The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue 6–7 July 2006

Conference Report

Swiss Re
Centre for Global Dialogue


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Foreword

At Swiss Re our 143 year history of handling risks has shown us the importance of new and emerging risk dialogue. By engaging in dialogue at this early stage of the development of nanotechnology we can help assess anticipated benefits and explore from different perspectives those risks that are either poorly or not at all understood, in a context of collaboration with stakeholder groups from all sectors of society. Certainly, for a global risk carrier like Swiss Re, it is not a question of rejecting risk per se. Insurance enables risk taking and there is a long list of technical advances in fields such as aviation, pharmaceuticals and energy that have brought great benefit to societies and presented new and difficult challenges that have been successfully overcome.

Sustaining innovation in a new technology is closely linked to good governance for several reasons. Firstly, it can help address and avoid potential negative side-effects before they occur. Take the example of asbestos where side-effects were largely ignored until it was too late, at the cost of jobs, economic wealth and much human suffering. This must not become a reference case on how to handle future potential risks. Secondly, with new technologies the public perception of potential hazards can take on a life of its own separate from what scientists would consider to be the facts of the matter. Good governance can create the transparency that is vital for gaining trust when public concerns need to be addressed. And thirdly, these new technologies are global in their development and will not respect national or cultural borders. Responses should be based on collaboration between stakeholders internationally with active and open sharing of know-how and information.

We are honoured to provide the frame for such a stakeholder dialogue. It is one of the first steps in reaching open-minded solutions on a governance framework for nanotechnology, thereby helping to gain the benefits from the new technology and contributing to a safer environment for all.

Jacques Aigrain
CEO Swiss Re

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Key Findings

Broad agreement on a flexible and adaptive governance approach that integrates risk assessment with social context

- Stakeholders motivated to develop risk governance alongside technology roadmap
- Emphasis on gaining trust and creating transparency at the broad social level and engaging in ethical and social debate
- Recognition of potential scope and breadth of new applications enabled by nanotechnology
- Global perspective required including adaptive approach to developed and developing country needs

Further work required on finalising White Paper

- Scoping of distinction between Frame One and Two
- Incorporation of additional benefits into the White Paper to balance focus on potential risks

Nanotechnology: Poorly characterised and understood

- Further research monies needed for risk related research and better understanding of the fundamental behaviours of nanoparticles
- Standardised measurement of and nomenclature for the nanoscale urgently required
- Special governance approaches for safety should be considered for future applications if unexpected developments occur

Preparation needed for informed social debate

- Potential ethical and social implications need to be addressed early and involve industry, government, research, public and political groups and other stakeholders
- Scientists are poorly trained communicators and given little incentive to engage in ethical debate
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Data collection before regulation

- Requirement to share data and information to accelerate development of regulation internationally
- Voluntary schemes have the potential to establish good practice and support a co-ordinated approach to data collection
- Need to adapt elements of existing regulatory regimes which are applicable to nanotechnology

Multi-agent approach

- Identify incentives and motivations for agents to take up responsibilities
- Use existing international channels through organisations such as OECD and ISO to accelerate process
- Explore potential for international voluntary agreements on basis that good governance will benefit all parties


Swiss Re
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irgc
Jacques Aigrain

1
Introduction and Conference Overview

A stakeholder dialogue on nanotechnology

Introduction

This document reports on the discussions undertaken at the Conference "The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue" held at the Swiss Re Centre for Global Dialogue on the 6th and 7th of July 2006. Stakeholders from industry, government, research and civil society gathered to give feedback on the International Risk Governance Council (IRGC) White Paper[1] on Nanotechnology Risk Governance and to explore how its recommendations could be implemented.

The mission of the IRGC is to support governments, industry, NGOs and other organisations in their efforts to deal with major risks facing society and to foster public confidence in risk governance. It achieves this mission through targeted project work guided and implemented by members of the IRGC Scientific and Technical Council and other appropriate experts. The IRGC offers a conceptually robust risk governance framework and applies it to specific priority risk issues such as nanotechnology.

This conference facilitated by the Swiss Re Centre for Global Dialogue is a logical next step following the publication of the White Paper. The IRGC sees governance as a joint effort of industrial, public and civil society actors, often acting within inter-connecting networks and with the goal of making the best use of respective resources, skills and capabilities. Such an approach implies a transition from constraining to enabling types of policy and regulation, recognising that a top-down legislative approach regulating the behaviours of people and institutions in detail is not applicable to risk issues that are dynamic, global and that affect the deep fabric of our socio-political cultures.

Nanotechnology is developing fast, at a global level and presents mankind with the opportunity to manipulate the fundamental building blocks of the physical environment. As such it offers huge potential and raises many concerns. The challenge all interested stakeholders and organisations now face is to create a flexible risk governance framework which enables responsible development while minimising potential harm. This Conference was an opportunity to assess the relevance and applicability of the White Paper recommendations and start to map out how to implement them.

Creating a two frame distinction

Risk Perception: Frame One and Frame Two

Much of the conference centred on distinguishing two frames of reference for nanotechnology: Frame One, where many existing risk management approaches are directly applicable, but where developments are outpacing the regulatory framework and, Frame Two, where a set of new risks could emerge through the profound shift in technical capabilities that nanotechnology offers. This distinction was broadly welcomed but underwent robust scrutiny from all stakeholder groups. It was seen as a useful indicator of current priorities for governments and could help establish a sense of urgency on the issues of establishing standards and testing procedures and ensuring international co-ordination in the regulatory approach. On the other hand, the question of the relationship between the two frames arose: how to incorporate the debate on the ethics and desirability of the technology in Frame One, how continuity could be managed across the frames and whether additional measures are needed for Frame Two?

[1] Nanotechnology Risk Governance, White Paper no. 2 by Ortwin Renn and Mike Roco

Achieving standards and agreed nomenclature needs an intensified effort

The White Paper emphasised the critical role that Ethical, Legal and Social Issues (ELSI) could play in the development of Frame Two applications. Our societies are not well prepared for the breadth and depth of both benefits and challenges nanotechnology could offer and it is therefore important to address these issues today and not only when they have fully emerged. Stakeholders at the Conference felt strongly that this emphasis downplayed the role of ELSI in Frame One, leading to one suggestion of a Frame Zero in order to decide the ethical and social desirability of nanotechnology in any form at all.

So, while the stakeholder groups welcomed an approach that integrates traditional risk assessment with concerns about the societal implications of the technology, the need emerged to simplify the Frame One and Two distinction and enhance its communicability, without weakening its explanatory power.

Balancing speed, depth and precaution

Unlike genetically modified foods, nanotechnology offers the opportunity to implement a risk governance approach early in the development of the technology and its applications. To achieve this, however, requires action in the near term. Nearly every speaker emphasised the importance of achieving a standard nomenclature for nanotechnology and to set handling and testing procedures for industrial usage. Without intensified effort to agree standards and definitions it will not be possible for regulators to formally approve any regulatory framework. Despite some misgivings, it was also clear that voluntary systems within industries would play an important role, in establishing patterns for the collection of information and setting both minimal and best practice codes for different industrial application categories.

The precautionary principle was also discussed at some length. It was noted that there are many versions of this principle varying in strength and practicality. Additionally the idea of "precautionary science" and "precautionary research" were proposed to indicate the need for a fuller understanding of the potential impact of particular applications. Past negative experiences, such as that with asbestos, show the need to explore and understand new materials and applications before their implementation, in order to avoid devastating losses at a later date. There was also recognition that it is important when discussing potential hazards and their harm to place them in the full context of the benefits that may emerge.

How can the needs of developing countries be met?

Multiple perspectives

One aspect of such a stakeholder dialogue is the scope of different perspectives and views which must be engaged with and included in the process of decision making. Whilst the White Paper underlined the need to include all stakeholders and work at a global level, the group highlighted the importance of addressing the concerns of both developing and developed countries. The tendency to treat the pace and direction of technological development as inevitable was also challenged. For example, is it possible to bring the requirements of developing countries, such as nanoscale innovation in water treatment, energy and agriculture, closer to the top of the international research agenda? This could play a major role in shifting the existing pattern where developing countries are treated as secondary technology markets for applications designed and built for developed economies.

Each stakeholder goup is diverse in approach and values

Organisational challenges

Who or what organisations could take leadership in this governance process? The tendency of the White Paper to be didactic in assigning responsibilities to different actors was commented on. It faced the challenge that most stakeholder groups are by no means uniform in values or activities and that this approach tends to downplay the incentives of actors to help solve the problem. A recommendation emerged that IRGC focus on enabling the interaction of the different stakeholders: influencing through information sharing; establishing common frameworks; and highlighting the need for further investment in managing risks and setting clear priorities. Both the White Paper and this Conference are good examples of this process and were warmly welcomed as such.

All stakeholders have a role to play

The question of who can take leadership suggested a multi-agent approach. First the role of international organisations such as OECD, UNESCO and ISO is vital. Each has tried and trusted methods of establishing dialogue across borders, none of which is sufficient alone, but all of which could play a significant role. Second, national organisations will be important, often seeking agreement within their existing national institutions before accepting international regulation. Third, industry is motivated to collect and structure research in order to avoid a regulatory vacuum, understand the risks involved and avoid a potential backlash on the industry. It is important to balance the role of regulation as a competitive barrier to entry and important structural element in establishing a competitive market, with the reluctance of companies to share their intellectual property. Fourth, civil society organisations will play several roles as watchdogs, agitators, specialists and sources of important and valid questions and challenges. Fifth, research and academia need to help develop an understanding of how specific particles operate within set conditions and how the nanoscale environment operates as a whole.

Public involvement and dialogue

An additional organisational challenge arose of how to involve the public at large, not only in debate but in active decision making on issues of technological progress? Examples were given of "citizen juries" and discussions between scientists and the public. It was noted that scientists today are provided with no institutional or career incentives to engage in such debates. Particularly in the context of Frame Two, it was felt that the ethical and social challenges demand changes to existing organisational frameworks to allow the public to engage more fully in both the debate and decision making on the future desirability and implementation of specific technologies.

Collaboration & information sharing are key

Finally, the role of collaboration and information sharing emerged as a key enabler in helping organisations to learn, react and contribute quickly and with synergetic effect. Nanotechnology is leading to a convergence of scientific disciplines and cross-sector collaboration. Suggestions included an international clearing house for the collection and dissemination of relevant material and a clearer allocation of monies to further risk-related research that could be shared internationally.

Conclusion

Feedback following the Conference has suggested it was a success on several levels. First, it was an exemplary stakeholder dialogue. Second, it both endorsed the general direction of the White Paper and provided many useful comments and recommendations for improvement. And thirdly, it encouraged many parties to come forward and offer support for continuing this process, especially as questions of practical implementation arise. The IRGC will publish a Policy Brief on Nanotechnology Risk Governance in 2007, that will reflect the output of this Conference and other helpful discussions surrounding the White Paper. Further work by the IRGC in this field will then focus on the application of the Risk Governance Framework to individual nanotechnology applications and overcoming obstacles to its implementation.

1.1
Nanotechnology and the two frame distinction

Dr Mihail Roco, Senior Advisor for Nanotechnology at the National Science Foundation, USA

Characterisation of nanotechnology

The importance of Nanotechnology cannot be underestimated. It deals with the basic organisation of atoms and molecules where many of the properties of living and man-made systems are defined. This means it has the potential to transform the tools we use, medical treatments, our environment and indeed how humans themselves further develop. Nanotechnology can be defined as the control and restructuring of matter at the dimensions of about 1 to 100 nanometers in order to create materials, devices and systems with fundamentally new properties and functions. The consistent use of such a definition, and the avoidance of using the term "nanotechnologies" to also cover various products and applications developed using the technology, is to be recommended.

At the nanoscale matter operates within the probabilistic paradigm of quantum mechanics, so that down-sized materials of the same chemical elements can change their optical, magnetic and electronic properties. The tiny size also leads to an increase in the relative surface area of a molecular structure, meaning there are potentially more atoms on the edge of the structure, less tightly bonded and more able to react with the environment around them. The question therefore arises how well these new size-dependent and high-reactivity characteristics are understood?

Frame One provides a context for classic technology assessment

Introducing the two frame distinction

The two frame distinction is a heuristical tool to help prioritise risks and concerns and give a position from which to observe the dynamic development of the technology. The main implications for risk governance are the difference in the level of complexity and dynamic behaviour during use. Frame One is a context of classic technology assessment where one must look into the impact of nanoparticles in different areas of application such as paints, cosmetics, food and coatings. These are inert or reactive nanostructures that have stable behaviour and quasi-constant properties during their use. This type of assessment has been done at a social, scientific and regulatory level in a number of other areas. What is new here is that the particles and other nanostructured materials under scrutiny behave differently from the bulk substance from which they have been derived, and could penetrate cells and living tissues because of their small size. These new properties of course need to be properly researched as the knowledge base is currently insufficient. The new properties of the nanotechnology products in both frames must be considered in the context of potential uses and exposure rates. Also, the implications for the economy, workforce, safety, ethical and other societal aspects need immediate and specialized attention.

