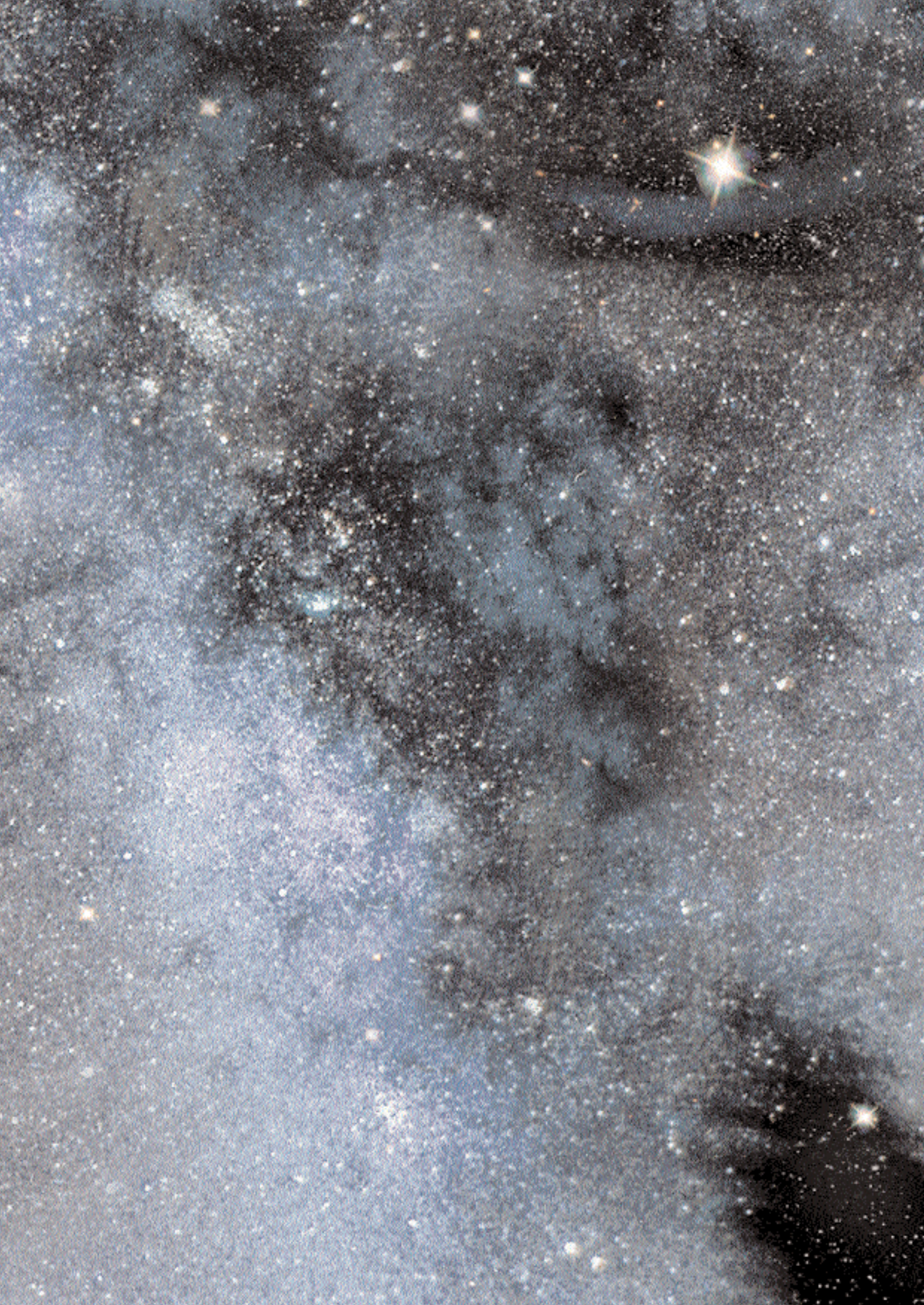


Nanotechnology
"Small size – large impact?"

Risk Dialogue Series

Swiss Re
Centre for Global Dialogue



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The Risk Dialogue Series of Swiss Re's Centre for Global Dialogue is designed to inform readers about ongoing debates and discussions between Swiss Re and the stakeholders of risk and reinsurance business issues.

