications. • A framework describing the way forward to protect people's health and the environment. • Models used in medical research could also be used for self-governance. • Processes are needed that enforce rigorous and analytic approaches to assessing the causes, likelihood's, and effects of negative scenarios. • Scenario planning needs to include a worst-case scenario.
Stakeholder engagement recommendations	• The debate over benefits and risks needs to actively involve all sectors of society, rather than being confined to 'experts'. • Continued dialogue among interested parties at the international level through one umbrella organization is needed. • Engage developing countries early and often in charting the course of nanotechnology and invest in capacity building, primarily of education and institutions.
Risk communication recommendations	• Communication of benefits and risks should be open and undertaken jointly. • New findings should be communicated rapidly. • Open dialogue and transparency about the contents of products. • Education amongst those potentially using and disposing of the products. • Risk communication and discussion should avoid extreme views. • In the short term, broadly accessible information on nanotechnology needs to be made available through a number of outlets. • In the long-term, risk communication should be integrated into education programs alongside the ability to critically evaluate technical information. • For interested parties - through understandable, but semi-technical reports by independent organisations (for instance, outside of government, industry and polarised NGOs). • For the general public—by independent organisations in collaboration with good science reporters who can translate results in a balanced and fair way. • At the grass roots level – through focus or stakeholder groups or public education at local libraries. • Establishment of an open forum for exchanging information on safe working practices.

Type of governance strategy	Recommendations, suggestions and ideas
Governance approaches	***International expert bodies*** • Communicate the known risks and identified research gaps and – if asked or if appropriate – what the worst-case scenarios could be. • Knowledge networks that incorporate the media and the public and that set the agenda for national action by calling attention to risk issues, sharing concerns and attempting to engage national legislators. • Internationally accepted risk assessment and management models. • Global strategic plans for identifying and addressing information gaps. • Reports that provide more specific, yet flexible guidance on governance will be useful. ***Self-regulation (by industry, NGOs and research organisations)*** • Conduct lifecycle analysis which is independently and publicly evaluated by a third party. • Nanotechnology developers and producers should also support independent research about potential risks. • Good occupational hygiene practices, including carrying out risk assessments based on the best available information. • Risk evaluation and management frameworks that address characteristics of nanomaterials that may lead to an increased risk compared to comparable non nano-structured materials. • Hazard information on engineered nanomaterials. • Material Safety Data Sheets (MSDS) risk phrases relevant to engineered nanomaterials. • “Dustiness” standards for nanopowders. • Cost-effective personal exposure monitors for airborne nanostructured particles. • Global harmonization of safe working practice guidelines, approaches and standards. • Cost-effective rapid-response ecotoxicity screening tests. • International guidelines and standards on ecotoxicity tests. • Cost-effective monitoring methods for nanomaterials in soil and water. ***Government*** • Government investment should include research and analysis, systematic planning, allocation of resources in order to create organisational or network capabilities. • Nanoparticles should be considered as a new substance and the usual regulatory processes for new chemical substances should be followed. • Coordinate currently leading nations and anticipate the rise of nanotechnology in developing nations by getting them involved in the conversation early. • National and global strategic plans for identifying and addressing information gaps. • Increase R&D spending on risk-based research substantially. • R&D effectiveness and impact models that reward proactive risk-based research and development. • Public funding for applications geared towards sustainable development, both for developing countries (e.g. food security, water quality, energy infrastructure, vaccines, medical treatments for developing world illnesses, etc.) and for applications for which there are not immediate financial returns (e.g. energy and environmental applications in all countries).

ANNEX D – SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME D. THE ROLE OF NON-GOVERNMENTAL ORGANISATIONS (NGOS)

Background

This summary is an extract from a survey report on the role of NGOs in nanotechnology risk governance. The survey was originally sent to 25 potential participants. During the relevant time period 9 responses were received from ETC Group (Canada), Demos, The Forum for the Future, Greenpeace (UK), the Center for Responsible Nanotechnology (CRN), Environmental Defense, Foresight Nanotech Institute, the National Resources Defense Council and Sciencecorps (US). These respondents represented NGOs with a broad range of activities and focus, for example: the conservation and sustainable advancement of cultural, human and ecological diversity, accountable and effective public policy, sustainable development, environmental protection, the environmental and societal implications of nanotechnology, public education, and, the right to live and work in a healthy environment.

