



Policy Brief

## Nanotechnology Risk Governance

Recommendations for a global,  
coordinated approach to the  
governance of potential risks



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IRGC's White Paper, Nanotechnology Risk Governance, can be downloaded from the Downloads & Links section of IRGC's website.

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# The International Risk Governance Council and its project on nanotechnology risk governance



The International Risk Governance Council (IRGC) is an independent foundation based in Switzerland whose purpose is to help the understanding and management of important, emerging global risks. It does so by identifying and drawing on the best scientific knowledge and, by combining it with the understanding of experts in the public and private sectors, developing fact-based risk governance recommendations for policy makers.

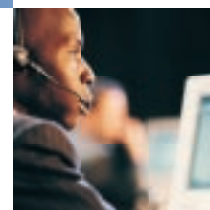
A particular concern of IRGC is that the opportunities flowing from new technologies and innovations are not forgone due to inadequate or inappropriate risk governance, including poor communication. When these technologies have the capacity to alleviate major global concerns, a failure to adopt them has potentially catastrophic consequences.

In 2005, the IRGC decided to address the risk governance of nanotechnology as an emerging technology that both offers potentially enormous benefits and presents significant challenges to government, industry and society at large. The recommendations and the model presented in this Policy Brief are the final product of a multistage project process that included two expert workshops, a White Paper<sup>1</sup> prepared and reviewed by a team of scientific and technical experts, key stakeholder surveys, and a multi-stakeholder conference in July 2006 attended by participants from more than 30 countries.

The project was led by Dr. Mihail Roco of the National Science Foundation and Prof. Ortwin Renn, Department of Environmental Sociology at the University of Stuttgart. Both were also co-authors of the IRGC White Paper. Other members of the project's leadership team were Dr. Lutz Cleemann, Head of the Allianz Center for Technology in Ismaning, Germany, Dr. Thomas Epprecht of Swiss Re, Prof. Wolfgang Kröger, Director of the Laboratory for Safety Analysis at the Swiss Federal Institute of Technology Zurich, Dr. Jeffrey McNeely, Chief Scientist at the World Conservation Union, Prof. Nick Pidgeon, Professor of Applied Psychology at the University of Cardiff, Prof. Joyce Tait, Director of the INNOGEN Centre at the University of Edinburgh and Dr. Timothy Walker, former Director General of the UK's Health and Safety Executive.

The project has been made possible through financial support provided by the US Environmental Protection Agency and Department of State, the Swiss Agency for Development and Cooperation and the Swiss Reinsurance Company (Swiss Re).

**The aim of this report is to suggest ways to improve the risk governance of nanotechnology applications**



<sup>1</sup> IRGC White Paper N° 2, "Nanotechnology Risk Governance", IRGC, Geneva 2006 (available as a download from [www.irgc.org](http://www.irgc.org)). The White Paper includes a full list of references for material which has been summarised in this Policy Brief.

# Introduction

**Nanotechnology raises issues that are more complex and far-reaching than many other innovations**

This Policy Brief is targeted at policy makers engaged in the planning, oversight, and funding of nanotechnology regulation, research and practical applications. We hope it will assist risk decision makers in developing the processes and regulations that are essential to assuring the development and public acceptance of the many benefits that nanotechnology promises to deliver.

Nanotechnology is an important and rapidly growing field of scientific and practical innovation that will fundamentally transform our understanding of how materials and devices interact with human and natural environments. These transformations may offer great benefits to society such as improvements in medical diagnostics and treatments, water and air pollution monitoring, solar photovoltaic energy, water and waste treatment systems, and many others.

The transformations may also pose serious risks. The social, economic, political and ethical implications are significant. Because nanotechnology raises issues that are more complex and far-reaching than many other innovations, the current approach to managing the introduction of new technologies is not up to the challenges posed by nanotechnology. Decision makers worldwide need to work towards a system of risk governance for nanotechnology that is global, coordinated, and involves the participation of all stakeholders, including civil society. This Policy Brief identifies key areas where relevant stakeholders could contribute to improved risk and benefit governance in a coordinated fashion, and proposes a model to national and international policy makers to review and improve their current practices of risk governance for nanotechnology.



## Recommendations

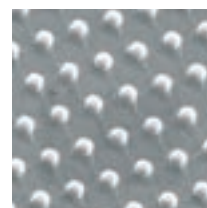
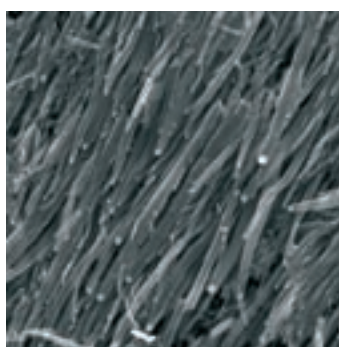
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# I Nanotechnology products processes and related risks

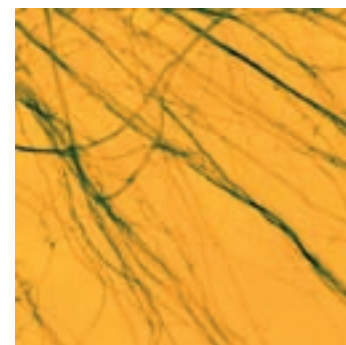
**Downsized material structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties**

Nanotechnology refers to the development and application of materials, devices and systems with fundamentally new properties and functions that derive from their small size structure (in the range of about 1 to 100 nanometers) and from the recent ability to work with and manipulate materials at this scale. This new tool-kit for science, technology and medicine allows scientists and engineers from different fields to work with atoms and molecules at a size visible only with the most powerful microscopes available today.

At the nanoscale, the physical, chemical, and biological properties of materials differ in fundamental and valuable ways from the properties of individual atoms and molecules or bulk matter. Downsized material structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties, as well as their chemical reactivity, leading to novel applications for industry, health-care and consumer goods.

The same novel properties that may provide benefits to society also raise concerns about how nanomaterials may interact with human and other biological systems. A major concern is that the techniques to measure, predict behaviour and control particles, devices and systems at the nanoscale are still relatively immature, and therefore their long-term impacts are unpredictable.

Both governments and industry are investing heavily in nanotechnology research and product development. Hailed by some as a major driver in the next post-industrial revolution, it is estimated that by 2015 \$1 trillion worth of products will use some form of nanotechnology. Current leaders in this highly competitive field include the US, Japan, and the EU, and government-led nanotechnology initiatives are already underway in more than 60 countries.



In order to distinguish between different types of nanotechnology applications and the benefits and risks that might accompany each type, IRGC has identified four generations of nanotechnology products and production processes:

- **First Generation: Passive (steady function) nanostructures** (as from 2000). The main applications are intermediary system components such as particles, wires, nanotubes and nanolayers whose properties allow for improvements to the performance of existing materials and products. One inventory lists over 500 consumer products on the market claiming to incorporate nanostructures, ranging from clothing and sporting goods to personal care and nutritional products.
- **Second Generation: Active (evolving function) nanostructures and nano-devices** (as from 2005). These products can change their state during operation. Typical applications are expected to be in device and system components such as sensors with a reacting actuator or drug delivery multi-component particles that change their structure as they reach their intended target.
- **Third Generation: Integrated nanosystems (systems of nanosystems)** (after 2010). In this generation, it is anticipated that synthesis and assembly techniques will allow for: forms of multiscale chemical and bio-assembly; networking at the nanoscale; and, scaled, hierarchical structures. In nanomedicine this could mean the development of artificial organs and scaffolds for skin tissues. In nanoelectronics, this could lead to the development of devices based on states other than that of the electric charge.
- **Fourth Generation: Heterogeneous molecular nanosystems** (after 2015). The system components and devices are reduced to molecules and supramolecular structures that have specific structures and play different roles within the nanosystem. For example, the molecules can be used as devices or engineered to assemble on multiple length scales. Natural biosystems work in this way, but researchers currently lack sufficient control at the nanoscale to duplicate them. Potential applications include nanoscale genetic therapies and supramolecular components for transistors.