Swiss Re's first conference on nanotechnology was hosted by the company's Centre for Global Dialogue in Rüschlikon, Switzerland, on 6 – 7 December 2004. This summary publication includes statements given by the conference's keynote speakers and provides several "outside-in" views on this cutting-edge technology. The publication also serves as a pendant to *Nanotechnology: Small matter, many unknowns*, the "Risk perception" series title in which Swiss Re shares its position on the subject with a broad readership.

Power of Ten images courtesy
of The Florida State University

Front cover:
10^{+22}
1 million light years

Opposite:
Stars in the Milky Way galaxy
10^{+19}
1,000 light years

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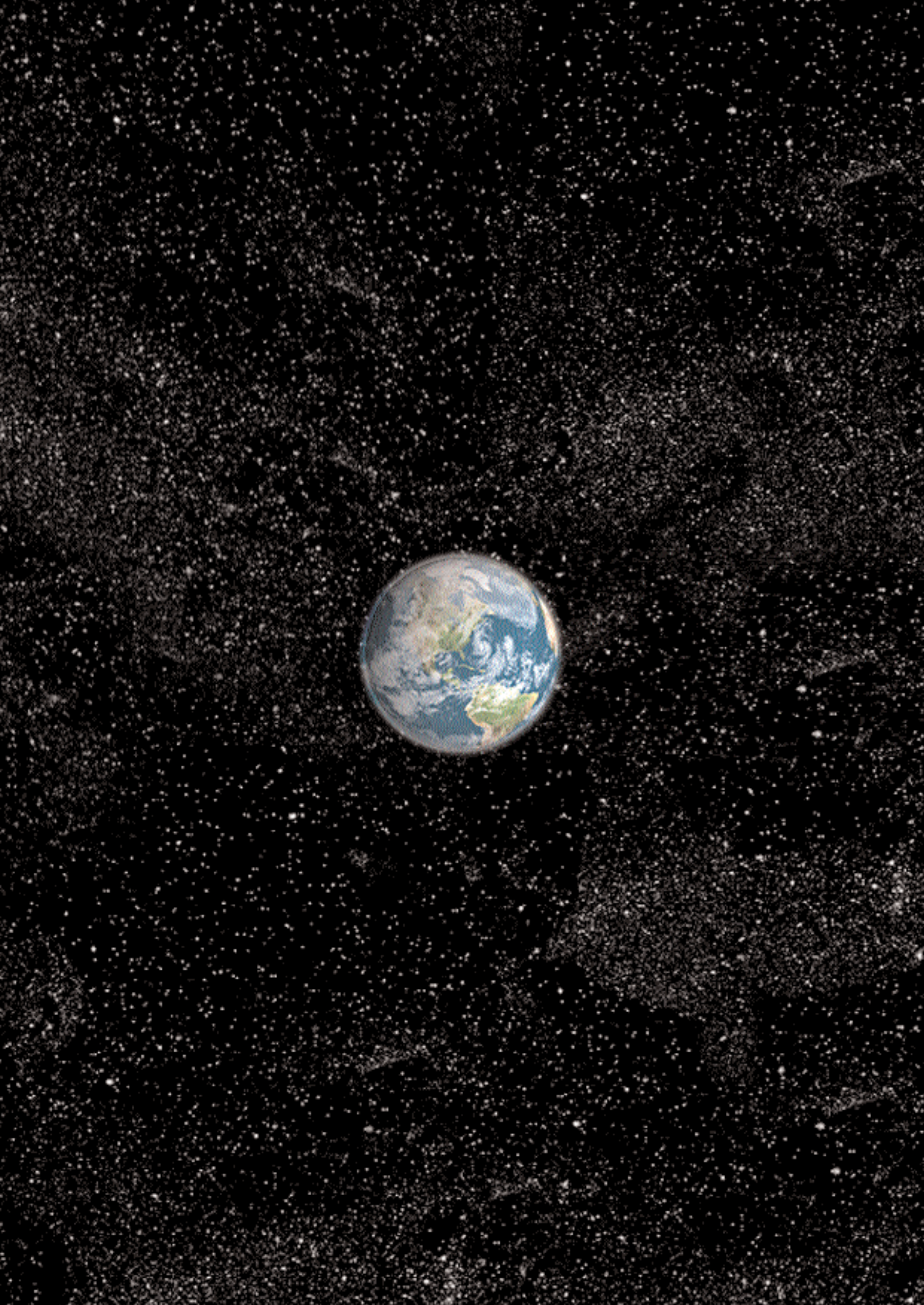

Preface

1
A welcome to Swiss Re's first conference on nanotechnology

The role of the insurance industry is to assume the risks and uncertainties of its business partners. In the case of new technologies, uncertainties prevail, since neither the probability nor the extent of potential losses in these areas are precisely calculable. This is in contrast to the large number of familiar risks in more traditional insurance portfolios, which can be reduced to numerical terms on the basis of experience.