Frame Two presents deep questions of social and ethical desirability

In Frame Two, the active and more complex nanostructures and nanosystems, that may be integrated with Information Technology or Biotechnology, lead to new applications beyond the creation of discrete materials, better processes or production methods. This raises deep questions of ethical and social desirability, concerning changes in man-machine interfaces, ecosystems and the environment. There is also a transition between the frames identified at the beginning of the second generation of nanotechnology (see below) when active nanostructures begin to change their state or properties during use. How this transition will be dealt with needs further consideration within the context of the IRGC Risk Governance Framework.

As part of the development of the White Paper the IRGC undertook a survey exercise of the major stakeholder groups: Government, Industry, Research and Non-Governmental

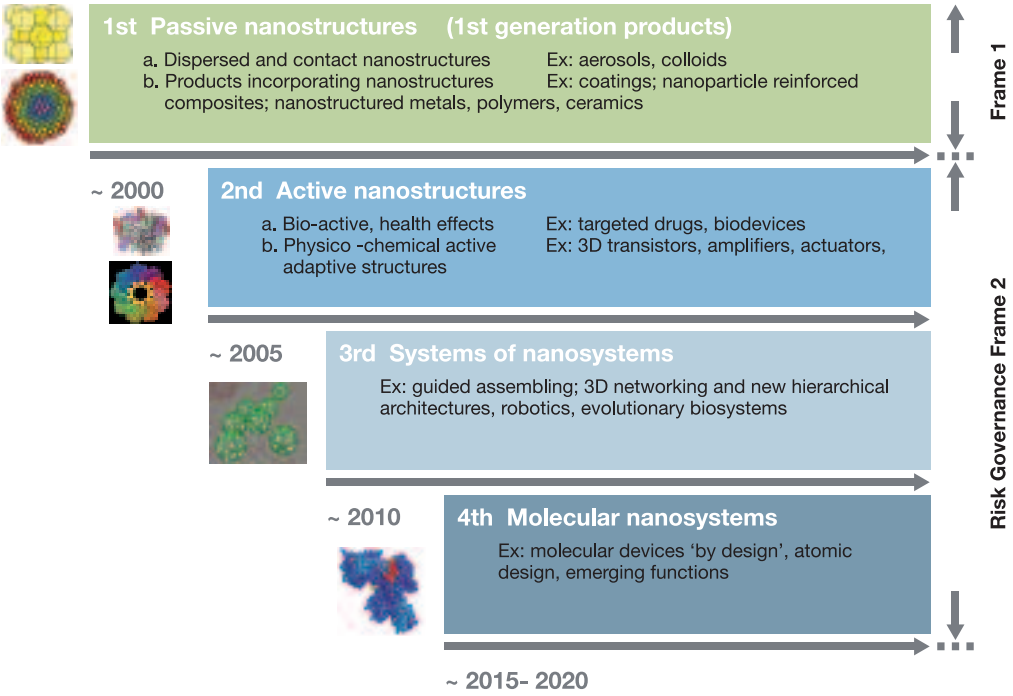
Organisations (NGOs). Interestingly the findings showed a strong emphasis on the environmental and health issues characteristic of Frame One. The NGOs also emphasised the ethical, legal and social implications (ELSI) and industry the educational issues, but overall security issues or the influence on human development were not considered highly relevant to nanotechnology governance. This may need to be challenged in the context of Frame Two.

Four generations of nanotechnology

The diagram below indicates the schematic path of nanotechnology, from the passive nanostructures produced today to molecular nanosystems of what is here described as the fourth generation.

In 2000 the estimate was made of a 25% per annum increase in markets with products incorporating nanotechnology. So far this estimate has proved more or less accurate, if anything underestimating the growth. Significant applications will develop after 2010 when the ability to measure and manipulate molecules and atoms has been significantly enhanced and standardised. The envisioned fundamental scientific and technological developments, that will lead to an accelerated rate of change, will require an adaptive, global governance framework involving industry, governments, civil and international organizations, NGOs, media and other stakeholders.

Four generations of nanotechnology products and production processes



1.2
Applying the IRGC Risk Governance Framework to nanotechnology

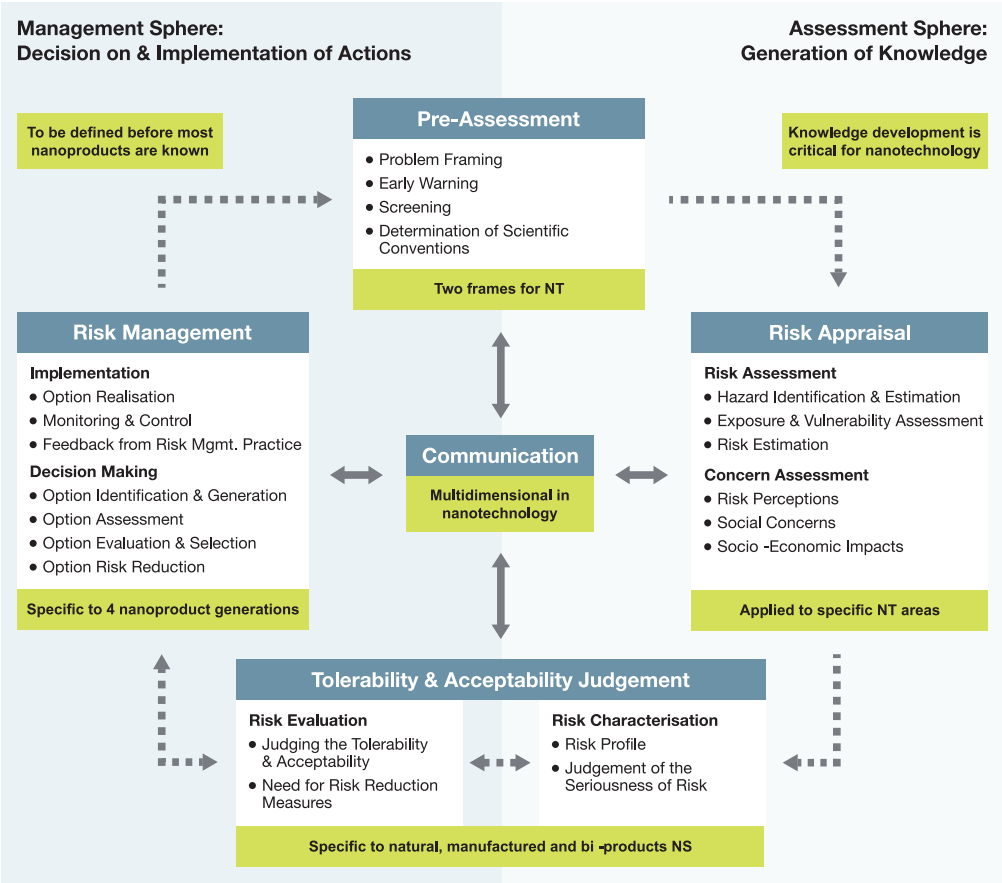
Professor Ortwin Renn, Chair of Environmental Sociology, University of Stuttgart, Germany

The general IRGC approach to risk governance adopted for the White Paper is based on developing a robust conceptual framework that is useful to decision makers from all stakeholder groups. It should help to generate risk management and policy recommendations at the national and global level, including, but not limited to trans-boundary and long term issues. The notion is to play a transformative role, avoiding uniform regulation or the creation of a centralised organisation to manage it.

Importantly, this framework actively recognises the potential importance of the social context in risk assessment and the central role that communication must play in such multi-stakeholder situations. It also seeks to be iterative, allowing review, correction and adaptation according to the changing conditions.

Within the IRGC Risk Governance Framework there are two new elements which should be highlighted. The first is the idea of a Pre-assessment in which the way that the question and consideration of particular risks is constructed can be reviewed and discussed and the second is a Tolerability and Acceptability Agreement, which is an explicit way to review how a technology relates to social concerns. It is important here that this agreement is explicitly dealt with as a discrete step rather than made on an implicit basis.

IRGC Risk Assessment and Management Framework for Nanotechnology



NT = Nanotechnology, NS = Nanostructures

The two frames help made a pre-assessment of risks related to nanotechnology

The creation of the two frames relates to the first step in the Pre-assessment phase of the IRGC Risk Governance Framework which is called "Problem Framing". Two distinct phases in the development of nanotechnology and its form of application have been identified as described above.

Risk Appraisal

Three concepts that have a strong explanatory power within all the IRGC risk frameworks are Complexity (assessing causal and temporal relationships), Uncertainty (unclear knowledge about quantification and system boundaries) and Ambiguity (in interpreting results). The risk appraisal process includes the classic risk assessment process but also makes explicit assessment of social concern, looking at the context in which the risks materialise and how this influences the socio-economic impact, the hopes and the risks perceived by various stakeholders and individuals.

For nanotechnology, Frame One presents primarily Complexity issues, with some Uncertainty questions, whilst Frame Two increasingly introduces additional questions of Uncertainty and Ambiguity. Frame One, then requires a classic risk assessment approach looking at, for example, the workplace, the public, and the environmental media, water and soil. This is a similar approach to the assessment of other potentially toxic materials. With regard to the questions of social concern, initial surveys suggest that people do not have strong opinions yet on nanotechnology but there are the usual concerns on the introduction of new technology regarding harmful side-effects. One issue that arose in qualitative interviews is the need for a distinction between those who propose and promote a technology and those who regulate it. It is important to have overt checks and balances.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2
Overview of issues in Nanotechnology Risk Governance

2.1
Innovation and good governance

Fritz Gutbrodt, Head of Swiss Re Centre for Global Dialogue, Switzerland

- **Important to take steps towards shaping public risk perception of nanotechnology**
- **An integrated governance approach supports sustainable innovation**

Today, with approximately 300 products internationally available, the nanotechnology market remains small in all senses of the word. Estimates contained in the IRGC paper, however, suggest as early as 2015 over 2 million workers will be engaged in a US$ 1 trillion industry. Such rapid growth of the technology and its applications calls for a risk governance framework that can support effective planning and enable investment of all types in this new market. In this sense, the IRGC initiative is a perfect example of how risk governance can be considered an integral part of the innovation process for the benefit of all stakeholders.

This conference is also a step in shaping public risk perception on nanotechnology. Given the powerful role of information and media in our society it is important to engage in shaping the discussion on the risk perception of different stakeholders where and whenever possible, whilst also recognising that the task of managing such perceptions presents a considerable risk in itself, as well as an attractive opportunity.

Risk governance can be considered an integral part of the innovation process for the benefit of all stakeholders.

Finally, as the conference has drawn together many parties from differing stakeholder positions it is an opportunity to recognise that exploring the potential of nanotechnology is more than to forecast a boundless blue sky of future opportunity. Indeed one must actively anticipate weather of all types, flexibly responding to what actually occurs and what can be predicted, rather than simply what is either wished for or feared. In this way all can play a part in ensuring risk governance keeps up with and is integrated into the development of nanotechnology over the years to come.

2.2
Comprehensive, fast and global action

José Mariano Gago, Minister for Science, Technology and Higher Education, Portugal

It is necessary to define and execute actions with regard to nanotechnology that are comprehensive, global and fast.

- **Governance activity needs to be comprehensive, fast and global**
- **Potentially a good time to re-visit the precautionary principle**

The IRGC offers a global platform for the advancement of risk governance. It is an independent body that includes a network of diverse and interrelated social actors including government, industry, research and non-governmental organisations that must come together to advance governance. With nanotechnology there is for the first time the potential to implement a new technology with a sound risk governance strategy from the beginning. But for this to happen it is necessary to define and execute actions with regard to nanotechnology that are comprehensive, global and fast.

The response must be comprehensive because scientific results suggest that nanotechnology shall be materially more invasive than Information Technology and Communications (ITC). Indeed, it could have as profound a material impact as the scientific chemistry of 100 years ago. The answers must be global in scale because of economic globalisation. Whilst national policies can solve local critical infrastructure problems, they cannot alone deliver effectively on such a global issue. And fast, because if not dealt with quickly, there is the danger of repeating the type of mistakes seen with genetically modified organisms in the 1990s. The potential economic impact of poor risk governance is clear but there are also other risks too, including the potential delay in implementation and useful development of nanoscience.