Summary of Current Governance Strategies

NGOs have significant involvement with nanotechnology

It was clear from the survey responses that NGOs were, even at an early stage in nanotechnology development, significantly involved in associated issues. The range of areas in which the respondents were active is widespread and the difference in focus meant that there were many diverse views, opinions, approaches, concerns and recommendations. There was a significant commonality of response with respect to broader debate and opinion concerning risk governance and this was evident from the balanced approach that these NGOs seemed to be adopting towards nanotechnology. In fact many were actively seeking the development of applications which could be beneficial for the environment and for human health. Nevertheless, it was evident that the majority of the respondents were predominantly concerned about the mitigation and prevention of potentially new risks. In terms of organisational focus, respondents were split between those who were concentrating on ELSI and those who were concerned with EHS:

- **Ethical, legal and social issues.** The NGOs surveyed had ELSI projects looking mainly at public policy, equitable development, intellectual property rights, international trade, molecular manufacturing, non-proliferation, public engagement and sustainable development. The primary concern on ELSI issues is a particularity in the NGO's survey.
- **Environment, Health and Safety.** The NGOs surveyed had projects considering the implications of nanotechnology for EHS, safety within the R&D community, safety of engineered nanoparticles, regulations and corporate standards.

A focus on identifying current gaps

With respect to current governance practices, the respondents did not identify any regulations or other decision making processes considered adequate for ensuring the safety of nanomaterials. In addition, no-one mentioned any measures being planned to specifically address the size-specific nature of nanotechnology. This applied for both ELSI and EHS risks. Nevertheless, a great deal of information was provided regarding governance gaps in current decision making practices, including gaps within national regulatory programmes, cross-border regulatory programmes, self-regulation, and within laboratory practices. The majority of the survey participants seemed to agree that while the risks of most concern stem directly from the inherent – and novel – properties of nanomaterials; the deficiencies in current regulatory systems serve to increase the inability of those involved in risk governance to adequately identify and address those risks. An important element of risk mitigation, which informed many of the responses, was the need for values to be incorporated into decision making by considering at the very start of R&D what the potential applications and implications might be. In particular, many of the respondents saw a need for decision makers to begin a proactive consideration of what should be developed for the benefit of society and what developments should be avoided. It was suggested that this process would allow governance policies to be defined which would allow society to reach (or prevent) these goals.

A focus on engagement of stakeholders

In order to address the potential for risk and ensure the safe development of nanotechnology, a common approach favoured by the respondents was for a broad community of participants to be involved in dialogue and debate. In particular, the majority felt that members of civil society should be engaged, considered and consulted in the risk governance process from the very beginning. In order to increase the level of stakeholder engagement the respondents were themselves engaging with government, international organisations and nanotechnology networks comprised of NGOs, industry, government and academia to discuss topics such as public engagement, the development of standards, societal impacts and policy implications.

Considering regulation

Finally, many respondents agreed that government and industry were beginning to take risks seriously, although they might still have a long way to go from thinking about the risks to taking action. Some respondents noticed a tendency for government and industry to focus on EHS issues rather then ELSI. There was a clear emphasis on the need to adopt a proactive or precautionary approach and consequentially a focus on governmental action rather than, or as an ultimate replacement for, self-regulation to ensure the closure of risk governance gaps as soon as possible. Despite this emphasis very few of the respondents were campaigning for R&D to be halted completely, what was being stressed was proactive risk management before a major incident happens, and for promised benefits to be directed towards sustainable development rather than just the creation of more attractive consumer products.

The following table provides a listing of the recommendations for risk governance made by the survey respondents. The recommendations are made to other stakeholders except for NGOs. The list includes all of the recommendations proposed but does not imply that each suggestion is endorsed by all of the survey respondents.

Recommended Governance Strategies

Table 1: Risk governance recommendations from NGOs (suggested in the survey)