By providing cover for these uncertainties – more specifically, by enabling a launch into ventures involving risk – the insurance industry makes a key contribution towards technological progress. To be an effective and competent risk carrier for industry, it must focus upon identifying, analysing and measuring risks so that assuming them does not present unpleasant surprises. Making risks assessable and calculable is the acknowledged strength of the insurance industry, a strength from which everyone benefits. In this, however, it must pool its knowledge and engage in dialogue with all the representatives of a community bound together by a shared risk. Indeed, pooling specialist knowledge and engaging in dialogue around nanotechnology will foster clarity that no one party can expect to achieve alone.

Admittedly, the parties joining in Rüschlikon for the first conference on nanotechology, "Small size – large impact" cannot provide any hard and fast answers to the many issues that will arise in connection with the topic. Ours is simply an attempt to bring decision makers together and to offer a forum for expert exchange so that each of the stakeholders can derive benefit by collectively – and more astutely – dovetailing their own interests into those of the other members of the risk community. Each of us will draw conclusions, but one is unanimous: when it comes to this ubiquitous new technology, not one of us can afford *not* to care.

John R. Coomber
Chief Executive Officer, Swiss Re

Opposite:
The Earth
10^{+8}
1000,000 Kilometers



The American and Japanese perspectives



2
Responsible nanotechnology development
Phillip J. Bond

Phillip J. Bond *is Under Secretary of Commerce for Technology, United States of America*

Dawn has broken on the Age of Nanotechnology. Sustained global investments by governments and private companies around the world are already beginning to deliver on the economic and societal promise of nanotechnology. In the near term, nanotechnology is likely to deliver evolutionary advances in existing products and processes; in the longer term, nanotechnology is likely to deliver revolutionary advances – amazing, economy-disrupting, life-changing advances – across a broad swath of industries.

Anything revolutionary is unnerving to some. And so, as with other technologies throughout history, some have responded with a call for a slowdown or outright moratorium on nanotechnology research and commercialization. To those who advocate such a position, I have three messages:

First, nanotechnology is coming, and it won't be stopped. The economic promise, the societal potential, and the human desire for knowledge are forces that cannot be held back. Across the globe, research is underway. Wealthy and developing nations alike are investing more each year to reap the economic and societal rewards of nanotechnology. With this level of investment, nano-based innovation is inevitable.

Second, given nanotechnology's extraordinary economic and societal potential, it would be unethical, in my view, to attempt to halt scientific and technological progress in nanotechnology. Nanotechnology offers the potential for improving people's standard of living, healthcare, and nutrition; reducing or even eliminating pollution through clean production technologies; repairing existing environmental damage; feeding the world's hungry; enabling the blind to see and deaf to hear; eradicating diseases and offering protection against harmful bacteria and viruses; and even extending the length and the quality of life through the repair or replacement of failing organs. Given this fantastic potential, how can our attempt to harness nanotechnology's power at the earliest opportunity – to alleviate so many earthly ills – be anything other than ethical?

Opposite:
Southeastern United States
10^{+6}
1,000 kilometers

Conversely, how can a choice to halt be anything other than unethical?

Third, technology has always been a two-edged sword, offering both upsides and downsides. Nanotechnology is no exception. Our focus – our dedicated commitment – must be to hasten the benefits of nanotechnology while minimizing any potential downside. We learned much in the 20th Century about honing the useful edge of technology's blade, while dulling its other edge. We must apply these lessons to the development of nanotechnology. We must also recognize that given the revolutionary potential of nanotechnology, we are likely to see applications that create ethical and societal challenges beyond our current framework. Therefore, we cannot afford to wait to address legitimate societal and ethical concerns.