The risk governance debate should also be seen as opening up new opportunities. This is important because increasingly innovation and risk governance are part of the same process, as with regulation and competition. This is true for competition at the company level, and also with regard to political developments where the time may well be ripe for a new discussion of the precautionary principle and how it can be used in the context of nanotechnology.

IRGC will hold its International Conference in Lisbon in October 2007 at the same time as Portugal is President of the European Union, also allowing risk governance issues to be integrated into the political landscape.

2.3
The need for a deeper understanding of nanotechnology

Werner Schaad, Head of Product Services, Swiss Re, Switzerland

- **Nanotechnology risks are currently covered under a wide variety of insurance policies**
- **Nanotechnology specific perils cannot be quantified due to their ambiguity, complexity and uncertainty, as well as a lack of loss history**
- **Future nanotechnology underwriting measures must be based on a legally sound definition, grounded in risk characteristics unique to nanomaterials**

Novel technologies have one aspect in common: their possibilities, and their inherent risks, are only just beginning to unfold. As an enabler of risk taking, the insurance industry focuses on understanding these risks in order to help its business partners to mitigate the financial consequences of possible losses. Nanotechnology offers enormous innovation potential and encompasses many disciplines. And as with acceleration and miniaturisation in information technology, technological convergence in the nano-sphere will be both a global challenge and change daily life.

The insurance industry is finding it difficult to evaluate and measure the surge of nanotechnology. Today, there is no loss history available so that insurers have less influence on the risks they are asked to cover, and are highly sensitive to change and uncertainty, possibly in advance of other stakeholders. The limited possibility of comparison with familiar patterns of risk and its financial consequences means going beyond classical actuarial methods.

Zero risk is not the goal, we must seek to quantify and understand the risks, even when they appear unclear.

To be insurable, risks must be calculable and accepted by the majority of the public. But what is "risk"? Risk is a household term, that everyone uses and has an idea what it means. But do we all understand it in the same way? As a concept, risk includes both the notion of threat or peril, things to avoid, and the antonym of such dangers, opportunity and benefit. Although a positive stance prevails today, not least because risks are largely unexplored, a fundamental technological change sooner or later also triggers resistance, apprehension and an elevated need for safety.

Risk Management is a balancing act between threat and opportunity. If risk is difficult to assess, it does not only influence insurability, but also public risk perception. The difficulty we face with nanotechnology is that the peril aspect cannot be quantified due to the ambiguity, complexity and uncertainty surrounding the subject. For example, what is the causal relationship between nanoparticles and certain health effects, how can it be measured and what tolerance limits need to be set?

Materials often change their physical properties fundamentally when manufactured at the nanoscale. This, however, does not necessarily make them harmful. The challenge for science is to establish criteria which will facilitate identification of the novel and potentially harmful properties. Nanoparticles can accumulate in the environment and in human organs through time and may have serious health and ecological implications. These aspects are currently not well analysed, described or understood. Thus, the insurance industry is interested to participate actively in shaping both a risk governance and legal framework. There is some urgency involved, since progress is gathering pace and nano-based products are already widely used in both industry and consumer goods.

Currently nanotechnology risks are covered under a wide variety of insurance policies such as product liability, general liability, professional liability and workers' compensation. However, the portion of nanotechnology in existing acceptancies is unknown, largely due to the fact that nanotechnology is neither exactly defined nor separately accounted for. Whatever underwriting measure is considered, it is bound to the need for a legally sound definition of the borderline between what is nano, and what is not.

Making broad and blanket underwriting decisions about exclusions or other contract adjustments is complicated by the fact that the various nanotechnologies encompass a broad array of particles, products and manufacturing methods with very different risk characteristics. On the other hand, however, there is no reason so far to target particular applications.

Since it may take years to establish a direct relationship between exposure to certain manufactured nanoparticles and health and environmental effects, Swiss Re emphasises the importance of intensifying nanotechnology risk research and that the precautionary principle be applied to the implementation of this new technology. This includes an increased examination of risk characteristics specific to nano materials, in order to keep pace with the development and marketing of new products.

There is also a need to improve and standardise the accepted terminology base, including definitions of how one measures, tests and validates within the nano environment. And common risk governance rules, processes and approval procedures must be developed in the sense of who is responsible for approving what. Finally and, in the spirit of this conference, it is necessary to seek co-operation between all stakeholders, to provide a transparent framework that will help to manage the development of nanotechnology in a beneficial and safe manner.

2.4
Dialogue and questions

This section reflects the key questions, comments and debate undertaken at the Conference after the Introductory presentations.

Beyond the Precautionary Principle?

It is important to understand the context in which the Precautionary Principle is being applied.

There are at least 18 working definitions of the Precautionary Principle, ranging from weak to strong so it is inaccurate to talk about the Precautionary Principle without further qualification. It is essentially a political tool, in the good sense that it helps make life possible in a social environment. Of course it is primarily used in the regulatory context and plays an important role in making individuals feel confident about the type of decisions being made. When it is applied however, it is important to recognise the competition, both economic and political, which is going on in the background. For example, the need for politicians to match the application of the principle to prevailing economic circumstances in order to satisfy voters and their parties within a country: at a time of high unemployment a politician will not want to be exposed to accusations of blocking progress or the creation of new jobs, for example or may support strong regulation without considering the long-term ecosystem implications.

This calls for a move beyond a simplistic application of the Precautionary Principle, so that a type of segmentation can be undertaken. And it suggests that the competition going on behind what appears to be a very safe principle should be made more transparent.

From Precautionary Principle to Precautionary Science?

The Precautionary Principle is an international legal principle operating within a prescribed context and generally being applied to a particular technology under review. To move beyond this may require another approach that asks whether science cannot operate in a more precautionary way altogether? For example, do we need the proposed new product? Is there another solution? Are there implicit environmental and health issues at stake? This approach seems better suited to the Frame Two issues that are being outlined and it would be helpful to ask if the organisational structures exist for addressing the issues in this light?

Do the organisational structures exist to support a precautionary approach?

Which Precautionary Principle to apply and how?

The suggestion above reflects the on-going debate about how scientific integrity is moving from the individual to the organisational level. But it is perhaps also important that the focus here is not on agreeing on the precautionary principle in general, but that there is a decision on what type of organisation is needed to assess and discuss specific governance approaches to safety that can be applied to specific applications of nanotechnology and how this can then be reviewed through time.

Democratic structures

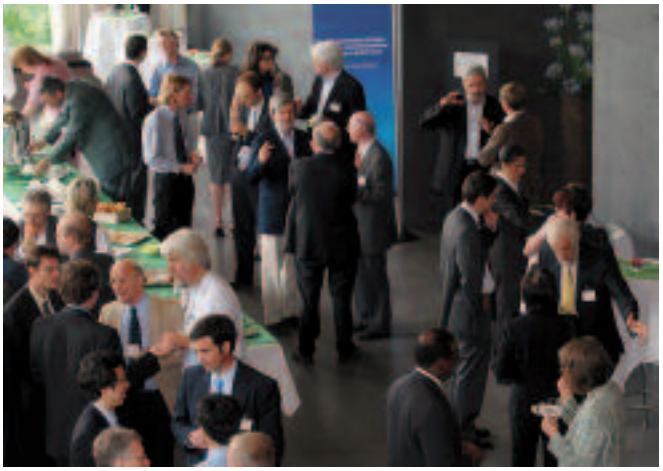
Nanotechnology presents a challenge where society will be faced with complex issues and decisions and requires information and education to address them. This is important because the large investments required for nanotechnology also have unexpected secondary effects, as well as military and other less transparent applications. Such applications are always bound up with security and safety questions, and imply a high level of secrecy. It is therefore important that the scientific and technical discussion is had now so that our democratic institutions are in the right position to understand the issues and control both military applications and the tendency towards any independent and secret activities.

Transparency and accountability are critical terms in this discussion.

Transparency and accountability are critical terms here. We need methods to address both the positive and negative potential of nanotechnology and that calls for us to develop the right regulatory and organisational structures today, so that we are prepared to deal with new applications as they emerge in five or ten years time.

Where do the real risks lie?

Most organisations including governments and NGOs that are considering these issues have focused on risks associated with the first generation, generally presented by nanoparticles and that definitely need to be addressed in the next few years. They are not however, preparing for the potentially revolutionary products that could emerge in the next five to ten years.



3
Stakeholder Perspectives on Frame One Nanotechnology Risk Governance

3.1
Industry

Dr Nora Laryea, Manager Quality Control, Nanobionet, Germany

Industry safeguards for nanotechnology processes are currently based on the behaviour of particles at the micro-scale.

- **Identify and categorise isolated nanoparticles with full descriptions of their health effects**
- **Create clear guidelines for the safe handling of materials based on their properties as nano particles**

A key industry application for nanotechnology today is the generation of high performance coatings. Such "nanocoatings" have many advantages introducing new levels of corrosion and abrasion protection, self-cleaning surfaces, anti-fog effects and anti-fingerprint or surface markings, to name a few. Among others, the automotive industry is interested in the development of these products. The key steps required to create the nanocoating begin with the creation of the nanostructures through hydrolysis and condensation. The resulting coating solution is applied through spraying, flowing or roller coating and cured using light to create the "nanocoating". Such a process generates no isolated nanoparticles and the nanocoating is in a form where the molecules are tightly bound together in inorganic-organic binder formulations, meaning the nanoparticles cannot, at least in the short term, be isolated and break out into the surrounding environment.

For workplace safety, there are several potential points of contact between humans and the nanomaterials which are today safeguarded by use of the recommended protection equipment and correct handling of processed materials. These safeguards are based on the behaviours of the materials at the micro scale as this is well researched, but may not fully reflect behaviour at the nanoscale. They include the handling during processing, application techniques such as spray coating and the handling and treatment of wastes.

This type of process generates no powders with nano dimensions, only solutions that are bound using organic solvents. However, there is a more general need within industry to identify and categorise isolated nanoparticles with full descriptions of their health effects, safe exposure limits, handling conditions, waste treatment and in what types of application process they can be treated.

Summary of Frame One Industry Workshop

Dr Terry Medley, Global Director of Corporate Regulatory Affairs, Dupont Environment and Sustainable Growth Center, USA

- **Frame distinction is a useful yardstick to set priorities**
- **Real risk evaluation will occur at the application and product level, not that of the frames**
- **Hazard and exposure assessment is a priority**
- **Further training required for scientists in risk communication**
- **Industry will want to avoid a period of regulatory uncertainty**

The distinction between Frame One and Frame Two creates a useful starting point for discussion on the regulation of nanotechnology. At the simplest level it creates a sense of focus by distinguishing between the product groups and approaches which are becoming available today and those more complex applications that will emerge tomorrow. Of course there is the issue of how the transition between the two frames is to be thought of and it remains important that the real evaluation must be of the risks emerging from potential products and applications and not of the frames per se. But it is a useful start.

A useful addition to Frame One would be the potential interaction of nanotechnology products with living systems, including any cumulative or adverse effects. It is also important that the risk governance framework continues to evaluate and adjust within the context of Frame One in the light of new knowledge. This should be seen as an on-going obligation.

Hazard and exposure assessment is a priority.

It is important that the risk management is set in the context of the best practice in risk assessment methodologies and guidelines today. With risk communication, both the benefits and the risks, for example, new functional properties or non-intended side effects must be communicated. This plays a vital part in establishing trust with the public and develops good practice, encouraging transparent behaviours that will in turn create more trust. It would be helpful in the case of risk communication to state more explicitly the objectives of a communication and decide on priorities within the communication in the light of the stated objectives, otherwise one is only left with a "checklist" of useful elements. Certainly some training for key scientists is also required, to support in this risk communication process, possibly with a preventative and not only a reactive approach.

Government clearly has a key role to play but given the constraints under which it acts it seems unwise to leave it to take the lead or act alone. That all parties need to be involved and take responsibility seems to be the only practical implementation option. From the industry perspective it is important to avoid a long period of regulatory uncertainty, but also to recognise that regulation relies on the collection and ordering of data and standards and needs industry to engage in responsible development from the very start. Hazard and exposure assessment is a priority.

Finally, some comments and watchwords emerged in conversation that may connect with other comments made during the conference: China? One size does not fit all. What is the role of the military? And how can one avoid burdensome, non- risk based and repetitive regulatory processes?

3.2
Government

Elizabeth Surkovic, Head of Branch, Risk Management: Nanotechnology and Chemicals and GM policy, Department for Environment, Food and Rural Affairs, UK

- **UK Government approach currently focused on Frame One**
- **Evidence gathering is a critical step to any form of control regime**
- **Industry developed "good practice" guidance important**
- **Objective to create a national view whilst working in collaboration with international bodies**

These comments shall deal with nanotechnology from a UK government perspective as opposed to purely from the Department for Environment, Food and Rural Affairs (Defra). That said Defra has a clear aim in this area to promote the responsible development, use and fate of deliberately engineered nanoscale materials. This indicates that the basic approach is towards Frame One issues and certainly towards the earlier generations of nanotechnology.