IRGC has identified four generations of nanotechnology products and production processes



## II IRGC's approach: two "Frames" which distinguish between "passive" and "active" nanostructures

We still have only a limited understanding of passive nano-materials potential environmental, health and safety risks but active and more complex nanostructures require a far greater level of knowledge to assess potential risks

A particular problem posed by nanotechnology is its breadth, both in terms of science – it cannot be termed as only biology, chemistry, physics or engineering – and as a result of the extremely wide range of the potential applications which it can help to develop – in no country is there a single regulatory structure that covers food, chemicals, personal care products, medical devices, water quality, and so on. IRGC found that it was not possible to address nanotechnology's risk governance by considering it as a single technology or by addressing all of its potential applications at once.

To help our thinking, the four generations described above provided the basis for our development of two frames of reference:

- Frame One, or "**passive**" nanostructures (Generation 1).
- Frame Two, or "**active**" and "**more complex**" nanostructures and nanosystems (Generations 2-4).

IRGC found this distinction to be particularly helpful and we believe it can help policy makers as well.

Hundreds of products which include "passive" nanostructures are already in the marketplace although – as many other organisations have pointed out – there remains a considerable need to research whether or not their incorporation of nano-materials has in any way affected their toxicity. The applications in IRGC's Frame One are developments of existing products or products that will be developed in the future which contain relatively simpler nanostructures, which exhibit stable behaviour during their use and which, in our view, do not present consumers or society with excessive novelty.

In our Frame Two, on the other hand, new capabilities are expected to be developed to both create new molecules by design and change the structure of the existing molecules; together with their increased complexity and dynamic behaviour, this could directly increase the risks associated with these active nanomaterials and nanodevices. The active and more complex nanotechnology applications of Frame Two may, therefore, require a far greater level of knowledge and ability to control nanostructure behaviour and to assess potential risks. Additionally, a large number of the potential Frame Two applications involve genuinely new products and the social, economic and political consequences are expected to be more transformative. This greater level of novelty could, IRGC has concluded, heighten the potential for societal concern.



In both frames, there is the need for appropriate risk management, informed by thorough risk assessment. In Frame One, this can be mostly achieved through current regulatory structures and processes. Many Frame Two applications, however, are likely to fall outside the remit of existing regulatory bodies and risk assessment methodologies may simply not exist. One of the risk governance challenges is to ensure that appropriate assessment methodologies are developed in line with the pace at which the applications themselves become reality.

A second result of our use of the two frames is that it allowed us to see that, although there are risks common to both frames, there are also significant differences. We describe these risks below and, later in this document, present our recommendations for dealing with them.

## Risk appraisal of passive nanostructures (Frame One)

Despite the steady introduction of passive nanomaterials into the marketplace (in, for example, cosmetics, paints and lubricants) we still have only a limited understanding of their potential environmental, health and safety (EHS) risks. More research is required for:

- hazard characterisation (in areas such as toxicity, ecotoxicity, carcinogenicity, volatility, flammability, and persistence and accumulation in cells).
- exposure characterisation, 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.

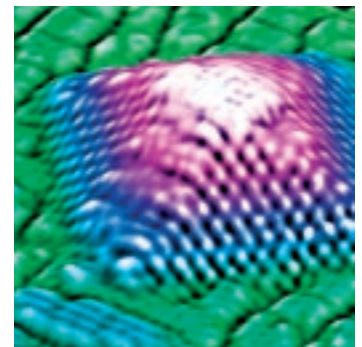
Specific risk categories include:

### Human health risks

Several studies have shown that:

- 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 is non-toxic at the (larger) microscale or macroscale.
- some nanosized particles are able to penetrate the olfactory system, the liver and other organs, passing along nerve axons into the brain.
- nanomaterials may combine with iron or other metals, thereby increasing the level of toxicity and so pose unknown risks.

One of the risk governance challenges is to ensure that appropriate assessment methodologies are developed in line with the pace at which the applications themselves become reality



**Some nanomaterials may have similar characteristics to known high-risk materials at the microscale**

- engineered nanomaterials raise particular concerns because of the unknown characteristics of their new properties and their potential use in concentrated amounts.
- some nanomaterials may have similar characteristics to known high-risk materials at the microscale.

### Environmental risks

Nanostructures may have a significant impact on the environment due to the potential for:

- bioaccumulation, particularly if they absorb smaller contaminants such as pesticides, cadmium and organics and transfer them along the food chain.
- persistence, in effect creating non-biodegradable pollutants which, due to the small size of the nanomaterials, will be hard to detect.

### Manufacturing risks

Radically new manufacturing methods may change the market, production levels, and geographical distribution of industry, as well as the distribution of the workforce. Also, workers potentially face greater exposure to the human health and safety risks noted above. For example, it is known that dust explosions can occur in manufacturing sites that have ultrafine particles of flour, coal, metal or other materials. The higher surface reactivity and surface-area-to-volume ratio of nanopowders may increase the risk of self-ignition and explosion.

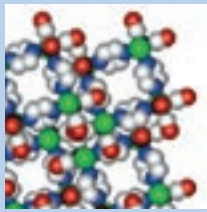
The following societal impacts of nanotechnology development have been raised for Frame One, although many also apply to Frame Two:

### Political and security risks

Decisions about the direction and level of nanotechnology research and development (R&D) may result in:

- use in criminal or terrorist activity.
- a new military-driven technological race.
- an uneven or inequitable distribution of nanotechnology risks and benefits among different countries and economic groups (e.g. North-South divide).
- insufficient investment in key areas to achieve the potential future economic and social benefits.





## Educational gap risk

If the knowledge within scientific/industrial communities is not appropriately shared with regulatory agencies, civil society and the public, risk perception/management may not be based on the best available knowledge, innovative opportunities may be lost, and public confidence in transparency and accountability may erode.

## Risk appraisal of active nanostructures and nanosystems (Frame Two)

The risks identified above for Frame One are also relevant to active nanostructures in Frame Two. When in production, Frame Two products may need special safety measures because of their higher complexity and their dynamic behaviour. Additional risks may exist now for Frame Two, even for products that have yet to be developed, that are primarily related to stakeholder concerns regarding the societal and ethical impacts of anticipated nanotechnology applications. More study is needed to understand how the public perceives nanotechnology, and how those perceptions are influenced and acted upon. Some concerns raised so far include:

**More study is needed to understand how the public perceives nanotechnology**

### Essential human and environmental risks

There is apprehension about the use of nanotechnology to fundamentally change how human and environmental biosystems work. Examples include:

- further enhancements to genetic modification.
- devices to control the human brain and body.
- changes to the environment, human safety and quality of life.

### Societal structure risks

Risks may be induced and amplified by the effect of social and cultural norms, structures and processes, such as:

- the inability of the regulatory environment to react rapidly to new technologies.
- an unintended availability to the mass market of products based on applications developed by and for the military (e.g. tiny airborne surveillance devices).
- the economic impact of the mass application of nanotechnology.
- the emergence of a new technological and cultural environment based on the ability to purchase new revolutionary products, cognitive technologies and promises of enhanced quality of life.



The use of active nanostructures and nanomaterials has been linked with fundamental ethical questions



### Public perception risks

Recent surveys show that the public is less concerned about a particular application or risk, and more worried about the capacity for human misuse, unexpected technological breakouts, or nanotechnology's potential to exacerbate existing social inequalities and conflicts. These concerns may grow if nanotechnology becomes associated with specific dangerous incidents that occur in a context of deep suspicion of industry motives and doubts regarding government's ability or desire to act if required. Attention should be paid to the impact of the specific stakeholder agendas and the mass media on risk perception.