That bears repeating so none miss the point: we cannot wait to address legitimate concerns. Neither can we afford to devote time and limited resources to imaginary concerns. We must quickly and effectively sort the legitimate concerns from imaginary ones, debunking and dismissing the latter while devoting time, attention and resources to the former. And it is important to tackle these issues early, since the public policy apparatus in democracies are not designed to move quickly. We must think and act far ahead.

Addressing societal and ethical issues associated with nanotechnology is the *right thing* to do and the *necessary thing* to do. It is the right thing to do because we should be serious about ethical development, about stewardship of our environment, and about bettering both the dignity and condition of humans. And it is the necessary thing to do to speed technology adoption, to accelerate and increase our return on investment, and to broaden and deepen its economic and societal benefits.

Looking back, I hope one day historians will write that while this era – and the technological frontiers that we are pioneering today – was fraught with pitfalls and dangers, men and women from around the world came together to ensure that future generations would reap the benefits of our work, while forethought and action on our part safeguarded them against any adverse consequences. The United States is committed to working in partnership with nations around the world to see that history is written in this manner.





3
Framing the issue of nanotechnology – from a Japanese perspective

Masahiro Takemura

Masahiro Takemura
represented the Nanotechnology Researchers Network Center of Japan, National Institute for Materials Science, Japan

In the 2nd Science and Technology Basic Plan (2001 – 2005), the research area of nanotechnology and materials is designated as one of the four prioritized areas in funding. Following this plan, both of the main funding ministries, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Economy, Trade and Industries (METI), and their respective organizations, JSPS, JST, NIMS, RIKEN, NEDO and AIST have been promoting research programs. Besides, in order to encourage interdisciplinary and international collaboration among researchers, the Nanotechnology Support Project was started by MEXT in 2002. In terms of health and environmental issues, MIHS and MOE, and their institutes, NIHS, NIIH and NIES are involved; the institutes are responsible for safety of foods and drugs, occupational health, and environmental protection, respectively. The importance of health, environmental, and societal issues of nanotechnology are becoming rapidly and widely recognized in Japan; committees and workshops have been taking place, in which AIST and NIMS are proactive.

Japan's nanotechnology policy

Nanotechnology is now recognized worldwide as one of the key issues in science and technology in the 21st century. For sustainable economic development and the comfort and safety of people, the Japanese government is committed to providing strong support for nanotechnology research based on the Second Science and Technology Basic Plan (2001 – 2005), prepared by the Council for Science and Technology Policy (CSTP) whose chairperson is the Prime Minister, in March, 2001 (Government of Japan, 2001). The Basic Plan assigns strategic priority in R&D to basic research and four prioritized areas in funding: life sciences, information and telecommunications, environmental sciences, and nanotechnology and materials science/technology. In nanotechnology and materials science, CSTP exemplified five fields: nano-devices and materials for next-generation communication systems (information technology), materials for the environment and energy-saving (environment), nano-biology for new medical care

technologies and biomaterials (biotechnology), underlying technologies such as fabrication and analysis/simulation technologies (generic technology), and novel materials with innovative functions (materials) (CSTP, 2001).

Following this plan, government funding for R&D on nanotechnology and materials science was increased and reached USD 855 million in 2004. The Nanotechnology and Materials Project Team (NTPT) of CSTP is in charge of the coordination of the whole ministries. MEXT and METI are the main funding ministries, and their principal R&D organizations are shown in Figure 1. MEXT has two funding agencies and two research institutes: the Japan Society for the Promotion of Science (JSPS), the Japan Science and Technology Agency (JST), the National Institute for Materials Science (NIMS), and the Institue of Physical and Chemical Research (RIKEN). JSPS supports basic research with grant-in-aid for scientific research, and JST coordinates challenging research which will need 10 – 20 years for industrial application by dispatching both funds and researchers.

NIMS and RIKEN are mainly in charge of generic technology. On the other hand, METI has one funding agency and one research institute: the New Energy and Industrial Technology Organization (NEDO) and the National Institute of Advanced Industrial Science and Technology (AIST). Both organizations are in charge of flagship-type research which will need 5 – 10 years for industrial application.