This aim will be achieved through an evidence based approach, developing a method to control deliberately produced free engineered nanoparticles, whilst not hindering the progress and competitiveness of UK industry. In practical terms this means the UK Government will press industry to develop cross industry "good practice" in the manufacture, use and disposal of nanoparticles and that UK companies will be inspected against these guidance documents and are expected to comply with or exceed the stated benchmarks.

The UK Government will press industry to provide evidence via a Voluntary Reporting Scheme to ensure that evidence is gathered as quickly as possible, to come to the most appropriate form of control.

The UK Government is undertaking research in five areas: Metrology, Exposure, Mammalian hazard and risk, Environmental hazard and risk and Social and ethical issues. It is felt that these Ethical, Legal, Political issues (ELSI) are also important within Frame One. Research will be reviewed every six months with the first information available in September 2006 and a fundamental review in 2008.

The UK Government has also undertaken consultation on a Voluntary Reporting Scheme. Initial findings suggest that this is welcomed within this data gathering phase, though some civil society organisations pressed for something more than a voluntary scheme. An international perspective and harmonisation of schemes was felt to be important and industry also proposed that further work was required on Intellectual Property issues and how sensitive data could be protected. There was a consensus that research institutions should be involved in such a voluntary scheme. Finally, it was also felt that it is critical that the definition of "nano" is worked on.

UK Government is forming a national view, always seeking to work in a collaborative fashion with the EU and OECD. But the approach, currently different from IRGC, would be to have a framework of equivalence of control, based on national policies, allowing individual states or regions to determine what regulation would be required. Final comments on the White Paper would be that the Frame One and Two split is interesting and needs further discussion. The UK Government is currently focused on Frame One and needs to review how to approach Frame Two. We would perceive our attempts in the UK to act as a test bed for many of the proposals and ideas that IRGC is helpfully proposing.

Summary of Frame One Government Workshop

Pontsho Maruping, Acting Chief Director, Frontier Programmes, Department of Science and Technology, South Africa

- **Two frames useful in discussion and indicate where existing regulation may be applicable**
- **Distinction may, however, be too complex to implement**
- **Governments must work at transparency to build public trust**
- **Information sharing will be critical**

Within the context of these discussions the two frames distinction can be helpful, especially in indicating where existing regulation may or may not be applicable. The distinction may, however, be difficult for the public to interpret and the media will always connect what is happening today with potential future developments. This suggests the two frames will be difficult to implement and would need to be treated as a continuum with a more adaptive element. The roles of the stakeholders need to be made clearer so that the public understand where the responsibility lies. Existing regulation is not always very effective, so its usage for nano is not always straightforward. It is also not clear whether Intellectual Property is clearly dealt with and ethical, legal and social issues also need to be addressed in Frame One.

Governments need to improve their transparency.

Governments need to improve their transparency in order to create the basis for greater public trust. There is a difference between the public and the representatives of the public. Often, not enough is done to speak directly with people to understand and deal with their concerns. International co-operation on key issues is going to be important, such as with the OECD and regulators are going to have an important leadership role. Clearly the sharing of information is also going to be important and one suggestion that emerged was that of creating national clearing houses to facilitate cross-border exchanges. Trans-boundary recommendations are critical, as is the ability to adapt existing regulations.

3.3
Civil Society

Dr David J. Grimshaw, International Team Leader, New Technologies Programme, Practical Action, UK

- **Risk profiles differ between developed and developing countries**
- **Nanotechnology could both improve and save lives in the developing world**
- **It should be asked: is this technology needed and in what form?**
- **Ethical and social issues must be addressed in Frame One**

Giving an NGO perspective in this context is an opportunity to look at issues from another position. This is because the relative importance and prioritisation of risk and governance issues is going to be different according to whether you approach them from a poor developing country or a rich developed one.

There must also be some consideration of the risks of ignoring the needs of poor people regarding such a vital new technology. How much more terrorism may follow or natural disasters? Instead of regarding the poorer countries as in deficit, where one simply attempts to plug the deficit gap based on richer country criteria, would it not be possible to seek to understand and support their requirements from within their own frames of reference? A survey by Toronto University in 2005 identified that the top three nanotechnology applications that would help the developing countries are: energy, agricultural productivity and water treatment. Such technologies can play an important part in the battle to reduce poverty if their potential impact is considered now and in the right way.

We should work towards a world where science-led new technologies deliver products which fulfil human needs rather than market wants. It is critical that the ethical and legal issues get included in Frame One.

There is a need for a greater democratisation of the decision making that leads to technologies being developed. It is possible to determine research and development priorities with greater citizen involvement, rather than introducing the broader community into the debate on how to live with technologies that have already been developed and implemented to maximise profit and not to meet needs. We should work towards a world where science-led new technologies deliver products which fulfil human needs rather than market wants.

Regarding the top level structure of the White Paper, the notion of the four generations is helpful, although the time-line may need adjusting. But it is critical that the ethical and legal issues get included in Frame One and, indeed, that the question of risk governance manages to transcend that of the two frames.

Summary of Frame One NGO Workshop

Dr Richard Denison, Senior Scientist, Environmental Defense, USA

- **Traditional risk assessment underplays the level of uncertainty in nanotechnology**
- **Where is the debate being had on the social desirability of various nanotechnology applications?**
- **Ethical and legal issue must be fully integrated into Frame One**
- **NGOs must play a full role in Frame One**

It is important to recognise that the term NGO covers a range of organisations and interests that are by no means monolithic in their values or approach. The traditional risk assessment paradigm is presumed a sufficient basis for decisions in Frame One, and this creates a set of problems. These include an effective exclusion of ethical, legal and social issues (ELSI), or dealing with them only after the fact, and a failure to address the real-world existence of cumulative, multi-source and life-cycle exposures within the paradigm. The existing risk assessment paradigm systematically downplays uncertainty, which is currently especially high in the case of nanotechnology. "Re-negotiation" of this existing framework then is required to ensure that ELSI issues are fully integrated and that the value judgments and assumptions are acknowledged. This extension of the framework to include a broader set of "risk" issues is acknowledged and initiated in the IRGC Pre-Assessment and Concern Assessment phases.

The existing risk assessment paradigm systematically downplays uncertainty and masks value judgments and assumptions.

Above all else, the existing risk assessment paradigm limits the potential of having a genuine debate on how we assess the desirability and acceptability of technology and impedes providing "technology choice" in both developed and developing countries.

Meaningful inclusion of NGOs and representatives of civil society in Frame One is also an issue. NGO responses to perceived or actual exclusion vary: Some see little choice but to force their involvement, while others emphasize the kinds of expertise NGOs can offer. NGOs can also play a valuable role in promoting transparency, and in getting systematic feedback from and helping to inform the public, though not always on the terms that will be easy for other stakeholders to embrace. In their watchdog role, NGOs also have a responsibility to ensure the accountability and justification of Government decisions.

3.4
Research

Professor Katzuo Katao, Ochanomizu University, Japan

- **Hazard assessment is difficult because measurement systems are not fully developed at the nanoscale**
- **Is there enough hazard assessment research in proportion to the overall investment in nanotechnology?**
- **Frame distinction can help governments set priorities**
- **International bodies can support governments and regulators that are struggling with lack of knowledge**
- **Voluntary industry schemes must play a role due to lack of data for regulation in the short term**

The key question under consideration in this presentation is what sort of research is required to lay a solid foundation for regulation in the field of nanotechnology? There are several examples of animal testing data that indicate nanoparticles have a stronger toxicity than larger particles of the same chemical formula. This indicates that there may be specific properties relating to size or the surface treatment of nanomaterials that can lead to greater toxicity, something that cannot be ignored in the development of safe handling procedures for nanomaterials or by the regulatory framework in which they are further developed.

The evaluation methods are not in place for assessing any size-dependent risks which could arise when existing chemicals are reproduced at the nanoscale.

Is there sufficient hazard assessment research in proportion to the overall investment in developing nanotechnology?

There are many ideas regarding how to regulate the field of nanotechnology, from nothing needs to be done to strong restriction. Whilst the Japanese regulatory control system for new chemical substances has the flexibility to be applied to nanotechnology, there are challenges that the field presents which need to be addressed.

Hazard assessment is difficult to make within the field of nanotechnology because the measurement systems and procedures used for larger scale substances are not fully developed within the nano field. For example, notification systems are currently triggered by weight for production, which would not necessarily be applicable to nanomaterials. These would fall into the category of small quantity exception when applying for status as a new chemical substance. The evaluation methods are also not in place for assessing any size-dependent risks which could arise when existing chemicals are reproduced at the nanoscale. To change this situation requires an assessment of whether sufficient investment in safety and hazard assessment is being made in proportion to the research and development budgets allocated to nanotechnology.

Overall, then there are two major issues which arise in considering regulation in the field of nanotechnology. Firstly the lack of knowledge in implementing evaluation and measurement procedures and second the need for a type of social and economic decision as to the value of this new field.

Regarding the specific recommendations of the IRGC report, the distinction between the Frames is both helpful and indicates where the emphasis must currently lie. The role of government leadership in regulation is critical and this will be strongly supported and facilitated by international cooperation and the active participation of organisations such as the OECD. Such international organisations can not only disseminate knowledge across borders and help harmonise testing guidelines. They can also help change the current passive position of governments that are struggling with lack of knowledge and resources in the area.

Lastly, given the lack of research in the field it is impossible to take an immediate step towards full regulation of the nanotechnology field. The types of voluntary schemes which are under consideration in the US and UK therefore are an important step at this time. Meanwhile, there is a need for very careful handling of materials whose toxicity profile is not yet fully understood.

Summary of Frame One Research Workshop

Dr Vicki Colvin, Director, Center for Biological and Environmental Nanotechnology,
Department of Chemistry, Rice University, USA

- **IRGC should influence actors to get involved in an integrated approach**
- **Split responsibility by competence and motivation to do a good job**
- **More money needs to go into fundamental research of nanoparticles**
- **Frame One must include the ethical debate and NGOs**

Information and research

Whilst nanotechnology is new there is a considerable body of knowledge available from existing research fields that could support early development of standards and good practice. Surface chemistry, research on skin, metal oxides, nano-data storage and the extensive occupational health literature would all be helpful in creating solid hypotheses for further testing. Currently a small percentage of such information is collected and reviewed. One issue is that much of this existing information is about micro substances and does not cover what occurs differently at the nanoscale. In the 1990s there was much research done on particles, for example, in the lungs, but nano particles present issues, for example, of transferability from the blood to the brain which is a very large shift and not well understood.

Predictive toxicology

Let us identify the incentives for players to be involved and divide activities according to skill and experience.

More basic research is required to develop models capable of predicting how nanoparticles will respond. Approaching it by testing simply what particle "x" does in situation "y" will be too narrow and could lead to an unrealistic and cost prohibitive attempt to test each particle in each situation.

Intellectual property and information disclosure

Currently exposure and usage data is very lean. Access to industry data will be influenced by concerns over losing competitive advantage, but again there is existing experience of legal mechanisms to manage the use of data and assess the fair use of other organisations safety studies. Given the important role the military is set to play in nanotechnology there must also be recognition that secrecy and conflicts of interest will influence disclosure. Also, small innovative companies will not prioritise disclosure because of cost and time considerations.

Stakeholder diversity

One comment on the construction of the report was the tendency to treat the stakeholder groups as monolithic, internally consistent in their values and views.

Two-way model

There is a tendency for the tables in the report to be didactic, telling actors what to do, rather than seeking an integrated solution that would identify who has what competence and how can they communicate with other stakeholders.

Delaying the ethical debate?

Concern that the Frame One and Two distinction gives the impression that Frame One is relatively straightforward and it is therefore possible to postpone the ethical debate until Frame Two. The role of NGOs as watchdogs in Frame One is similarly underplayed.

Co-ordinated effort divided by competence

One suggestion was to apply the type of model used on the Human Genome project. Here different countries took responsibility for different areas of research based on their interest and competence. Rather than seeking to attribute responsibility to stakeholders, this model has the benefit of drawing on the incentives for players to be involved and divides activities according to skill and experience.

3.5
Dialogue and Questions

This section reflects the key questions, comments and debate undertaken at the Conference after the Frame One presentations.

Voluntary reporting schemes

What is industry doing to develop good practice?

The exploration of voluntary regulatory schemes is one of the only options at this time. This is simply because there are statutory rules demanding that sufficient evidence must first be available before any form of formal regulatory system can even be proposed and following this, more time is required to finalise and put the regulatory system into practice. For nanotechnology this evidence is currently not available and even if it were, there would still be a significant time interval before establishing new regulations.