### Ethical risks

The use of active nanostructures and nanomaterials has been linked with fundamental ethical question relating to:

- issues of human identity if devices based on nanotechnology applications able to guide or influence behaviour are incorporated into the human brain.
- issues of tolerability for "nanobio" and hybrid devices if they escape beyond the reach of human control.
- the application of nanotechnology in products of pervasive computing, thus impacting on basic human or social values such as privacy or self-efficacy.

### Transboundary risks

The risks faced by any individual, company, region or country are affected by their own choices as well as by the choices 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. Additionally, there also exists the possibility of the physical transboundary movement of nanoparticles in, for example, the air and rivers.

# III Shortcomings of current systems of risk governance for nanotechnology



Governments, industry, academia and NGOs worldwide are looking for the best risk assessment, management and governance practices with respect to nanotechnology. However, innovation in the field of nanotechnology development is far ahead of the policy and regulatory environment, which is fragmented and incomplete at both the national and international levels. IRGC has identified four areas of governance gaps that ideally should be addressed in a coordinated fashion at the international level<sup>2</sup>. These deficits include:

## Environmental, health and safety

- More information is needed on the effects of nanoparticles and other nanomaterials on human health and the environment. Research on toxicity and biocompatibility is not keeping pace with the creation and introduction of new materials.
- More attention is needed to the monitoring, impact and control of nanomaterials in the workplace and in the environment.
- More studies are needed into the hazards and exposure to the hazards posed by active and more complex nanostructures and nanosystems (Frame Two applications), particularly their impact on human health and the environment.

## Institutional issues

- Regulatory structures and processes are fragmented with respect to jurisdiction, type of regulation, and the lack of harmonisation of risk assessment and management procedures, both nationally and internationally.
- Current regulatory measures deal mostly with the cause-and-effect of single events, and not the impact of a technology over its life cycle, or its secondary or interactive effects.
- Ongoing regulatory uncertainty in some areas, especially concerning measures to protect the public, may hamper industrial innovation and the ability of investors and insurers to estimate future gains, risks, and losses. This is especially applicable to Frame Two active nanoproducts.

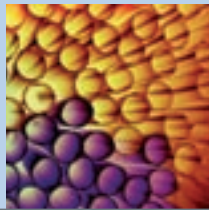
## Social and political issues

- Differences in national regulations may complicate international policy coordination and a harmonised approach to risk management. In trade, these differences may hinder the development of standardised products and production methods, and lead to competitive arbitrage as companies and governments

Innovation in the field of nanotechnology development is far ahead of the policy and regulatory environment



<sup>2</sup> For the complete list of risk governance system deficits, see pp. 27-32, *White Paper on Nanotechnology Risk Governance*, IRGC, Geneva 2006.



**It is essential to create platforms for stakeholder interaction that can serve as the catalyst for both improving risk management and gaining more public acceptance**

seek advantage by lowering safety and regulatory barriers for research and manufacture, or by transferring risk to countries with weaker controls.

- Individual and cross-national equity conflicts may arise from a focus on products that primarily benefit the rich, or do not address wider human needs such as clean water, affordable energy, and conserving biodiversity.
- Differences of interest between developed and developing countries may arise because of new manufacturing processes and changes in the need for and use of raw materials and natural resources.

### Risk communication issues

- Lack of communication and understanding about the science, application and regulation of nanotechnology among all stakeholders may have negative effects on societal impressions and political/regulatory decision making.
- Gaps in communication between different scientific disciplines – from the natural, technical and ecological sciences to the economic, social and psychological disciplines – limit the ability to fully consider and act on potential innovations and risks.
- Gaps in communication between various regions of the world, which may lead to their developing different expectations and adopting different and contradictory regulatory measures.
- The lack of engagement with stakeholders with different perspectives and value systems in a continuous dialogue about the best procedures to exploit the benefits and avoid most of the risks has caused an increased polarisation between nanotechnology's optimists and those who are more pessimistic. This polarisation has, in past instances involving other emerging technologies, rarely helped to pursue a rational and well-balanced path of development. Although one cannot convince all parties, it is essential to create platforms for stakeholder interaction that can serve as the catalyst for both improving risk management and gaining more public acceptance.

In response to the risk governance gaps listed above, the challenge to policy makers is to develop a flexible and adaptive approach to risk governance that supports the responsible development of the technology while minimising harm. It should be global, look to both the short- and long-term, and proactively address the interests of all affected parties.

The following recommendations are directed to national and international decision makers who can lead a coordinated effort to address key nanotechnology risk issues, and they offer an overview of the key areas that demand urgent attention. Detailed action steps for Frames One and Two can be found in Annexes 1 and 2 at the end of this document.

Our recommendations are organised into five categories:

- Improve the knowledge base.
- Strengthen risk management structures and processes.
- Promote stakeholder communication and participation.
- Ensure social benefits and acceptance.
- Collaboration between stakeholders and nations.

Some of these activities have already been taken up by actors at the national level and specialised organisations. The emphasis here is on the extension of those national efforts to a collaborative, coordinated effort at the international level.

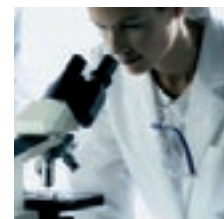
## Improve the knowledge base

Nanotechnology is a dynamic field, and all actors are jockeying to advance the science and develop applications. However, funding agencies need to focus resources on critical information gaps. Top priorities include the establishment of scientific norms and the commissioning of research which is focused on risk assessment.

## Standardised nomenclature, measuring and handling systems

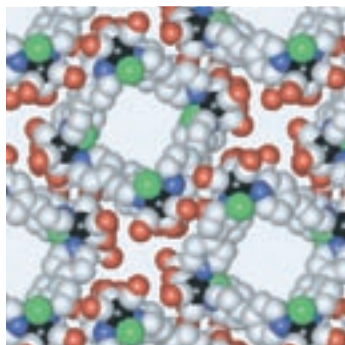
Neither voluntary nor formal regulatory frameworks for nanotechnology can be developed in the absence of a standard approach on how to define, characterise, measure, test, and validate the products and processes emerging in this field.

**Funding agencies need to focus resources on critical information gaps**





Currently, governments are not able to set up or modify comprehensive regulatory structures quickly enough to match the pace of innovation and product introduction



### Better understanding of risk

A greater proportion of both public and private R&D funds should be targeted at better understanding how to characterise, assess, and manage risk related to the production, application, exposure to and disposal of nanomaterials and products. Ideally, a precautionary approach to widespread application is needed with research efforts directed towards closing existing knowledge gaps and developing fast and responsive early warning and monitoring systems.

### Improved data sharing

The tendency of private and commercial interests in science and technology development to take a proprietary approach to research findings and data constrains the ability of all stakeholders, but especially government, to adequately predict and manage risks. The goal should be to develop a common understanding of potential risks to deal with them preventively rather than reactively.

### Understand the full implications

Undertake research specific to the wider implications of active nanotechnology applications, including the development of scenarios, infrastructure models, and systems for early detection of major societal or environmental change.

## Strengthen risk management structures and processes

Currently, governments are not able to set up or modify comprehensive regulatory structures quickly enough to match the pace of innovation and product introduction. Nor, for nanotechnology, is the evidence base adequate to support an appropriate regulatory approach – there is a dearth of risk assessment data. The following intermediate steps should be undertaken in the meantime:

### Identify gaps and remedies

Governments, industry and researchers need to assess the current strengths and weaknesses in their existing risk management and regulatory systems. Within the US, this is particularly important for the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA). Within Europe, it remains to be seen how the new chemicals regulation Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) will impact on nanotechnology risk assessment. They should also look at the potential contribution of regulatory frameworks from analogous fields to speed up implementation.