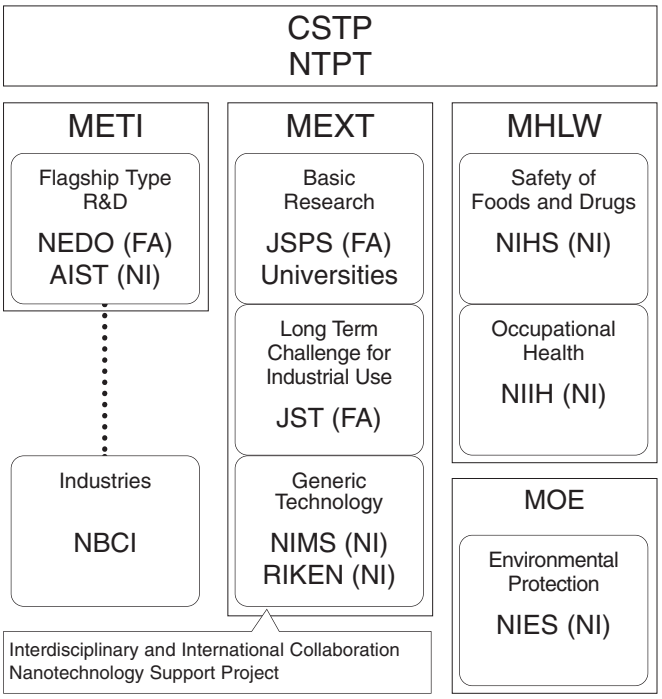

Figure 1.
Organizations for Research, Development and Assessment of Nanotechnology

The overall programs supported by MEXT and METI are illustrated in Figure 2 and Figure 3, respectively (MEXT, 2004, METI 2004a and METI 2004b). Both ministries have several highlights of research programs such as the Leading Projects by MEXT, the Nanotechnology Virtual Laboratories by JST, the Focus 21 by METI, and the Nanomaterials and Processing Sub-Program by NEDO. In terms of technology transfer, intellectual properties, and centers of excellence, there are also several programs in which nanotechnology is involved (Government of Japan, 2001). Furthermore, the Nanotechnology Support Project (NSP) (Nanonet, 2004) and the Nanotechnology Business Creation Initiative (NBCI) (NBCI, 2004) are also shown in Figure 1.

NSP was started by MEXT in April, 2002 in order to support researcher network for the promotion of interdisciplinary and international collaboration. NSP has two missions: informational support and common use facility support. The Nanotechnology Researchers Network Center of Japan (Nanonet) is responsible for informational support: 1) collecting information on nanotechnology including its health, environmental, and societal issues and sending it by website (www.nanonet.go.jp) and e-mail newsletters, the Japan Nanonet Bulletin, 2) organizing and supporting symposia and workshops, 3) organizing international programs such as bilateral researcher exchange programs and symposia with the US and European countries, 4) providing education and training opportunities. Common use facility support is conducted by 14 universities and national research institutes which supply the opportunities to use four types of facilities: ultra-high voltage TEM, synchrotron radiation, nano-foundries, and molecular synthesis and analysis. NBCI, a consortium of more than 300 private companies, was founded with a help of METI in October, 2003 to promote industrial application of nanotechnology.

In terms of health and environmental issues of nanotechnology, two more ministries should be involved: the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of the Environment (MOE). MHLW has the National Institute of Health Sciences (NIHS), responsible for the safety of foods and drugs, and the National Institute of Industrial Health (NIIH), responsible for occupational safety and health. MOE's National Institute for Environmental Studies (NIES) is responsible for environmental protection.