Such a voluntary scheme runs on the basis of good rather than best practice. It is the responsibility of industry to propose this good practice and, once it has been tested and validated, this becomes the minimum standard by which players in the field will be assessed. This means that there is no attempt to confirm that either all the players in a particular field or all the data available are known. At this stage in the development of such a scheme industry must be urged to consider what it is doing to develop such a code of good practice.

In response to the question of whether the size of particles was included in such a scheme and whether UK companies were accepting a self-declaring labelling system for products, the importance of achieving a tight definition of nanotechnology was again emphasised. Size was envisaged as a potential key criteria in such a definition, but was still under discussion from a practical perspective. At this point a labelling system was not envisaged because of the threat of false marketing, that is companies seeking to exploit the "nano" label or avoid it, for example because the particles are 101 nanometres and therefore 1 nanometre too large, although carrying essentially the same risk characteristics.

Watchdog role in Frame One

NGOs can play different roles in each frame.

Concern was expressed at the role of the NGO or civil society in Frame One. It is currently described as a "watchdog role" rather than one of full participation. The issue is that if not fully involved, an NGO will resort to using media channels to have their voice heard. The envisaged role of NGOs in Frame One could be considered more broadly. Some NGOs are independent watchdogs and definitely do not want to be part of the system. This can also be acknowledged as an important role. In Frame One it is envisaged that NGOs can bring, for example, specific toxicological and epidemiological knowledge as part of a risk appraisal team. NGOs also have a role in the risk evaluation phase when the trade-offs between hazard and benefit are made. In this phase it is not just their specific expertise which is welcomed but also their view of what is good for society and how this may be reflected in the trade off assignment.

There is also a need to treat the notion of participation with caution, however politically correct it is. Money and time remain scarce resources. It is important that the time involvement of NGOs is also valued and appreciated and that their often limited resources are used effectively for the overall process.

The ethical question remains of how risks and benefits are distributed.

Frame One and ELSI risks

While the Frame distinction is useful, there is a danger that it seeks to protect Frame One passive nanostructures from certain types of questions that relate to Ethical, Legal and Political Implications (ELSI). For example in the case of a sun-screen, there is not just the question of whether the nanostructure is harmful or not, but also whether other solutions have been assessed and whether the nanostructure brings significant improvement in performance? In this sense, even in the case of passive nanoparticles, the question remains of how risks and benefits are distributed and this is essentially an ELSI question. While a deep and important concern, the issue remains, however, that within a consumer-driven, market-led economy it is the individual that decides not the society. Only where third parties may be harmed do governmental structures step in and regulate.

The issue is that risks and public benefit remain external factors to the market economy system and are therefore not directly calculated in any cost-benefit estimations. Would it be possible to follow the principle that only if we are not making anyone worse off, either in the developed or developing world, that the new technology should be applied?

Global stakeholder vs. country or regional perspective

The distribution of risks is different between developed and developing countries.

While the passive and active frame distinction may be useful from a governance point of view, does it deal with how risk perspectives differ between developed and developing countries? This is particularly important because globally the distribution of risks is tied to specific country and regional characteristics, not least of which is economic wealth. The White Paper may need to further strengthen this aspect.

Precaution and Intellectual Property

The transparent flow of information plays an important role in citizen trust.

An underlying concern was the willingness and ability of larger corporations and nations to share data on toxicity when their intellectual property is embedded within the product and may become available to direct competitors. From an emerging nanotechnology industry viewpoint, this must be balanced against an urgent need for the characterisation of nanoparticles and more data on how one may come into contact with them. Currently industry test procedures and equipment are still operating with traditional methods and equipment used at the micro-scale because new ones are not available.

There is also a strong public interest in the dissemination of both technical data and that targeted directly at broader stakeholder groups. The public trusts that via the transparent circulation of information there is a sufficient number of groups to play a watchdog role and cry foul if something is not right. The transparent flow of information therefore plays an important role in citizen trust in our social institutions.

From a developing market perspective, can industry work in partnership with developing markets, creating new business models to share their intellectual property in a way that ensures the most needy have access to technology to eradicate real suffering and poverty?

4
Stakeholder Perspectives on Frame Two Nanotechnology Risk Governance

4.1
Industry

Del Stark, CEO, European Nanotechnology Trade Alliance (ENTA)

Industry has a strong interest in promoting a good standards regime.

- **Case-by-case approach is important for nanotechnology governance**
- **Joint research between industry and science will be critical in building evidence based approach**
- **Industry has a strong interest in promoting a good standards regime**

ENTA is a European trade body consisting of both major industrial and new nanotechnology companies. It believes in the need to be responsible custodians of this exciting branch of science and will seek to ensure a fair regulatory and competition framework that will enable the EU to compete on the world stage.

It is important when assessing nanotechnology that both the benefits and the risks are taken into account and that this is done on a case by case basis. While public debates are a good thing, they can become very emotive and it is therefore important to provide facts and evidence and reach decisions on this basis. In particular, careful use of language is required to avoid use of terms such as "unstable" which can shake confidence in new developments.

Industry has a strong interest in promoting a good standards regime. Already all chemicals require documents called Material Safety Data Sheets that describe relevant known hazards, indicate handling procedures and accident responses. They are fact-based and call for appropriate data interpretation. This means it is critical to initiate unbiased evidence based analytical research conducted jointly between leading industrial and academic scientists.

This evidence based approach is also critical to support the harmonisation of environmental, health and safety regulation related to nanotechnology and support the removal of bottlenecks within national and international institutional frameworks that could prevent its commercialisation.

Summary of Frame Two Industry Workshop

Dr Markus Pridöhl, Senior Manager, Research and Development, Degussa Advanced Nanomaterials, Germany

- **Risks must be discussed alongside benefits to understand the trade-offs involved**
- **How does the transition between the two frames operate?**
- **Industry self-regulation can be difficult to implement**
- **Better to focus on initial data exchange as a sound basis for regulation**

The frames are useful to a certain extent. But the transition period between the two frames needs clarification and it appears currently that Frame Two could be applied to any emerging technology. Could Frame Two be made more specific to nanotechnology? The hazard recommendations need to be worked out in more detail. This cannot be done through scenario analysis, which has its uses, but will not get to the detailed level of identifying hazards. Also it is important not to map the recommendations from Frame One directly onto Frame Two on a one-to-one basis. If the frames are different then this will not work. Risks must always be coupled to potential benefits, otherwise there is no sense of the types of trade-offs that will occur between risks and benefits or for secondary influences that may off-set the perceived risks. It is important that in Frame Two, the future is not simply buried under a mound of potential hazards and risks.

Risk assessment will be closely linked to products and will not occur at the level of the frames.

In coming to understand how to think of the frames, it may be helpful to remember that any specific risk assessment will not occur at the level of the frames. Such assessments will be more closely linked to products and categories and it is therefore important to be cautious about making general statements about risk assessment at the level of the frames.

Regarding communication, it was felt that scientists will be crucial as risk communicators. Education will play an important role, including educating people about regulatory systems to help build trust. In communicating to the public it should also be recognised that nanotechnology products are in use today, including a million computer chips that are produced everyday. Frame One tends to focus on nanoparticles, but there are many applications and appliances which the public can relate to that could already be included in a communications strategy.

Finally, there needs to be a careful assessment of the recommendation for self-regulation in Frame One. This may be better phrased as an initial phase of exchange by voluntary programs. In general industry will support such voluntary programs and recognises their importance in generating a basis for further regulation, although the difficulty of implementing them should not be underestimated.

4.2
Government

Professor Oscar L. Malta, Ministry of Science and Technology and Nanodevices, Brazil

- **Avoid emotive and inflationary language in the White Paper**
- **Frame Two must be seen in the context of complex systems and their emerging properties**
- **More safety tests are required before marketing nanotechnology products**
- **Government regulation will be required**

One important issue is the use of language in the White Paper. Terms used in related literature, such as "intelligent systems" and "nanorobots" will cause more public alarm than one thinks and could lead to a potential over-reaction. It will be some time before there are systems that replicate themselves, if this would ever be feasible. The report properly does not use such terms as self-replicating nanoscale structures for which there is no evidence at least in the near future. A better description would be molecular systems with designed functionality, such as that used for targeted drug delivery in cancer therapy. But most of all the avoidance of terms such as "nanorobotic" is important.

More information is required on the possible health and environmental implications of nanotechnology and there must be more research and safety testing prior to marketing.

One feature of Frame Two which perhaps goes beyond the characteristics of uncertainty and ambiguity is the systemic aspects and emerging properties of complex systems. It is important that the risks do not become isolated but are seen in the context of networking systems that will also influence how the probabilistic pattern of cause and effect can be understood. In terms of public involvement, the report "Informed Public Perceptions of Nanotechology and Trust in Government" from the Woodrow Wilson International Centre for Scholars in September 2005 came to some important findings, namely that more information is required on the possible health and environmental implications of nanotechnology and that there must be more research and safety testing prior to marketing. Finally, mandatory governmental controls are definitely necessary.

Within the Brazilian context, a vital part of the development of regulatory procedures has been the involvement of a National Committee for Ethics in Scientific and Technological Research, working on a local and national level. This helps to ensure that the right sort of debate is being held and that the type of transparency that the public deserve is implemented.

Summary of Frame Two Government Workshop

Dr Philippe Martin, Directorate-General Health and Consumer Protection, European Commission, Belgium

- **Whether considered as a continuum or as exhibiting a discontinuity, the two frames entail ethical and social issues as key drivers**
- **Excellence, independence, and transparency, along with debate and accountability will be critical**
- **Governments have a key leadership role to play, still they cannot proceed without the other stakeholders, with whom they should engage in a sustained conversation**
- **Work is needed on the practical steps to create a sound regulatory platform for nanotechnology**

The complexity of dealing with Frame One and Two was again a major theme of the discussion. In the previous workshop, the distinction was considered to be difficult to interpret for several stakeholders, that the regulators would not want two regulatory systems and that the public would be unable to quickly distinguish and interpret the significance of the division. In this workshop there was agreement that ethical and social issues must be a key driver in both frames and that one is dealing with a continuum, with the universal problem of not being able to foresee all future hazards or benefits. There were also interpretative differences with regard to Frame Two: is it "active and programmed" or simply "further in the future"? Is it an addition to Frame One or something completely different?

Ethical and social issues must be a key driver for governance in both frames. Excellence, independence, and transparency in assessment, along with debate and accountability are essential.

Industry wants to understand the rules of the game as early as possible and this requires conversation with government.

These different ways of interpreting the frames reflected the issue of where the regulatory focus should lie. For some taking a pragmatic stance, Frame One is the area to focus on simply because there are products requiring regulation. Such regulation should take into account the prevailing ethics and values. Concerning Frame Two, the most pressing task today is risk communication and looking at ethics. Still, risk assessment questions should be examined because Frame Two products are already with us today. In this respect, Frame Two could present new challenges to regulators, forcing them to move beyond their usual risk assessment approach. Frame Two might also require an engagement with a new type of stakeholder dialogue that would explicitly include questions of normative behaviour and values and management of public perceptions. Common agreement was reached on the need for excellence, independence, and transparency, along with debate and accountability.

Leadership needs to come from different sources, because all stakeholders have responsibilities as well as stakes in the development of nanotechnology. While governments must play a key role, the international organisations such as the OECD are also vital. Such organisations are well-tested forums for international debate and multi-stakeholder dialogue. And, dialogue is most important. Industry wants to understand the rules of the game as early as possible. This requires conversation with government. The sharing of data is critical to this process. In addition, it is important not to exclude other stakeholders such as NGOs from the dialogue to build trust.

Further work is also required in understanding what one is really regulating. Is "smallness" per se a justification for regulation? Or are there other criteria that are more product-based that will provide a practical basis for executing a regulatory framework?

4.3
Civil Society

Dr Douglas Parr, Chief Scientist, Greenpeace, UK

- **New technology is a lightning rod for discontent**
- **Values and visions matter in this debate more than risks**
- **Frame two discussions need to begin now**
- **Public are hungry to be involved, but lack decision making power**

As the frames distinction is broadly speaking a useful thing, it seems best to avoid discussing the terminology and step further into the debate. It should be clear that getting Frame One right will be a prerequisite for Frame Two. Frame Two requires public confidence in public institutions to act in their interests, if this is lost in Frame One, Frame Two debates cannot happen meaningfully. New technology has become a lightning rod for discontent within our societies, often expressing broad political and institutional concerns via a specific issue. Globalisation, for example, has become socially controversial, a symbol for discontent with the broad thrust of the pace and direction of progress. This discontent however, rests on deeper value based judgements about the nature of society.