## Voluntary systems

Industry, governments, and other stakeholders must collaborate now to lay the foundation for later regulatory action and to assess the potential for international voluntary agreements. Voluntary risk governance systems should include:

- Development of standards and good practice guidelines in all areas, from basic research to product testing and tracking. Methods for assessing hazards and exposure should be a priority.
- Development of occupational safety guidelines and information disclosure programmes for consumers.
- Establishment of transparent reporting schemes, especially of data and events that have a bearing on risk management. Such reporting schemes are controversial: when they are voluntary, it is difficult to assure adequate participation and transparency and thus the watchdog function can be diluted. Voluntary or mandatory, industry has concerns about protecting intellectual property and competitive advantage.

A recent example of a voluntary system is the “Nano Risk Framework” developed jointly by Environmental Defense and DuPont and launched in June 2007<sup>3</sup>.

It should be acknowledged that voluntary systems often result in a “lowest common denominator” approach, and may not pose a sufficient deterrent to those who prefer to play outside the system or not comply with it. Competitive and investor pressures may lead to product introduction without the full evaluation of potential risks. These weaknesses should be an incentive to strengthen regulatory systems sooner. Above all, there is a need to consider anticipatory and coordinated measures for possible events where nanotechnology based applications would produce irreversible and significant damage.

## Role of international organisations and regional efforts

The International Organization for Standardization (ISO), United Nations Educational, Scientific and Cultural Organization (UNESCO), Organisation for Economic Co-operation and Development (OECD) and others have begun work on standards development and the analysis of social, ethical and political considerations of nanotechnology from the international perspective. This work is complemented by regional collaborations in Europe, Asia and the Americas. These efforts should be supported and expanded, to consolidate progress globally and to minimise duplication and inconsistencies as many countries attempt to address these issues individually.

**Industry, governments, and other stakeholders must collaborate now to lay the foundation for later regulatory action and to assess the potential for international voluntary agreements**

<sup>3</sup> *Nano Risk Framework*, Environmental Defense-Du Pont Nano Partnership, June 2007 (available as a download from [www.nanoriskframework.com](http://www.nanoriskframework.com))

**Currently the public has only a limited awareness of the science, uses, impacts and implications of nanotechnology**

## Promote stakeholder communication and participation

Soliciting and integrating the social concerns of all stakeholders, especially civil society, is central to the IRGC approach to risk governance and crucial for improving risk management and gaining public confidence. Currently the public has only a limited awareness of the science, uses, impacts and implications of nanotechnology. Not all stakeholder groups that might be interested in or affected by nanotechnology applications have the same level of awareness about these issues, nor do they share identical interests in participating in the decision making. The potential benefits and risks must be examined together in order for a realistic discussion about tradeoffs to occur, and much more must be done to raise the knowledge level of all parties to prepare for meaningful participation in decision-making about the current and future role of nanotechnology.

### Distinguish between Frame One and Frame Two

Communication about nanotechnology benefits and risks should reflect the distinction between passive and active nanomaterials and products, stressing that different approaches to managing risks are required for each. Care should also be taken to ensure that potential societal concerns about the possible impacts of Frame Two active nanomaterials do not have the effect of unnecessarily increasing anxiety regarding Frame One products using only passive nanostructures.

### Improve communication strategies

All stakeholder groups should assess and improve their communication strategies within their own constituencies and amongst each other on a national, regional, and international level with the goal of sharing information and facilitating collaboration.

### Engage the public and make participation count

Governments and stakeholder groups should use a wide variety of models to engage the public in debates and consultation about the implications of nanotechnology and how risk tradeoffs are made. The challenge is how to make this participation ultimately meaningful. Currently, many strategies for public participation allow for a comment role only – final decisions are taken by those in positions of authority and do not always reflect public concerns. If the public is to be asked to participate, there needs to be a genuine willingness to respond to what is said. There is also a need to accept that “the public” will not have a single, unified view: genuine engagement with the public will require acceptance of and responsiveness to a variety of opinions.



## Ensure broad social benefits and acceptance

As the public and civil society learns more about the potential and risks associated with nanotechnology, the discussion must broaden to explore the social and moral implications of future innovations. From the individual to the global level, the question arises of how the benefits of nanotechnology will be distributed. Some applications may offer universal benefits; e.g. health-improving or life-saving medical treatments, but be inaccessible to the poor due to cost. Nanotechnology has the potential to offer solutions to pressing social challenges – such as water treatment, energy generation and environmental remediation – but the divide between rich and poor countries will only grow if these applications are not broadly shared. Stakeholders need to explore how to shift the current pattern of treating developing countries as secondary markets for applications that primarily benefit developed countries.

### Stakeholder participation in setting priorities

All stakeholders should be involved in setting directions for research and product development that reflect social values and needs, especially those of developing countries. The dialogue should be expansive, including advance discussion of what kinds of nanotechnology applications are desirable and acceptable (to avoid the backlash that has accompanied genetically modified organisms). Research in Switzerland by TA Swiss<sup>4</sup> has already demonstrated that public acceptance of nanotechnology is positively associated with knowledge about broad societal benefits (such as medical treatments and environmental renovation). In addition, stakeholders have to be reassured that their concerns are taken seriously and that private and public risk management institutions demonstrate accountability and good performance. This will also enhance their credibility and trustworthiness.

### Funding for the public good

Governments should prioritise funding for R&D aimed at broader social applications and public good benefits.

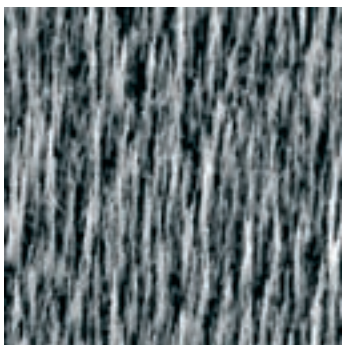
### Reduce barriers for developing countries

For the benefits of nanotechnology to be shared broadly across the world and by all of those to whom some applications will bring particular benefits (e.g. the millions needing clean drinking water in developing countries), new approaches to intellectual property rights are needed to make technology transfer affordable.

**All stakeholders should be involved in setting directions for research and product development that reflect social values and needs**

<sup>4</sup> Les nanotechnologies en Suisse : les défis à relever sont désormais connus. Report of a “Publifocus” project by TA-Swiss, December 2006

**An individualistic approach will simply perpetuate the lack of coherency and increase the possibility that significant gaps will persist in both the science and the debate**



### Economic planning to reduce adverse impacts

Risks may vary on a regional or country-by-country basis. Developing countries face specific challenges when used as manufacturing hubs or sources of raw materials. A shift in the balance of trade for economies dependent on the export of raw materials may result if high quality and more efficiently produced substitutes are developed as a result of nano manufacturing.

### Collaboration between stakeholders and nations

As an emerging technology that is complex, fast-moving and unpredictable, nanotechnology requires an approach to risk governance that is collaborative and coordinated. There are many potential avenues to explore and actions to be taken, and existing approaches and frameworks are not up to the task. However, an individualistic approach will simply perpetuate the lack of coherency and increase the possibility that significant gaps will persist in both the science and the debate about applications, benefits and risks. Harmonisation between nations is also essential as nanotechnology and its applications are already global phenomena. The sheer quantity of work demands that all stakeholder groups work with each other, and the need for efficiency and effectiveness requires joint goal-setting and mutual accountability to avoid duplication of effort.

Collaboration works best when groups take on roles that make explicit their interests, values and competencies. While some tasks appear to be the natural purview of one stakeholder group or another, they should not be rigidly assigned. The table in Annex 3 identifies activities that different stakeholder groups could or should take the lead on, but always in the context of working with other groups to ensure that multiple perspectives are considered from the outset.