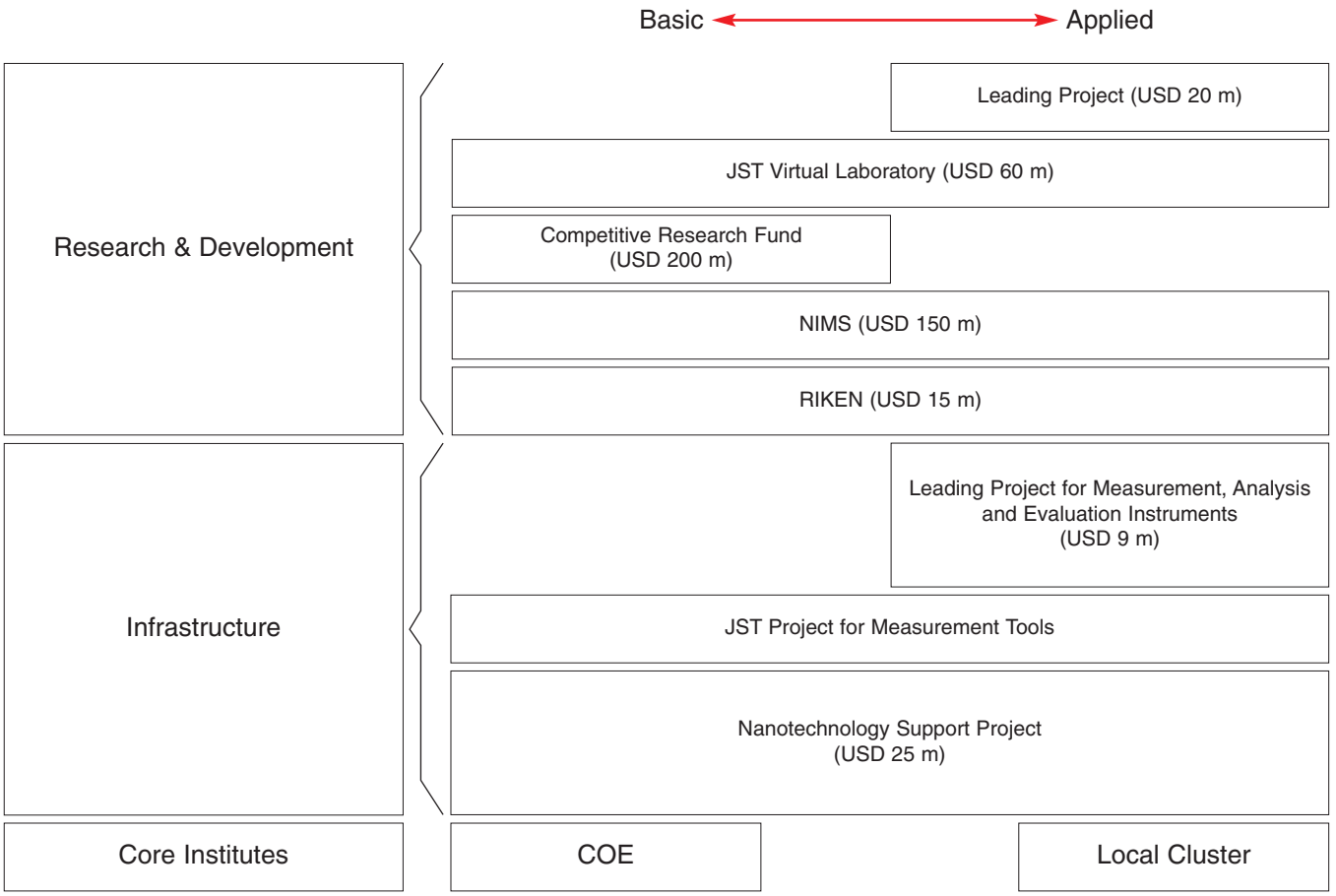

Figure 2.
Main Nanotechnology Programs by MEXT (MEXT, 2004a)