For nanotechnology this means that values and visions will become vital to the Frame Two debate, much more than risk. This helpfully comes out in the White Paper and should be welcomed. It presents a challenge to institutions to reflect on what values and visions they will embody and show in their research programmes and elsewhere. It must also be asked whether the primary question is how and when nanotechnology will be successfully implemented? If the key concerns are actually safe water, renewable energy or waste management, then the key question is will nanotechnology serve these goals and not whether it will be, in abstract, a success or failure.

Getting Frame One right will be a prerequisite for Frame Two. If confidence is removed through the bad handling of Frame One risks then one can forget Frame Two debates.

There is a hunger for the public to be involved in deciding where technology is going and why.

In the UK, one approach to involving the public in Frame Two debates is the use of Citizen Juries. These allow members of the public to meet with scientists to discuss and explore a specific topic. There is a panel made of various stakeholders who oversee the process and it is professionally facilitated to help discussion. Several interesting elements emerge through this process. First it is very difficult to provide the type of overview information that citizens' request. Partly about which companies are involved and when things are going to happen, but also on the values and goals of the technology and how it will affect them as individuals. Second, the output from the Jury is often broad and aspirational in tone, making it difficult to directly integrate into today's organisational decision making on technology.

There is a hunger amongst the public to be involved in deciding where technology is going and why. In general they are very precautionary on risk. But to involve them in Frame Two debates presents a challenge to existing organisational processes. For example, what is the appropriate level of involvement? Will it be token? And if the public is involved, shouldn't they expect something to change through their input?

New innovations and technologies require a justification, not just for industry or governments but also for the public. And this is an issue with nanotechnology because the research and development agenda today is already influencing which direction we are going to take. In this sense we need to be already engaging in the Frame Two debate, indeed we are already part of it. The problem is that we are very badly prepared for it and remain addicted to a standard form of risk discussion.

Summary of Frame Two NGO Workshop

Christine Peterson, Vice-President, Foresight Nanotech Institute, USA

- **Political and security issues are inadequately addressed in the White Paper**
- **Barriers to implementing governance exist and need to be explicitly discussed**
- **Developing country perspectives need to be accounted for**
- **Process must move faster to address longer-term issues in time**

The IRGC White Paper employs much specialized terminology: Environmental, Health and Safety (EHS), Ethical, Legal and Social Issues (ELSI), Political and Security Issues (PSI), Human Development Implications (HDI) Nano-bio-info-cogno converging technologies (NBIC), and Educational Gap Issues (EGI). Within the White Paper there is a stronger emphasis on HDI, with a secondary focus on ELSI and EHS. Political and Security Issues are not treated as primary, nor do the social risks of development delays by poorer countries or surveillance issues get much attention.

Military offence applications are particularly concerning because, unlike nuclear arms, verification difficulties mean there is no clear point at which opponents reach stability in the process of escalation and proliferation. Existing arms treaties may not apply to nanotechnology-based weapons, and there are important intellectual property, commercial confidentiality, and national security issues involved in addressing this challenge. One option is to brief and consult with relevant organisations for the next draft of the White Paper, with the goal of encouraging the eventual creation of an International Nanotechnology Arms Control Treaty (INTACT).

How can we build the organisational capacities of accountability and transparency fast enough and with sufficient trust that a wide variety of stakeholders have confidence in the risk governance framework?

The risk governance process must move faster to address longer-term political, military, and civil liberties issues in time.

The same political barriers of intellectual property, confidentiality, and military secrecy apply to implementation of the overall Frame Two risk governance process and need to be fully described and considered. How can we build the organisational capacities of accountability and transparency fast enough and with sufficient trust that a wide variety of stakeholders have confidence in the risk governance framework?

The IRGC must distinguish the different risk and benefit profiles of poorer and developing countries from those of richer developed ones. Issues include poor technology transfer, inadequate access to high priced intellectual property, and the need to participate in Frame Two nanotechnologies to replace existing commodity-based economies disrupted by Frame One. Potential ideas include the development of open source intellectual property and the inclusion in publicly funded research of wording which will later enable the extension of IP to developing markets at affordable prices. Development of nanotechnologies particularly suited to the needs of developing countries, such as those dealing with energy and water, should be invested in as a matter of urgency. One challenging formulation of this would be to adopt the policy that all public research and development funding be explicitly dedicated to public good ends.

Finally, while current attention is focused on near-term concerns, questions raised by Frame Two nanotechnologies are more difficult, particularly with respect to fourth-generation, atomically-precise manufacturing of macroscale products. The risk governance process must move faster to address longer-term political, military, and civil liberties issues in time.

4.4
Research

Dr Jennifer Kuzma, Interim Director and Assistant Professor, Center for Science, Technology and Public Policy, Humphrey Institute, University of Minnesota, USA

- **White Paper uses strong integrated governance approach**
- **Other approaches do exist, exploiting existing regulation and a product testing focus**
- **Two frames a question of what to emphasise at different stages of development**
- **Voluntary model is not the only response at this stage**

The IRGC White Paper includes a lot of important elements such as public participation, the social and ethical dimension, principles of good governance and the notion of adaptation through time. These are often not integrated into governance proposals. It is also forward looking, recognising the third and fourth generation of nanotechnology and defining an approach to things which have not yet taken full shape and are difficult to predict.

It is very helpful to be looking at what is the right framework for governance of nanotechnology. Typically, regulatory or non-regulatory oversight is evaluated by one or a few metrics depending on the perspective of the group doing the evaluation: Impact on the environment; impact on market; cost benefit review. Here there is the opportunity to look more at an "integrated oversight assessment" that can learn from previous regulation.

There is the opportunity to look more at an "integrated oversight assessment" that can learn from previous regulation and take account of multiple criteria and stakeholders in assessing the right framework for nanotechnology.

The White Paper includes a lot of important elements that are often not integrated into governance proposals.

While the Frame One and Two distinction is useful, it is not as clear cut as presented. The issue of public participation is equally true for Frame One and Two and questions of complexity and ambiguity cannot be removed from Frame One. Rather than a tight distinction there may be a question of emphasis, so that toxicity would be an issue in both frames, but have greater importance in Frame One. It may be helpful to think of the frames as part of a Venn diagram. This also holds true for the distinction between the roles of different actors within the report. Industry should also welcome good regulation and government public participation.

Another regulatory approach would be to use a co-ordinated framework similar to that used for the Regulation of Biotechnology Products in the USA since 1986. This has not been perfect, but uses existing regulation and a product rather than a process approach. In the case of nanotechnology many of the issues will lie at the product level. Testing product-by-product is problematic, but at least there is significant experience to draw on and it is in any case preferable to start rather than wait for the perfect regulatory regime to emerge.

It is important that we are optimistic about regulation and avoid a voluntary model as the only way to respond to the current pace of development. There are examples of national governments working together to ratify mandatory systems. Again none are perfect but they do work. Examples would be the Montreal Protocol or Kyoto process, including US involvement. This mandatory system could work in parallel with the efforts of ISO, IRGC and other NGO organisations.

Finally an important element of the IRGC recommendations is the emphasis on trust, independence and transparency. It is vital that public participation goes beyond the one-way model of communicating to the public allowing it to help set the scope of the risk analysis.

Summary of Frame Two Research Workshop

Vyvyan Howard, Professor of Bioimaging, School of Biomedical Sciences, University of Ulster at Coleraine, Northern Ireland

- **Frame two research is already underway with potential far-reaching effect**
- **Frame Two complexity will call for flexible and adaptive governance**
- **Nanotechnology field needs segmentation, possibly by pervasiveness**
- **Delegate decision making on governance to remove self-interest**

For the regulation of Frame Two it was felt that the conditions set out in Frame One must be satisfied. This indicates a more formal solution of how a transition between the two frames could be defined. There was also a more general discussion as to whether the definition and application of standards should also be a prerequisite for oversight in Frame Two. Frame Two type applications of nanotechnology are already taking shape, for example, the extension of the genetic code by adding a fifth nucleotide that could lead to the manufacture of novel living organisms, with potential implications of mutation, toxicity, allergy and containment. Such examples indicate that future risk assessment in Frame Two will be applied to complex systems that are non-linear in behaviour and with properties that emerge only at the system level. Any system of regulation will therefore need to be flexible and adaptable with feedback mechanisms that allow the system to respond in the light of new knowledge. Reporting systems will play a crucial role in this.

Frame Two type applications of nanotechnology are already taking shape.

There are both positive (IT, telecommunications and the Internet) and negative (genetic engineering and genetically modified foods) lessons to be learned from previous regulatory attempts. One important step would be to find an appropriate way to divide the nanotechnology field, so that applications can be viewed according to key risk classes that would correspond to a different regulatory approach. One such division would be:

- Non-pervasive: e.g. integrated surface coatings and electronic chips
- Locally pervasive: e.g. nano-medicines within patients
- Widely pervasive: e.g. free nano-particles, with the ability to move within the environment

Some specific comments on the White Paper would be that the table describing risks lacks any reference to the benefits of technology and could perhaps be better placed in the context of risks and benefits, that is, what may happen if one does something and what will happen if one does not. Stakeholder roles as described in the report need a tighter description of the actions required and less tight boundaries between the stakeholder groups as most recommendations are relevant to all parties.

In terms of communication, it was noted that scientists are not highly motivated within their communities to engage with the public and understand their perspective. The performance criteria by which good science is measured places little value on this type of work. An interesting working model of delegating the decision making away from key actors is how committees comprising lay members, regulators and health workers decide who will receive a kidney for transplant in the UK. The surgeon is in effect relieved of this responsibility. Could such committees be formed to determine which technology applications should be developed and funded? This could be a potential role for both the public and NGOs, but presupposes a widely agreed format for research proposals that would need to include the methodological approach, the type of application and perceived benefits and the identification of potential hazards.


frame 2 debates
GREENPEACE

5
International Perspectives

5.1
How standards can help enable international nanotechnology risk governance

Dr Peter Hatto, Chair, Technical Committee 229 on Nanotechnologies, ISO

- **Standards will provide critical technical support for international regulation, but can also replace the need for regulation**
- **ISO validates proposals from member countries for international standards**
- **ISO progress is determined by member activity and interest**

Following the IRGC White Paper, how is it possible to give the process of implementing the recommendations both credibility and validity? One route could be through the International Organisation for Standardisation (ISO). This is a member driven organisation with global reach that provides an internationally validated mechanism for standards development through a democratic and inclusive process, creating a stable and verifiable basis for regulation.

ISO does not develop standards itself, rather it provides a consensus based process for members to propose, develop and approve a variety of standardization instruments. Such written standards provide agreed ways of naming, describing or testing things or managing or reporting on processes. The standards are voluntary unless used in contracts or regulation and can be normative or informative. In this way, ISO is not a regulator, rather it provides a robust basis on which good regulation can be based.

If individuals at this Conference believe there is a need for standards in the area of nanotechnology then they should talk to their national standardisation body to propose a draft to ISO.

In the context of nanotechnology, consensus based standards can provide internationally validated means to quantify both hazard and exposure, i.e. risk, through standardised methods, for example: detection, identification, testing, protecting and eliminating nano particles. In June 2005 ISO/TC 229, a Technical Committee, was established to enable the development of nanotechnology standards. So far the committee has had two meetings and is working on a terminology document for nano particles. New work items are emerging including a technical report on Occupational Practices and Sample Preparation for toxicology testing. As the Chinese have already published 8 national standards in 2004 and are working on another 12, there is a possibility these will be introduced into the ISO process. But it must be stressed that it is ultimately for the membership to decide the pace and scope of deliverables from the Technical Committee 229. If individuals at this Conference believe there is a need for standards then they should discuss with their national representatives how to propose a draft to the Technical Committee. The object of the Committee is to provide robust, working standards through a consensus based process.

The TC 229 Work Programme will not be completed in the short term and will be continually reviewed to ensure that it addresses the needs of it members. It is important that standards are not considered as commandments fixed in stone. They are subject to review, normally every five years and can be updated or deleted as necessary. A road map is being created for the coming 10 years, covering the areas of terminology and nomenclature, measurement and characterisation and health, safety and environment. And again, given the rapid pace of development of nanotechnologies, this road map will be reviewed on a regular basis to ensure its on-going relevance.

5.2
UNESCO: Ethical and social dimensions of nanotechnology

Simone Scholze, Programme Specialist, Section of Ethics of Science and Technology, UNESCO

An holistic approach to nanotechnology is needed because of the cross disciplinary nature of the field.