For example, the ISO needs member nations to make detailed proposals in order to develop and approve international standards. In turn, member nations need the collaboration of industry to provide initial field data to inform such proposals; they also need to listen carefully to both public and civil society organisation concerns. OECD has also begun work in this area.

The creation of effective and acceptable international standards requires the participation of all stakeholders and will benefit from multinational efforts to create common frameworks of understanding and practice.

Navigating the introduction and acceptance of new technologies is always difficult, both from the technical and the societal perspectives. Realising the benefits of these technologies requires a willingness to accept some risk, because without risk there can be no progress. The choice of a system to manage that risk – whether voluntary or top-down – will be influenced by, and have an impact on, the wide variety of perspectives that contribute to overall societal perceptions and acceptance of the new technologies.

The scope of activity to develop an international risk governance system for nanotechnology is broad and will develop over the course of many years. But certain tasks demand urgency:

- Development and dissemination of standardised terminology and measurement systems.
- Increased priority and funding for risk-related science.
- Development and implementation of worker safety guidelines, with the priority being to prevent risks that are, even now, highly uncertain.
- Better communication with the public about nanomaterials currently in the marketplace, including giving consideration to product labelling.

A global coordinated effort should also begin to:

- Ensure the transparency of risk assessment data to avoid duplication of effort and promote maximal information sharing.
- Synthesise and assess progress being made in each area.
- Make recommendations for further work, taking into account emerging areas of consensus and gaps that need further attention.
- Consider the development of internationally compatible, legally binding regulations for risk issues not amenable to voluntary restraints.

Most importantly, national governments and key international organisations must establish robust risk assessment methodologies that will inform governments, regulators and industry of the real nature of the hazards posed by nanoscale materials. This information will facilitate good risk management decisions and support fact-based communication, especially with consumers. These methodologies need to be developed now for the passive nanostructures contained in commercial products already on the market, to lay the foundation for full risk assessment of future applications and to avoid problems that may, in the future, unnecessarily constrain the full benefits promised by this exciting new science.

**Realising the benefits of these technologies requires a willingness to accept some risk, because without risk there can be no progress**

# Applying the IRGC risk governance framework to nanotechnology

National governments and other stakeholders need to work collaboratively at the international level to establish a coordinated, global approach to risk governance for nanotechnology. They also need to develop risk governance processes and structures for nanotechnology that reflect the needs, goals and values of their national cultures and institutions. In this appendix we offer concrete assistance to national decision makers by presenting the IRGC framework<sup>5</sup> for analysing nanotechnology risks and implementing a risk governance system. This model, which formed the analytic framework for the recommendations given in this Policy Brief, is unique because it:

- Distinguishes between risk problems that are simple, complex, uncertain, and ambiguous.
- Ensures the early and meaningful participation of all stakeholders, including civil society, by assessing and actively integrating their views, values, and potential roles.
- Incorporates the principles of good governance, including transparency, effectiveness and efficiency, accountability, sustainability, feasibility, equity and fairness, and respect for the rule of law.

IRGC believes that, with respect to nanotechnology, a risk governance framework should be:

- Adaptive, valuing flexibility in the application of risk management strategies as knowledge and understanding of the field develops.

- Collaborative, sharing information, skills and expertise internationally among different agencies and stakeholders.
- Global, proposing international minimal “level playing field” guidelines and reference models to generate confidence in safety management in a global economy.
- Realistic and fast, recognising that such a dynamic field calls for active and ongoing learning, rather than an “after the fact” approach; the speed of learning may be accelerated by sharing and building on emerging experience on a global basis.
- Responsive to essential human values, such as equity, respect of ethics, safety, equal opportunities and the right to privacy.

The IRGC approach<sup>6</sup> to the governance of risks takes a step beyond classical risk management (which is most often viewed as a linear process from risk assessment to risk management and risk communication). IRGC’s approach:

- adds a pre-assessment phase that includes ‘problem framing’, ‘early warning’, and ‘organisation of the risk governance process’;
- considers the assessment of societal concerns alongside conventional risk assessment (in order to allow the scientific consideration of stakeholder and public concerns by risk managers in the process of generating the knowledge required for risk evaluation and management);
- provides for a risk evaluation and management process that includes the concerns, interests and values of stakeholders and the public through different participative procedures; and
- considers risk communication as an integral part of all stages of the risk governance process and vital for effectively linking the different components.

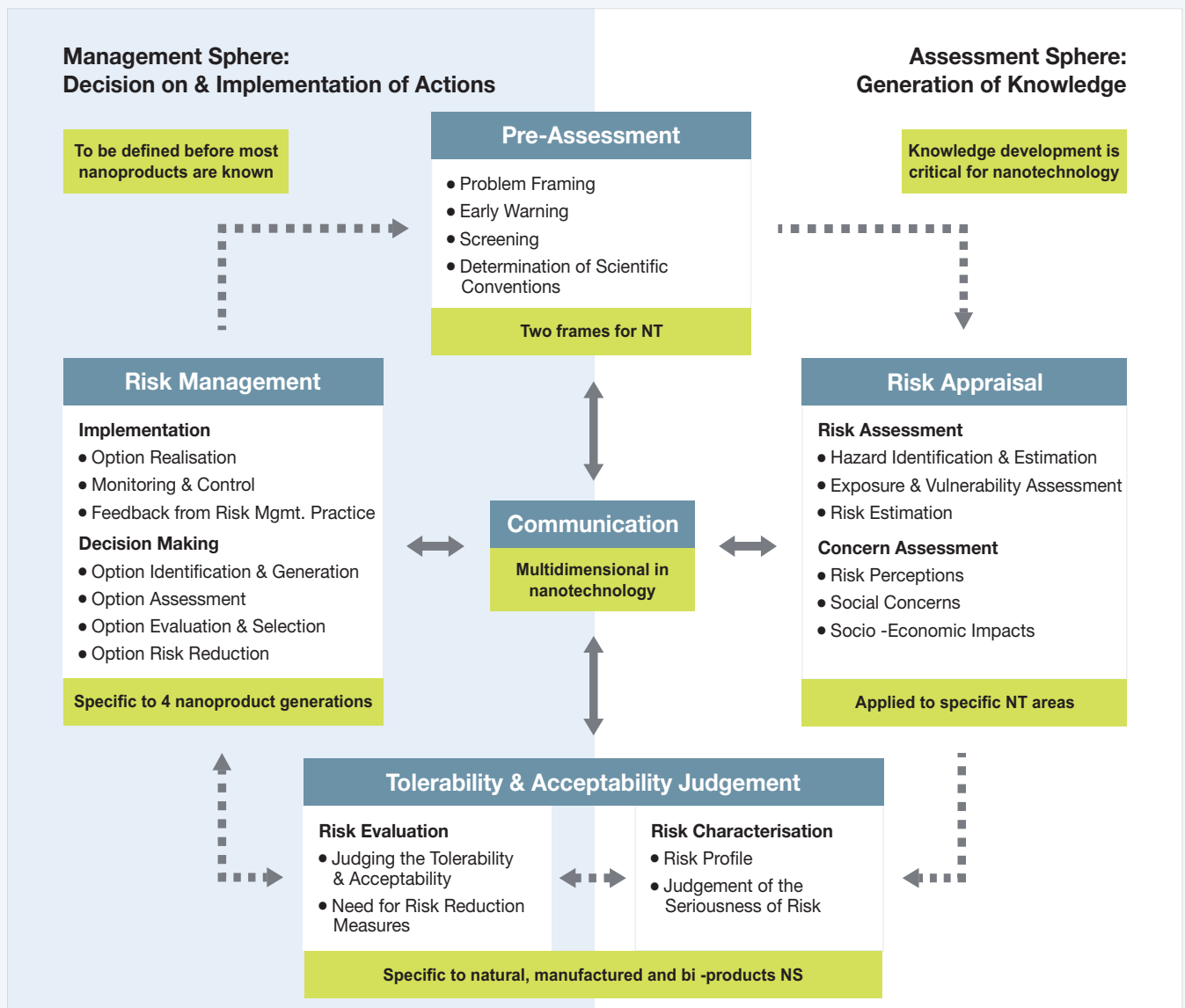
<sup>5</sup> IRGC White Paper No2, *Nanotechnology Risk Governance*, IRGC, Geneva 2006 available as a download from [www.irgc.org](http://www.irgc.org)

<sup>6</sup> The IRGC approach to risk governance is described in our White Paper No. 1, *Risk Governance—Towards An Integrative Approach*, published in 2005 and also available on our website.