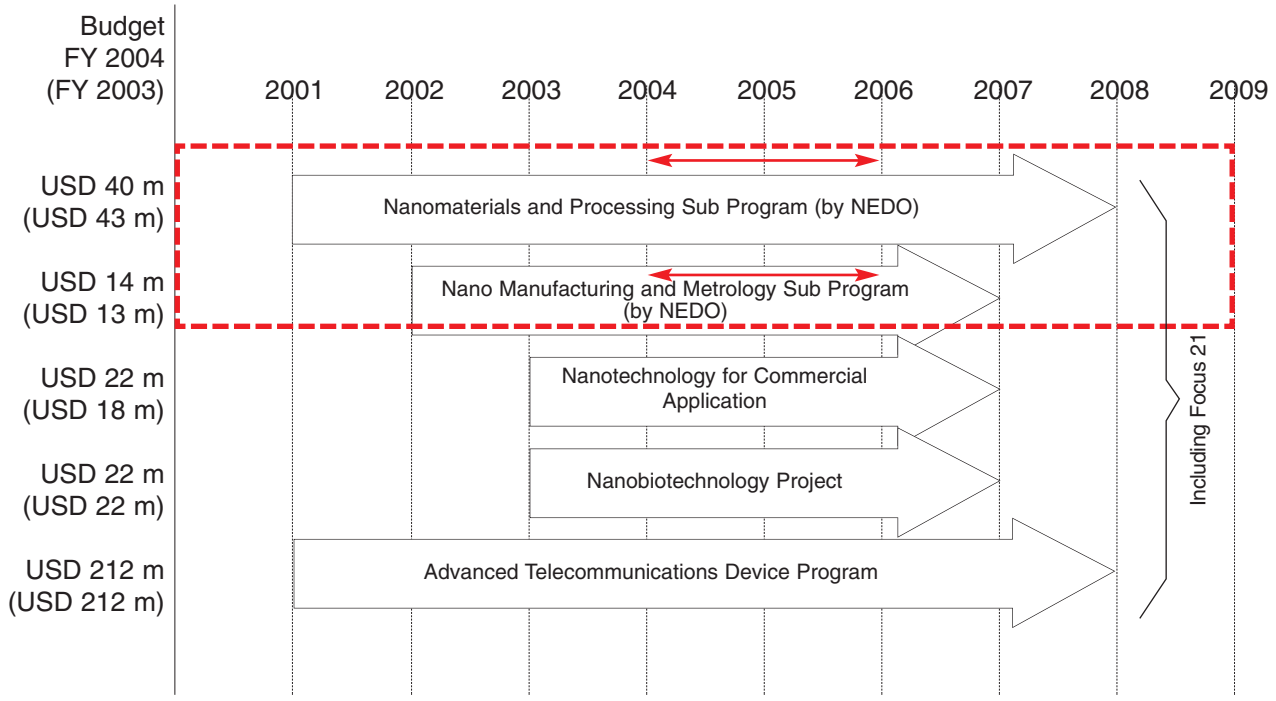

Figure 3.
Main Nanotechnology Programs by METI (METI, 2004b)

Efforts for health, environmental, and societal issues of nanotechnology in Japan

Discussions on health, environmental, and societal issues of nanotechnology in Japan take place in committees and workshops shown in Table 1, all of which were launched in 2004 and which join government agencies, universities, industries and toxicologists. The First Symposium on Nanotechnology and Society will be held on 1 February 2005, as the summary of the activities in 2004.

Health and environmental implications of nanomaterials have been studied by research groups and independent researchers. The most organized research on these issues was Scientific Research for Priority Area "Carbon Cluster", Grant in Aid for Scientific Research, MEXT, 1993-1995, headed by Osawa (Osawa et al., 1996). In this project, various aspects of C60 were examined. Although at that time nanotechnology was not paid as much attention as it is today, with a USD 8.6 million grant over three years, 166 scientists focused on seven research areas in an interdisciplinary collaboration and published more than 500 papers. In the research area of "Biological Effect of Fullerenes", nine scientists studied the solubility, the toxicity, and the mutation effect under photo-irradiation of C60 (Hamano et al., 1995, Sakai et al., 1999, Sera et al., 1996, Tsuchiya et al., 1996 and Yamakoshi et al., 1994).

Besides, metallic and ceramic nanoparticles such as nickel, cobalt, and titanium dioxide have been also examined in terms of occupational health. According to the study of Kusaka's group (Zhang et al., 2004), the toxicity of nickel and cobalt is much higher than titanium dioxide. NIES has been studying the toxicity of diesel exhaust particles and started expanding their research to industrial nanoparticles (Yamamoto et al., 2004).

Towards realization of nanotechnology for society

The importance of health, environmental, and societal issues of nanotechnology are becoming rapidly and widely recognized in Japan. In addition to the efforts mentioned above, much discussion on risk assessment of nanomaterials, communication with social scientists interested in science and technology in society (STS) has started. Some sociologists' experience in technology assessment, risk perception, and risk communication in nuclear power technology and aerospace technology also contribute to the case of nanotechnology. In terms of international collaboration, the Japanese government will basically follow the conclusions of International Dialogue on Responsible Research and Development of Nanotechnology, held in Alexandria, Virginia, June 2004 (Meridian Institute, 2004). In addition, Asian countries started the Asia Nanotechnology Forum in May 2004 (ANF, 2004), in which standardization and societal aspects of nanotechnology were defined as the most important agendas.