- **Cross disciplinary working calls for an holistic approach**
- **Caution needed on utopian or apocalyptic scenarios**
- **Further ethical education required**

The World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) was created in 1998 with the task of formulating, on a scientific basis, ethical principles that can shed light on the choices and impact of advances in science and technology, thereby fostering a dialogue on the underlying values at stake. It has 18 members drawn from all geographies and serving on an individual basis for a renewable four year term.

COMEST is actively working on nanotechnology using a three stage working methodology. The first phase involved the identification of the moral dimensions of nanotechnology. Here a multi-disciplinary group of experts looked at the ethical dimension of this field and identified opportunities for international action. In the second phase these potential international actions are being tested through a process of consultation that will lead to a draft COMEST policy document, reviewed by relevant scientists. In the third phase stakeholders will be consulted regarding the political feasibility of the draft proposals and a document will be prepared for the UNESCO General Conference in Autumn 2007.

Some of the early findings of this process include that nanotechnology requires a holistic approach because of the cross disciplinary nature of the field. In the area of awareness raising and enabling debate on nanotechnologies it is important to dismiss apocalyptic and utopian scenarios that lead to adverse public reaction, either too positive or negative. Environmental, health and privacy issues all need to be openly discussed. There is a general requirement for ethical education in this field and finally a need for research and development policies that will enable full involvement of developing countries as partners and not just as future markets.

5.3
Challenges for the Asia Nano Forum

Dr Khiang-Wee Lim, Executive Director, Institute of Materials Research and Engineering, Singapore and Asia Nano Forum

- **Frame distinction will help busy governments focus on priorities**
- **Some Asian countries will become manufacturing hubs with related toxicity risks**
- **Intense economic competition is major influence on implementing good governance**

Founded in May 2004, the Asian Nano Forum (ANF) is a network supported by 13 economies in the Asia Pacific region with the goal to promote excellence in research development and the economic uptake of nanotechnology in the region. Following a Summit Meeting in Australia in December 2005, a Headquarters is being established in Bangkok and working groups have been established in the four areas of Education, Research and Infrastructure, Business and Commercialisation, and Standardisation, Risk Assessment and Safety.

The ANF covers a broad diversity of economies with varying levels of investment in nanotechnology. There are several early movers within the group, such as China, that has already published standards in the area. Within some of the economies there is an implicit belief in the potential of technology and Taiwan has taken a brave step in creating a formal Nano mark to create a voluntary certification scheme.

It is important ot ensure risk governance issues are addressed in parallel with the progress of the technology.

Nanotechnology presents a challenge for economies without a strong science base. Given the strong competition for resources the question arises how one can balance between investment in a sustained broad scientific base and more targeted investments? Even in a wealthier economy such as Singapore there are resource constraints, not so much money as manpower.

The issues under discussion in Frame One of the IRGC White Paper are very real for the Asian economies. This is because they have the potential to become manufacturing hubs for mass-produced nanotech products, including cosmetics and IT. In many of the economies there is a lack of both know-how and regulation to deal with this. Again, a balance must be found between encouraging much needed investment within the economies and developing an appropriate legal and regulatory framework.

Regarding the position of the actors as described in the White Paper, academia has not yet developed the capability to undertake long term ELSI or EHS type studies or engage in communication between academia and the public on these issues. And there is no standard nomenclature or metrology across the economies for nanotechnology. A notable exception is Taiwan, which is actively integrating nanotechnology education programmes into schools and universities. Industry is actively focused on Frame One technologies. In particular, China, Japan and Korea have significant domestic industry. Other ANF economies tend to be dependent on corporate leadership from abroad and therefore cannot directly determine the pace of activities.

Regarding Frame Two, there is clearly an opportunity to develop and implement risk governance ideas in parallel with the emerging technology roadmap. Given the importance of economic decision making within the ANF region it is important and will take a special effort to ensure that risk governance issues are addressed in parallel with the progress of the technology. Meanwhile, there is much still to be done in the context of Frame One where standards are still lagging behind industry use and it remains unclear what new measures are required in addition to existing protocols.

5.4
Frame Zero

Dr Rye Senjen, Nanotechnology Project, Friends of the Earth, Australia

- **Create a Frame Zero to address values and assumptions**
- **What is the cost of ignoring marginalised stakeholders?**
- **Civil society must be integrated fully into decision-making**

Is it possible that there will be a community backlash to nanotechnology? If one makes a comparison with genetically modified foods (GMF) there seems to be cause for concern. A lack of participatory decision making, trivialising of community concerns that go beyond scientific risks and a resistance to a precaution based approach all seem to feature in the current response to nanotechnology. Marginalised voices such as the poor or disabled are not being listened to and the ethical issues are simply ignored. The effect of behaving in this way was seen with GMF. What is going to happen with nanotechnology?

Certainly the Frame One and Two distinction is only partially adequate to address the environmental and economic issues which one can identify. The deep integration of the bio and techno spheres and the ecosystem level risks of implementing complex nano products will present real challenges, indicating that the current concepts of risk, hazard and exposure will only partially address nano pollution and human health risks.

While there is a great interest in dialogue, the real question is if one is involved in decision making on whether a technology is going to get implemented and on what terms?

As scientists, we have not been trained to talk to people or interact with them.

Rather than first pursue technology goals, it is vital that the question of values is addressed. One proposal would be to create a Frame Zero that would precede Frame One and Two. Frame Zero would be driven by the need to place community and environmental interests first, take a precautionary approach to managing risk and identify new mechanisms to enable civil society participation in the critical stages of decision making. The cost of not addressing Frame Zero has been experienced with GMF. It is therefore in all our interest to urgently address these value based questions.

Frame Zero would be driven by the need to place community and environmental interests first, take a precautionary approach to managing risk and identify new mechanisms to enable civil society participation in the critical stages of decision making.

5.5
Dialogue and Questions

This section reflects the key questions, comments and debate undertaken at the Conference after the Frame Two presentations.

The European Commission, National Science Foundation, UNESCO and other bodies are addressing these complex ethical issues. One challenge is whether civil society is really involved in the decision making? While there is a great interest in dialogue, a deeper question is whether one is involved in decision making on whether a technology is going to get implemented and, if so, on what terms? Is it for the good of the community? Do we have another technology already that is good enough?

A specific proposal for nanotechnology, that would have value to all technology fields, is the introduction of Frame Zero, although discussions on nanotechnology have begun earlier in the development of the technology. It might be shocking but it is here to challenge. There is a need to engage people in a more inclusive way that goes beyond the existing democratic structures. The idea is to encourage civil society. Scientists have not been trained to talk to people or interact with them. Success is judged by work in the laboratory, new discoveries and patents.

Concern Assessment

Although the White Paper deals with the idea of concern assessment and social anxiety, it does so asymmetrically. Should apocalyptic scenarios be dismissed or ruled out? Surely, a better approach would be an opportunity to discuss these visions and assess them appropriately, adding a vision assessment element to concern assessment?

Frame One is helpful because it gives a sense of priority, that these issues need the attention of politicians and government today and not in ten years time.

The issue with the nightmare future scenarios is to try and ensure that they do not dominate the discussion. This can easily lead to creating views in the public mind that become very difficult to shift. Of course, dismissing a vision simply because it is apocalyptic cannot be sound. And the question remains why social groups take-up such visions, despite them often being very far from the facts or the development path of the technology? In the case of nanotechnology, there are currently no indications of the type of catastrophic events that are a characteristic of the nuclear field and have led to such apocalyptic scenarios being considered there.

The problem is that the term “nano” has taken on an extraordinary quality. Terms such as “intelligent molecules” tend to reach the public with a different meaning from that originally used and this is why the science fiction material should be dismissed as dangerous and our use of such terms in nanotechnology treated with caution. Although, of course scientists are very happy to use such descriptions in their research proposals because it helps them get funding. There is certainly a danger to particular words taking on a near mystical quality and this has perhaps already happened to nano.

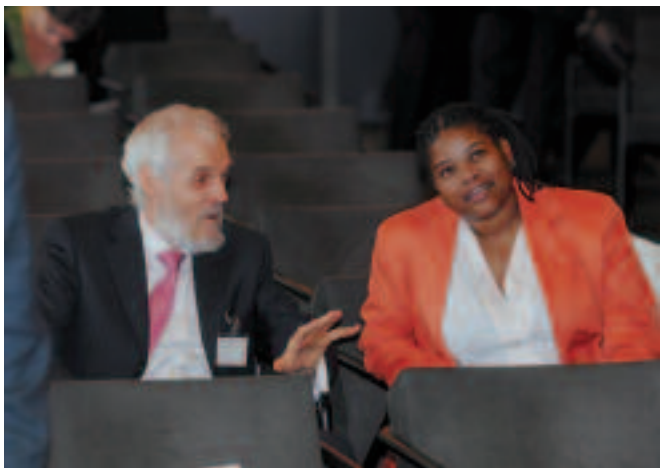
Asian Perspective

The Frame distinction is helpful within an Asian context. In particular Frame One indicates to governments where priority should be set. This is very useful. How will the role of ANF develop? There is a distinction between the economies and the members governments of ANF. Sharing of information and the creation of White Papers such as that of IRGC are obviously important in helping people to understand the governance issues.

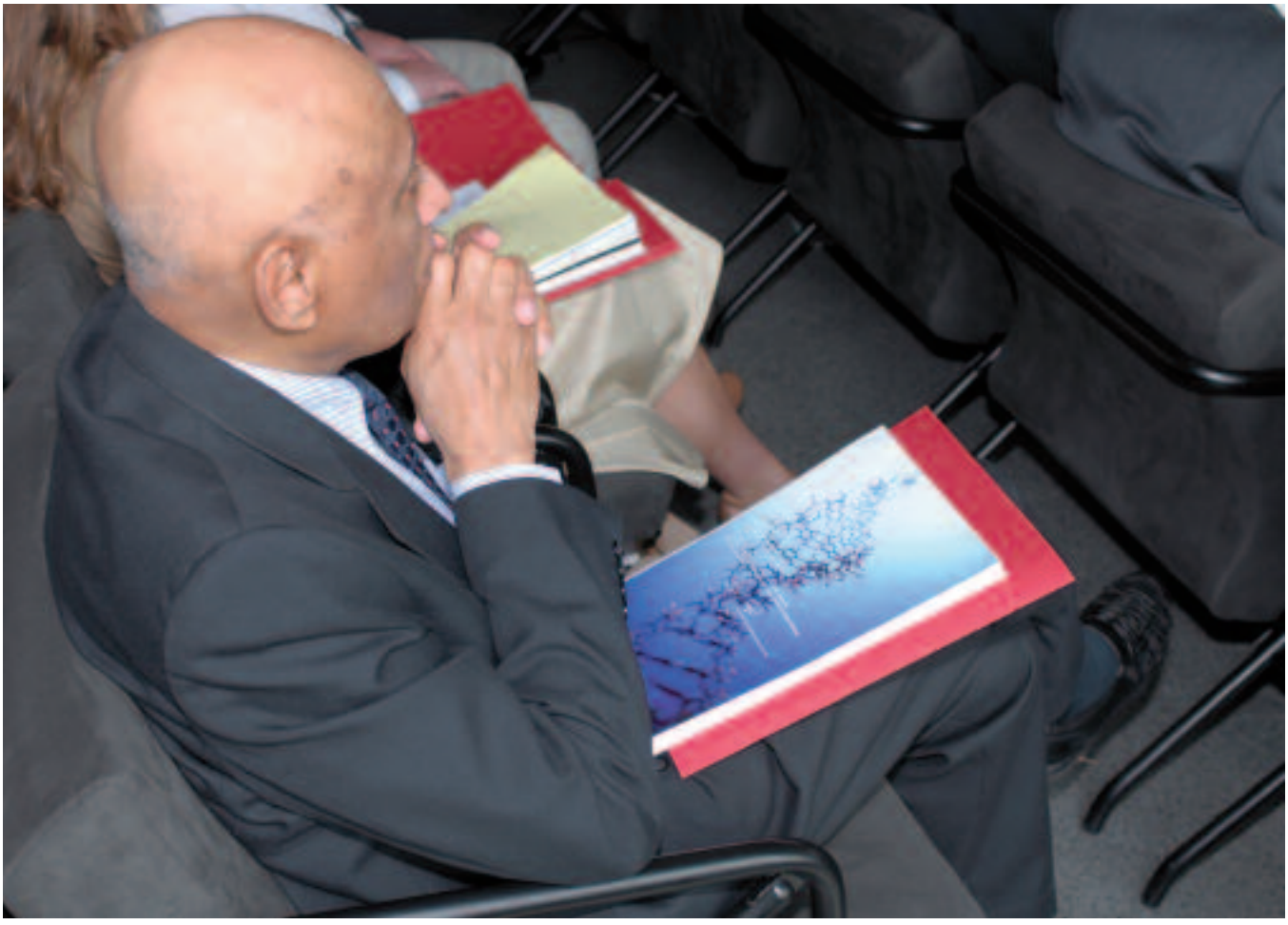
Why has Taiwan developed the Nano Mark? Taiwan is a small island and this helps support collaboration with teachers and scientists. The Nano Mark was inaugurated in 2004 to protect the consumer. The issue is the measurement of the nano products and establishing if there are new characteristics to do with their nanoscale. There are three products that can at the moment apply for the Nano Mark and there are six categories and twenty three products that have the Nano Mark.