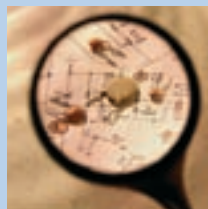
The IRGC's risk governance framework comprises five linked phases: Pre-assessment, Risk Appraisal, Tolerability and Acceptability Judgement, Risk Management and Communication. Communication is positioned central to the framework as it is both crucial in its own right and is also essential for the implementation of each phase as well as for coherence between phases. Figure 1 illustrates the framework, as specifically applied to nanotechnology.

Figure 1

Elements of the IRGC risk governance framework, applied to nanotechnology







The utility of this process can be demonstrated by understanding the dilemma faced by policy makers who need to design a risk governance system for nanotechnology. It is not just the actual or potential risks posed by a technology that must be managed – it is also society’s perception of those risks. If society does not understand the technology properly, people are likely to assign irrelevant or unfounded concerns to innovations, risking an overly conservative approach to new applications. Similarly, if those responsible for risk management do not adequately anticipate and prepare for potential adverse events, society may lose confidence in the ability of government to safeguard them, again reacting by putting a halt to further progress (even if other applications turn out to be safe).

In order to develop a system that will both manage risks and be acceptable to the public, policy makers must first define and characterise the technology in the context of current strategies for dealing with anticipated risks and what concerns about the technology are being raised by society (pre-assessment). Next they must deepen their understanding by conducting a thorough assessment of the technical risks, how the public perceives those risks, and what impact the technology is likely to have on society (risk appraisal). After this, policy makers must evaluate whether those risks are tolerable according to societal values (tolerability and acceptability judgement), and then design a risk management system that evaluates all these inputs through multi-stakeholder dialogue and decision-making and which can also account for, and respond to, the variety of views that the different stakeholders may express.

With respect to nanotechnology, these tasks will not be easy. As previously noted in this Policy Brief, reliable technical data on risks is not yet available, the public does not know enough about the technology or risks to have a common view, and few studies have been done

to assess the full range of concerns. These three deficits mean that making judgements about acceptability or tolerability will be difficult at the outset. The IRGC’s White Paper on Nanotechnology Risk Governance offers an analysis of the information that is currently available, and the following overview of the IRGC’s framework will enable policy makers to continue work on filling the gaps.

### The pre-assessment phase: characteristics and risk considerations for each category of nanotechnology

The first phase of the IRGC risk governance framework – pre-assessment – requires policy makers to outline the scientific characteristics of the technology and its potential applications, and to research and identify concerns that may be raised by major societal groups (governments, industry, the scientific community, non-governmental organisations (NGOs) and the general public).

Nanotechnology has the potential to become one of the defining technologies of the 21<sup>st</sup> Century. The 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 research and development (R&D) expenditure in all developed countries and many other countries have begun to invest in nanotechnology.

As discussed earlier, the four generations of nanotechnology demonstrate a wide range of properties, potential applications and potential risks, which IRGC has grouped into two broad categories: Passive (Frame One) and Active (Frame Two) nanostructures. Areas of concern that might affect how to manage the risks of each category include:



## Frame One passive nanostructures

- **Context for Frame One products and processes:** Ongoing research into the properties of nanomaterials and their environmental, health and safety (EHS) implications is needed to identify risks. Debates need to be focused on the development and implementation of best practices and regulatory policies.
- **Risk characterisation:** Ongoing research on how nanoscale components of the nanoscale products and processes result in increased systems complexity and unpredictability.
- **Strategies:** The establishment of an internationally reviewed body of evidence related to toxicological and ecotoxicological experiments, simulations and monitoring of actual exposure.
- **Potential conflict:** Can potential conflicts between advocates of and opponents to nanotechnology be managed? How much precaution in the development, regulation, and use of nanomaterials is necessary to achieve an optimal balance between technological progress and effective and transparent risk management?

## Frame Two active nanostructures and nanosystems

- **Context for Frame Two products and processes:** Debates are needed on the social desirability of certain of the predicted innovations. Although it has, historically, been very difficult to foresee the precise results of scientific research, some of the anticipated innovations (e.g. nanoscale genetic therapies) may not be welcomed across all sections of society. Discussions should focus on the process and speed of technical modernisation; the increased number of components and complexity of nanosystems; 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:** Knowledge is needed about Frame Two's nanoscale components and nanosystems as they will display higher dynamic characteristics and complexity. Currently this frame is also characterised by additional uncertainty and ambiguity because so little is known about most of these active nanosystems and their applications.
- **Strategies:** Stakeholders need to knowledgeably discuss the ethical and social implications of these advances for individuals and institutions, and there is a need to build institutional capacity to address unexpected risks. Projected scenarios are needed to explore plausible (as well as implausible) links between the proposed applications and potential social, ethical, cultural and perception threats. Strategies will also need to anticipate and account for statements and actions by public opponents to particular applications. Above all, the pre-appraisal process will need to be undertaken separately for each particular nanotechnology application under review.
- **Potential conflicts:** The primary concern of Frame Two 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 (e.g. converging technologies) and will affect stakeholder perceptions and concerns.

## The risk appraisal phase: assessing risks and societal concerns

Risk appraisal is the second phase of the IRGC risk governance framework and involves assessing *risks* (related to hazard, exposure and risk) and *societal concerns* (including how risk is perceived and what stakeholders are concerned about). For passive nanostructures, risk assessment is paramount, as product development and application is moving faster than risk assessors can appraise new risks.

For active (Frame Two) nanostructures and nanosystems, understanding society's concerns has priority because the products are more complex and have broader implications. Even though relatively little technical knowledge is available now, some stakeholders may be more concerned with the social desirability and potential implications of future innovations.

The results of IRGC's appraisal of nanotechnology's risks were summarised in this Policy Brief. Individual countries will want to conduct their own risk appraisals, not least because much of the knowledge generated will be context-specific, particularly regarding societal concerns.

## The tolerability and acceptability judgement phase

In the third phase of the IRGC risk governance framework, policy makers need to determine which nanotechnology applications would be considered acceptable or tolerable by society. These judgements will, most probably, not be uniform throughout society and are also likely to be different for specific nanotechnology applications. One approach is to match the probability of an adverse event against the extent of the consequences of such an event. Risky activities deemed *acceptable* would include those with a low probability of occurrence and

limited consequences, and would include use of most nanosized materials that occur in nature where chemical composition determines properties.

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

- *tolerable*, with the need for management to reduce it to the "as low as reasonably possible" level. This may include some engineered nanostructures;
- *intolerable*, as in the case of explosive nanomaterials designed to be used for other purposes; and
- *undefined*, as in the case of brain modification.

Making these distinctions, especially in the context of insufficient scientific evidence, is one of the most difficult tasks of risk governance, although collaborative processes for making these kinds of choices have been used to tackle other contentious issues for which there is incomplete information and high uncertainty. To be ultimately successful, a combination of technical data and multi-stakeholder (especially public) inputs should be part of the process. The total absence of technical data concerning some potential applications which are still some years from being developed into final products makes these judgements very difficult.