Type of governance strategy	Recommendations, suggestions and ideas (to industry and government unless otherwise stated)
Risk research recommendations	• Develop the methods, protocols and tools needed to characterise nanomaterials or to monitor and measure their presence. • Identify and understand the critical characteristics of nanotechnology, including toxicity and eco-toxicity, and biological and environmental fate and transport. • Determine whether existing testing and assessment methods and protocols need to be modified to allow for the particular characteristics of nanotechnology. • Ensure coordination between different agencies involved in risk research to ensure that all needs are being addressed and that sufficient resources are available. • Consider the social and ethical aspects of scientific training and how this influences the culture and practice of research. • Study the potential (positive and negative) issues of molecular manufacturing.
Stakeholder engagement recommendations	• Identify R&D priorities and agendas through upstream public engagement, with wider dialogue between scientists, policymakers and publics. • Government to initiate and adequately fund public dialogue. • Include civil society in discussion of risk assessment and management strategies.
Risk communication recommendations	• Develop standards of care in a transparent and accountable manner. • Make research and development funding transparent, including assessment and management of risk. • Conduct toxicity testing in a publicly accessible and transparent manner by a credible, independent authoritative body according to generally accepted laboratory practices. • Balance the communication of benefits and risks. • Label consumer products incorporating nanotechnology.
Governance approaches	***Recommendations to international expert bodies:*** • Collate and disseminate research into toxicology and eco-toxicology and make this publicly available. • Provide a clearing house for safer alternatives and new methodologies and make this publicly available. • Develop an inventory for all engineered nanomaterials and make this publicly accessible to the international community. • Develop an export notification and tracking system and make the results publicly available. • Provide educational training to organisations on potential benefits for sustainable development. • Explore new models of intellectual property specific for nanotechnology. • Create an International Convention on the Evaluation of New Technologies. • Create a new United Nations body to track, evaluate and accept or reject new technologies and their products.

Type of governance strategy	Recommendations, suggestions and ideas
	Recommendations for self-regulation by industry • Comprehensively identify risk and management systems prior to and following commercialisation. • Develop a risk management system to provide a clear explanation of company's actions to interested parties; present environmental and health information related to nanomaterials production, use and disposal; facilitate tracking and comparison over time and across organisations; and credibly address issues of concern to stakeholders. • Adopt feedback mechanisms to monitor assumptions concerning risks and the effectiveness of risk management practices. • Adopt lifecycle-based 'standards of care' for responsible nanotechnology development, taking into account worker safety, manufacturing releases and wastes, product use and product disposal. • Adopt worker safety guidelines that assume toxicity unless otherwise shown, provide for worker training, industrial hygiene and worker health monitoring, and treat wastes as hazardous materials. • Adopt environmental safety guidelines which restrict dispersive uses until hazard/ fate data is available to demonstrate safety, and provides for environmental monitoring after release. *Recommendations to government* • Guide 'beneficial outcomes' through appropriate public sector R&D, market guidance and regulatory behaviour (with the respondent adding that beneficial should not be interpreted as meaning good for corporate shareholders of existing companies). • Create environments for societal discussion of new and emerging technologies at an early enough stage to influence the direction of R&D. • Advise political leaders on how innovation can be driven to socially and environmentally beneficial goals. • Develop the 'Science Commons' to provide easier global access to new R&D materials, methods and processes and to prevent misuse of intellectual property rights. • Introduce open access publishing of intellectual property. • Prohibit production of free manufactured nanoparticles in environmental applications until research demonstrates that the potential benefits outweigh the potential risks. • Support substantial R&D in the evaluation of hazards associated with research, the expected outcomes and training. • Assess objectively the capacities of regulatory authorities and clarify roles and responsibilities. • Require toxicity testing for engineered nanomaterials intended to be commercially viable. • Require publication by manufacturers of available safety data sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment. • Require disclosure of full hazard characterisation and control during the development process, including: a full lifecycle analysis, including fate and effects information; solubility; bioavailability; basic physical/chemical properties such as electrical conductivity; particle size; configuration; mass/surface area ratio. • Require analysis of unintended outcomes and products and appropriate means of reducing these. Disclose this information to workers, potentially impacted communities and funding entities.

Type of governance strategy	Recommendations, suggestions and ideas
	• Develop an information source geared to the investor communities regarding liabilities and risks. • Require students, educators, laboratory managers and administrators to take appropriate training. • Develop financial and career incentives for those who use safer alternatives, employ safe practices, provide training and produce new products which pose minimal hazards to health or environment. • Introduce strong financial and career penalties for the violation of safe practices. • Subsidise the use of safer chemicals and compensate institutions for time and costs. • Classify engineered nanomaterials as ‘new’. • Develop a protocol for the tracking of released nanomaterials. • Place a moratorium on the release of manufactured nanoparticles until lab protocols are established to protect workers and regulations in place to protect consumers and the environment (suggested by one responder).

international risk governance council
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