China was invited but is not in the meeting. Are they in the IRGC process?
The ANF can play a good role here, disseminating papers and sharing information.

Will the ANF develop a country perspective? One issue is that the ANF economies are very gung-ho on economic development and we need such White Papers to help the development of appropriate governance. Frame One is helpful because it helps give a sense of priority, that these issues need the attention of politicians and government today and not in ten years time.




Julia Moore



6
Implementation and next steps

6.1
Feedback on the White Paper from a risk assessment perspective

Dr Michael Rogers, Former Adviser for Science and Ethics, European Commission's Bureau of European Policy Advisers

- **White Paper focuses heavily on hazard and not on risk assessment**
- **In the light of current knowledge a precautionary approach is required**
- **Values must be openly discussed and the need for trade-offs recognised**

It is important to distinguish between hazard assessment where one looks at the potential for harm, and risk assessment, which assesses the potential exposure to harm, the probability that it will occur and then considers acceptable levels of exposure and what regulatory approach or procedures are required. One issue with the IRGC White Paper is whether it focuses too heavily on hazard assessment and not enough on risk assessment? In the case of nanotechnology there is a very uncertain relationship between exposure, say, to Titanium Dioxide, and the harm this exposure can cause. The shift in toxicology in moving from the macro to the micro and on to the nano level is simply not understood and without this understanding and the related evidence it is not possible to propose adequate risk scenarios.

This situation also questions the force of the distinction between Frame One and Frame Two. In the light of current knowledge it is unclear what the difference in risk between the two frames really is. So there needs to be more mention of the precautionary principle, in particular the requirement to review risk decisions in the light of the emerging data. Science research is highly dynamic and it is critical that this is reflected in any approach to regulation. At this point for nanotechnology it is clear that precautionary research is needed or even pre-regulatory research and this should be more clearly stated in the White Paper.

For nanotechnology it is clear that precautionary research is needed or even pre-regulatory research.

With Ethical, Legal, and Social Issues (ELSI) it is important to also consider the role of values. Inevitably, different priorities need to be balanced on the basis of understanding which values are most important, be it scientific research, environmental protection or security. Ultimately the decision being made is that of what sort of world our children and grand-children will grow up in.

6.2
Nanotechnology regulatory challenges

Dr Kazunobu Tanaka, Center for Research and Development Strategy, Japan Science and Technology Agency, Japan

- **Frame distinction makes sense and is useful**
- **Frame One recommendations such as measuring and characterising nano particles are vital**
- **Public anxiety grows with unease as to the direction of technology development calling for more information exchange and education**
- **Medical use of nanotechnology should be explicitly dealt with in Frame Two**

Nanotechnology is predicted to make a strong contribution to our economies in the not too distant future. The Japanese Ministry of Economy, Trade and Industry suggests the nanotechnology market could have annual revenues of 238 billion (USD) by 2030. In Japan, so far, expectations suggest people feel relatively positive about nanotechnology, but there is concern for both the potential side-effects of new technologies in general and specific concerns about the health effects of fine particles.

It makes sense to categorise nanotechnology risks into two frames or types, though there are elements of passive nanostructures which need to be reviewed in the context of Frame Two. In particular the medical use of the technology must be specifically assessed within Frame Two because of the ethical issues that arise. Such opportunities raise ethical issues and also present the risk of these issues being amplified through anxiety to create negative reactions, similar to those seen with genetically modified foods.

Public anxiety grows with the uncertainty about how a new technology will develop and whether the path of evolution can be foreseen.

In response to the challenge of risk communication for Frame One, Japan is creating a NANO-Toxicity Panel. This Panel will operate via the Internet and seek to make available scientific reports on key issues that will be reviewed and evaluated by people from different disciplines. This Panel will be run as part of the 2006–2010 project "Risk Assessment of Manufactured Nanomaterials" and aims to counter the problem that once hazard information has been published, it is difficult to remove the social anxiety it creates, whether this is or is not well-founded or well-researched. This can place huge Research and Development investments at risk and lead to moratoriums on specific technologies without good scientific grounds.

The IRGC has addressed some important issues in their recommendations. These include in Frame One the urgent need to develop methodologies for the measurement and characterisation of Nano particles, including size, shape, distribution, morphology and impurities. This must also include reliable measurement for determining the movement and translocation of nano materials inhaled or absorbed by living bodies. Such work will require interdisciplinary collaboration between toxicologists and researchers specialising in physical, chemical and biological measurements and instrumentation. And with Frame Two it is recognised that public anxiety grows with the uncertainty about how a new technology will develop and whether the path of evolution can be foreseen.

6.3
Risk governance and ecosystems

Dr Celia Merzbacher, Assistant Director for Technology Research and Development, Office of Science and Technology Policy, Executive Office of the President, USA

- **Stakeholders must be treated as part of a complex network or ecosystem, not a hierarchy**
- **Stakeholders must get involved in creating good international standards**
- **Trust and transparency are key values**
- **Sharing information and a collaborative approach are prerequisites to governance**

The IRGC should be commended for producing a White Paper that attempts to ensure we can enjoy the anticipated benefits of nanotechnology within a framework of good governance. The comments made here are personal in nature and arise directly from the discussions that have occurred over the past two days of conference.

First of all, whereas the White Paper discussed ideas about a hierarchical structure for nanotechnology development and governance, in fact progress in developing good governance will rely on actors or stakeholders interacting within what might be termed a risk governance ecosystem. Roles and responsibilities will be there for all stakeholders and, maintaining the ecosystem metaphor, each of these actors needs to be healthy for good risk governance to take place.

Progress in developing good governance will rely on actors or stakeholders interacting within what might be termed a risk governance ecosystem.

It is also important that the governance system must be adaptive and allow for modification as appropriate. Further work is required on ethical and social questions, across the globe, to give perspectives on the issues that go beyond expert scientific work. This work is critical to future decisions about risk governance frameworks. Standards in nomenclature and metrology are also going to be vital, so key stakeholders must get involved in helping set these standards. Implementation of good governance principles such as transparency and stakeholder feedback will be important to developing and sustaining public trust in the nanotechnology field.

Governance will be undertaken by different bodies around the globe reflecting different perspectives and norms in different countries, so maintaining a broad and flexible scope and establishing channels and mechanisms for sharing information and research will be important. This is a major benefit of participation in multi-disciplinary approaches to nanotechnology and will lead to better risk management and improved communication. Greater sharing of information, however, also calls for a quality of information that is well-researched, accurate and validated.

7
Closing Remarks

Wolfgang Kröger, Professor and Director, Laboratory for Safety Analysis, ETH Zurich, Switzerland

The IRGC proposals put forward in the White Paper have received a lot of positive comments and a lot of suggestions for improvement that have been most welcome. In particular the question of the division between Frame One and Frame Two for nanotechnology underwent serious scrutiny with both positive and negative remarks.

Please do be assured, the comments and proposals made will be considered very carefully in preparing a final nanotechnology Briefing. It was particularly pleasing to hear the encouragement to balance future hazards with potential benefits and include proposed visions for the future of nanotechnology.

What are the next steps? Certainly, there is a lot to do in a small amount of time. An issue is whether we are fast enough and this generates a pressure for us to agree on proposals and move forward before it is too late. IRGC wants to continue to build a framework for risk governance in this field based on a multi-agency approach. It is clear the White Paper alone is not the answer, but hopefully a contribution to finding a practical way forward for all the parties involved. One objective is to ensure a sufficient level of quality that governments can give the proposals careful consideration.

One issue is whether we are fast enough and this generates a pressure on all of us to collaborate and agree on next steps.

Implementation is critical and this will require further collaboration with other organisations that have greater skills and experience in specific areas than the IRGC. The inclusion of a so-called country perspective, alongside that of the general individual view, also calls for the involvement of more governments in developed and developing countries in the next stage of consultation. There is a need to be more specific about ranges of application, creating a multi-layered approach that moves from products through to international domains of application. There is also a risk of missing benefits, such as in water treatment and we must endeavour to avoid this happening. Other proposals that have emerged are around gathering of previous related research and identifying the barriers to implementation of a risk governance framework within the context of governments and commercial activities.

Through this Conference IRGC has shown a capacity to bring together talented and committed people for an open dialogue that can contribute directly to creating a difference in the risk governance of nanotechnology. As a young non-profit organisation, IRGC wants to remain involved in this challenging subject and will need further intellectual and financial support to play a full role.


nance of nano-
global issue
Global Dialogue

Epilogue

Dr Thomas K. Epprecht, Director, Expert Emerging Risks, Swiss Re, Switzerland

Nanomaterials are opening up opportunities that seem as big as the nanometre is small. Enthusiasm has spread beyond the small group of nano-experts to the business and scientific communities, where it is claimed that a real industrial revolution is under way, spreading from one sector to another.

Some of this is hype; much is not, and great opportunity is always accompanied by risk. As risk-carriers, insurers must be able to recognise and understand emerging risks: only then will they be in a position to safeguard their clients over the long term against the financial consequences of adverse events, and so enable society, and the economy, to take the risks that allow us to move forward.

Risk governance, the focus of the dialogue we were honoured to host, must provide the basis for a new approach. First, it must draw a boundary between macro- and nanomaterials that is legally and scientifically sound. Such a distinction must go beyond size alone (for example, the frequently proposed 100-nanometre threshold) to consider the novel material properties that only become apparent in the nanometre range. Second, within the nanoworld itself, it must distinguish between the numerous applications of nanotechnology, with their varied impacts and concerns. The IRGC, for example, proposes a distinction into two broad "frames": Frame One materials and processes, where classic risk assessment would prevail; and Frame Two applications where comprehensive issue management would be necessary.

Distinction

In order to introduce nanotechnology in a sustainable manner, uniform, risk-appropriate assessment criteria are required: criteria that consider nanomaterials' special properties. Such guidelines would not only reduce uncertainty, but also create a favourable climate for investment. However, nanomaterials are as diverse as the industrial sectors and applications in which they are found: there is no typical nano-risk, and no typical nano-risk solution."Gap analysis"is the current buzzword, a fact that betrays a lack of knowledge about the risk and the appropriate risk governance measures.

Challenges

Looking at gaps at the ordinance level of law, for example, it is unclear whether a material or product that is already approved for use at macroscale must be reassessed for nanoscale, and where does nanoscale begin? Present nomenclature does not distinguish between a conventional material and a nanomaterial. As a consequence, familiar approval requirements no longer offer adequate protection against emerging risks.

The challenge, then, is to address and regulate those elements that characterise the materials', and the business sectors', changed risk profiles, as production methods shift to nanotechnology.

To avert overregulation and licensing bottlenecks, as well as unsatisfactory catch-all wording in both the legal and insurance areas, research and development should rapidly provide clarity on the risk and regulation relevant scientific facts, in particular with regard to industrial safety. We are already seeing some efforts in the private sector orientated towards self-policing international agreements on research and commerce: these include voluntary codes of conduct and contractual restrictions, as well as best practice. In contrast, administrative authorities focus more on identifying potentially harmful properties and common threat patterns. Both will help to ensure insurability and thus to mitigate the potential consequences of calculated risks: for the ultimate

Risk Governance

purpose of insurance is to enable commerce and industry, and society as a whole, to engage in activities they might otherwise find too risky.

Once the challenges brought up in this workshop are met, researchers will be able to better assess the positive and negative aspects of nanotechnology with scientifically proven, comparable criteria; and authorities and insurers, and other stakeholders interested in controlling risk, will be better prepared to cope with possible future losses.

Outlook

A new technology always presents opportunities and threats; societal actors and individuals need to decide whether the disadvantages outweigh the potential benefits. This is not always easy in a pluralistic society, and one that calls for risk expertise, respect, tolerance and a sense of proportion.

The risk issues associated with nanotechnology are dynamic, global, and complex in scope. Swiss Re, as a global risk carrier, has a natural commitment to furthering any promising efforts towards a global risk governance framework. Although this IRGC conference focussed on possible downside effects and the measures necessary to contain them, one should not lose sight of the final aim of any risk governance system, of which insurance is a part, which is to enable progress and provide opportunities both for the society and the economy.

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Publisher: Swiss Re Centre for Global Dialogue
Design: WBG AG, Zürich

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