The next task is risk characterisation and risk evaluation. This involves identifying the scientific- and values-based evidence about a risk, and evaluating it by balancing the levels of tolerability or acceptability within societal norms. This process guides risk managers towards risk governance decisions that are practicable and account for the views and needs of different stakeholders.

Risks can be categorised in terms of what is known about them, how well the cause and effect relationship is understood, and how controversial and ethically challenging the risk is perceived to be by stakeholders. Applying this approach allows the initial categorisation of any risk into four groups: *Simple*, *Complex*, *Uncertain*

and *Ambiguous* and the development of appropriate risk governance responses.

Most Frame One applications, including naturally occurring nanomaterials, fall into the category of simple or simple to complex risks. Frame Two applications are characterised by both uncertainty (being more complex and unsteady, and in addition – at the present time – having insufficient or unclear scientific knowledge about the risks) and ambiguity (differences in how information may be interpreted due to different values and concerns).

Making these distinctions is vital, both to assure appropriate regulatory input and risk management strategies and to engage broad stakeholder debate early in areas where debate can be most sensitive or beneficial. However, given the dynamic nature of nanotechnology development and the many different countries involved in it, there is no one governance approach that can address all issues. Decision makers will need to recognise that societal concerns will vary among groups and over time, and that the body of knowledge will continually expand. It may therefore be easier to identify the *dominant* rather than the *single* category before deciding how to proceed; it will also help to ensure that decisions can be revisited as new knowledge emerges.

## The risk management phase: strategies for Frame One and Frame Two

Risk management, the final phase of the risk governance framework, requires the selection of strategies designed to reduce or transfer risks that have been judged to be tolerable and to decide how to prevent the occurrence of risks that have been deemed intolerable. For both of the IRGC frames there are factors particular to nanotechnology that will impact on the choice of measures.

These include:

- Nanotechnology is multidisciplinary, cross-sectoral and involves multiple stakeholders.
- Consistent participation of all actors involved in nanotechnology research, development and application is required.
- Most Frame Two nanotechnology applications can be characterised as more or less complex, uncertain or ambiguous. This characterisation may change over time as new knowledge emerges.
- The risk management approach must be adaptable to the availability of new knowledge and changing circumstances, have the flexibility to allow for necessary corrections, and include contingency plans for dealing with a wide variety of risk scenarios that would include changes in available scientific evidence and potential effects on the economy, society and the political arena.

The adoption of a strategy for the risk governance of nanotechnology requires that decision makers distinguish between Frame One and Frame Two, designing risk management and communication programmes that promise adequate and effective strategies for each frame. Currently, because there is so little actual data on which to base management decisions, much of the management focus must be on ensuring the adequacy of risk assessment and risk evaluation activities (see Table 1, next page).

Risk Frames	Hazard	Exposure	Risk
<p>Frame One</p>	<ul style="list-style-type: none"> <li>▪ Testing strategies for assessing toxicity and ecotoxicity;</li> <li>▪ Best metrics for assessing particle toxicity and ecotoxicity;</li> <li>▪ A nomenclature which includes novel attributes, such as surface area;</li> <li>▪ Pre-market testing, full lifecycle assessment and consideration of secondary risks;</li> <li>▪ Disposal and dispersion methods for nano-engineered materials;</li> <li>▪ Development of waste treatment strategies;</li> <li>▪ Collection of best available data.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Exposure monitoring methodologies;</li> <li>▪ Methods for reducing exposure and protective equipment;</li> <li>▪ Collection of best available data.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Risk assessment methodologies;</li> <li>▪ Guidelines and best practices made available internationally;</li> <li>▪ Evaluation of the probability and severity of risks, including loss of benefits;</li> <li>▪ Balanced knowledge-based communication and education of EHS and ethical, legal and social issues (ELSI), including uncertainties and ambiguities;</li> <li>▪ Collection of best available data.</li> </ul>
<p>Frame Two (in addition for those for Frame One)</p>	<ul style="list-style-type: none"> <li>▪ Identify the hazards caused by the emerging behaviour of nanosystems</li> <li>▪ Identifying the hazards using scenarios.</li> <li>▪ Matrix for assessing the identified hazards.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Estimation of exposure to active nanostructures and nanosystems</li> <li>▪ Estimation of exposure for events with great uncertainties using methods such as causal chain.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Identifying, communicating and educating others on EHS, ELSI, human development implications (HDI) and political and security issues (PSI);</li> <li>▪ Developing capacity to address uncertain/ unknown and ambiguous developments at national and global levels;</li> <li>▪ Identifying and analysing highly controversial developments.</li> </ul>

Table 1  
 Key Risk management needs for the two Nanotechnology Risk Frames

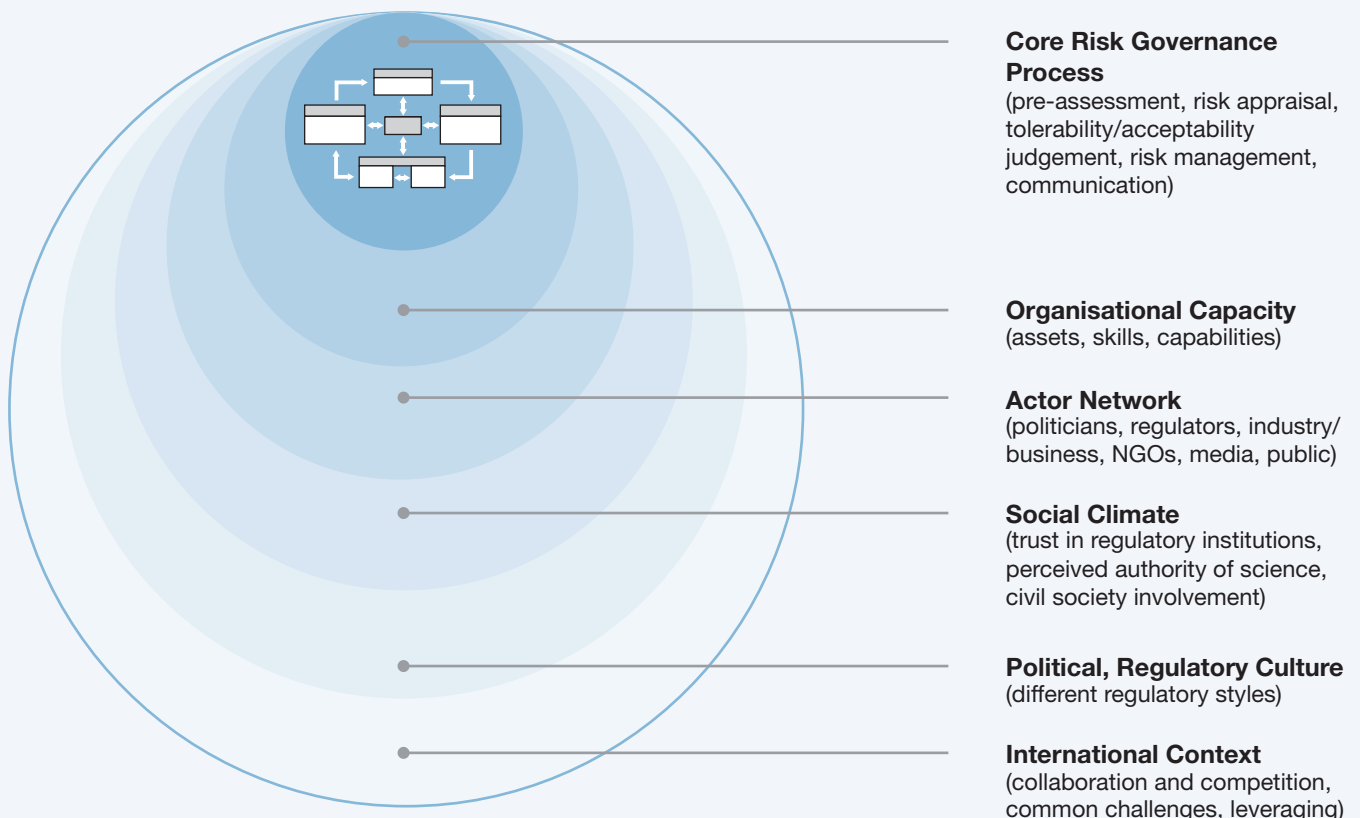
Overall, IRGC recommends the adoption of an approach emphasising “robustness” for Frame One applications, seeking to understand and – as far as possible – reduce the potential hazards posed to human health and the environment. For Frame Two applications, we recommend an approach that is both robust and resilient, with a strong effort by risk managers to build institutional and societal capabilities to deal with their uncertain effects. This must involve identifying and addressing, through careful communication and dialogue, the potential societal controversies that Frame Two applications are likely to cause.

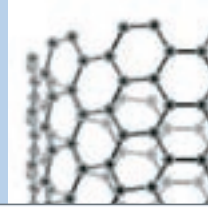
### The importance of context

Whilst IRGC emphasises the importance of international collaboration and, if possible, harmonisation of risks governance approaches for nanotechnology, we recognise that the risk governance process cannot itself be standardised. Many external factors impact on it, as summarised in Figure 2 below:

Figure 2

**Contextual factors impacting on the risk governance process**





As we have already made clear, many organisations – governments, regulators, industry, academia, non-governmental organisations, and others – are contained within the network of actors which is influencing and will be influenced by the future development of nanotechnology. Nanotechnology's global nature requires that the network in its entirety should have the capacity to create and execute an effective and global approach to nanotechnology risk governance. In turn, this means that each organisation must have the resources and knowledge to be able to fully undertake its individual part in the process.

Annex 3 contains some recommendations for actions by individual stakeholder groups. How each approaches its role is influenced by many other contextual factors. These include what IRGC calls the social climate (which includes such key variables as the willingness to accept risk and the extent to which science is trusted by the public) and the political and regulatory culture – countries and individual companies pursue different pathways in dealing with risk.

## Conclusion

In this appendix we have sought to introduce the IRGC's risk governance framework and to show how it may be applied to the many and diverse risks associated with nanotechnology. The IRGC framework offers an approach that is both comprehensive and flexible and thus enables in-depth understanding of the various issues raised by and related to nanotechnology.

# Risk governance recommendations for passive nanostructures (Frame One)



## Risk governance recommendations for passive nanostructures (Frame One)

### Hazard Recommendations

- 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.

### Exposure Recommendations

- Exposure monitoring methodologies.
- Methods for reducing exposure and protective equipment.

### 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 environmental, health and safety (EHS) and ethical, legal and safety issues (ELSI), including uncertainties and ambiguities.

### 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 research and development (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 methods 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.



# Risk governance recommendations for active nanostructures (Frame Two)

## Risk governance recommendations for active nanostructures (Frame Two) (in addition to those for Frame One)

### Hazard Recommendations

- Identify the hazards caused by the emerging behaviour of nanosystems
- Identifying hazards using scenarios.
- Matrix for assessing the identified hazards.

### Exposure Recommendations

- Estimation of exposure to active nanostructures and nanosystems
- Estimation of exposure for events with great uncertainties using methods such as causal chain.

### Risk Recommendations

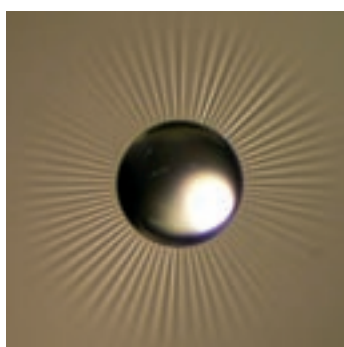
- Identifying, communicating and educating others on environmental health and safety (EHS) risks, ethical, legal and social issues (ELSI), human development implications (HDI) and political and security issues (PSI).
- Developing capacity to address uncertain/unknown and ambiguous developments at national 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.

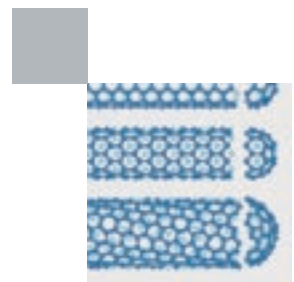




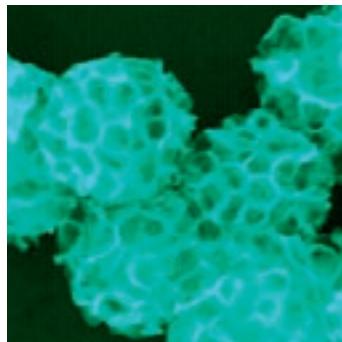
# Recommendations for stakeholder groups



Stakeholder	Recommendations
<b>Government</b>	<ul style="list-style-type: none"> <li>▪ Support research and development (R&amp;D) for environmental, health and safety (EHS) risks, education, ethical, legal and social issues (ELSI), human development implications (HDI) and political and security issues (PSI) and integrate the results into the planning of large research and development (R&amp;D) projects and planning for nanotechnology investments.</li> <li>▪ 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.</li> <li>▪ Build capacity to address accidents and other unexpected situations.</li> <li>▪ Provide incentives to reduce risks; for example, developing nanotechnology applications which replace polluting materials with green substitutes.</li> <li>▪ 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.</li> <li>▪ 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.</li> <li>▪ Address equal access to nanotechnology benefits and equity issues in society.</li> <li>▪ Prepare longitudinal surveys (of six to twenty four months) on public perception.</li> <li>▪ 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 clearinghouse information role for government organisations.</li> <li>▪ Facilitate public participation in addressing social impacts and ethical considerations.</li> <li>▪ Adopt transparent oversight processes with public input.</li> <li>▪ Encourage international collaborations in risk governance.</li> </ul>
<b>Industry</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Public disclosure of testing and possible risks of nanomaterials.</li> <li>▪ 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.</li> <li>▪ Develop mechanisms to exchange information with other industries, academia, public, and government.</li> </ul>



Stakeholder	Recommendations
<b>International organisations</b>	<ul style="list-style-type: none"> <li>▪ Promote communication between governments, business and non-government organisations in various countries</li> <li>▪ Encourage and support coherent policies and regulatory frameworks for nanotechnology.</li> <li>▪ Establish shared data bases for EHS/Education/ELSI results and develop programmes for periodical exchanges of information.</li> <li>▪ 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.</li> <li>▪ Coordinate intellectual property issues for nanotechnology.</li> <li>▪ Establish certification programmes for risk governance in an organisation.</li> <li>▪ Connect risk management practices to international practices and standards (ISO).</li> </ul>
<b>Academia</b>	<ul style="list-style-type: none"> <li>▪ Conduct research for physico-chemical knowledge, EHS risks, ELSI and on new methods for risk analysis and management specific for individual nanotechnology applications.</li> <li>▪ 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.</li> <li>▪ Conduct public outreach and engagement; participate in public debates on nanotechnology and its benefits and risks.</li> <li>▪ Engage impartially in risk related issues, without bias towards industry interests or pressure group values.</li> </ul>
<b>User, public, NGOs and civil organisations</b>	<ul style="list-style-type: none"> <li>▪ Serve a watchdog function for the impacts and effects of nanotechnology applications over research laboratories, industry production, consumer preferences, transportation, and environment.</li> <li>▪ 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.</li> <li>▪ Develop continuous channels of communication with industry, academia, and government.</li> <li>▪ Participate in processes designed to address social impacts and ethical considerations.</li> </ul>





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