Committees, Workshops	Coordinators
Nanotechnology Standardization Research Committee (2004.11)	Japanese Standards Association (JSA)
Workshop: Nanotechnology and Society (2004.8)	National Institute of Advanced Industrial Science and Technology (AIST)
Workshop on Nanotechnology Risk Assessment (2004.4)	Society of Non-Traditional Technology
Nanomaterials Risk Study Group (2004.9)	Chemo-Bio Integrated Management Society (CBIMS)

Table 1.
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4
Nanotechnology and human health: a risk-benefit analysis

Paul J.A. Borm

Paul J.A. Borm *is Professor at the Centre of Expertise in Life Sciences (CEL) Heerlen and Department of Particle Toxicology/Institut für Unweltmedizinsische Forschung (IUF), Department of Particle Research at the University of Dusseldorf, Germany*

Introduction

Recent years have witnessed unprecedented growth of research in the area of nanoscience and nanotechnology. There is increasing optimism that, as applied to medicine, nanotechnology will bring significant advances in the diagnosis and treatment of disease. Anticipated applications include drug delivery, diagnostics, nutraceuticals and production of biocompatible materials. Engineered nanoparticles (< 100 nm) are an important tool to realize a number of these applications. Nanoparticles (NP) are attractive for such purposes because of their key and unique features: their surface to mass ratio, which is much larger than that of other particles, their quantum properties and their ability to absorb and carry other compounds. Nanoparticles have a large (functional) surface which is able to bind, absorb and carry other compounds such as drugs, probes and proteins. However, many challenges must be overcome if the application of nanotechnology is to realise the anticipated improved understanding of the patho-physiological basis of disease, bring more sophisticated diagnostic opportunities and yield improved therapies.

One of the most challenging problems confronting nanotechnology is the research data about ultrafine particles generated by combustion processes (eg diesel exhaust particles, DEP). Research has demonstrated that exposure to these particles is associated with pulmonary inflammation (Donaldson et al, 2002), immune adjuvant effects (Granum and Lovik, 2002) and systemic effects, including blood coagulation and cardiovascular effects (review: Oberdorster, 2001; Borm & Kreyling, 2004). Since cut-off size for their definition (100 nm) is the same, both terms are now used synonymously. The meeting of nanoscience, with its engineered nanoparticles, and that of toxicology, with its understanding of ultrafines, has led to an impressive series of workshops over the past year. However, since little exchange of methods and concepts has taken place, the aim of this paper is to detail both opportunities and risks associated to applications of nanoparticles and materials in medical applications.

Opposite:
Tree branch with leaves
10^{+0}
1 meter

Nanomedicine: Health benefits and perspectives

Nanomedicine uses nano-sized tools for the diagnosis, prevention and treatment of disease to better understand the underlying complex pathophysiological mechanisms. The ultimate goal is to improve quality of life. The aim of nanomedicine may be broadly defined as the comprehensive monitoring, control, construction, repair, defence, and improvement of all human biological systems, working from the molecular level – using engineered devices and nanostructures – to ultimately achieve a medical benefit. In this context, nanoscale should be taken to include active components or objects in the size range from 1 nm to 100s of nm. These definitions originate from a working group initiated in early 2003 by the European Science Foundation (ESF). In its preliminary report, ESF identified four key areas in which development is expected (ESF, 2004):

Analytical techniques and diagnostic tools

Treatment of most diseases can only advance when progress is made in both the diagnosis and the treatment of any given disorder. A great deal of hope, hype and anticipation has been invested in better analytical techniques and diagnostic tools based on nanotechnology. It is realistic to say that nanotechnological tools will be routinely used in diagnosis long before they are approved for the treatment of diseases.

Nanoimaging and manipulation

There is little doubt that imaging is becoming an increasingly important tool in the diagnosis of human diseases. Both the development of imaging agents (micro- or nanoparticles, organic dyes, etc) and highly sophisticated instruments supported by powerful computation (2D, 3D reconstruction) have brought about a shift from invasive to less invasive imaging-based diagnosis in recent years. Imaging at the cellular, or even sub-cellular, molecular level is still a domain of basic research, but may one day find its way into clinical routine. The development of imaging techniques will further help to diagnose and treat diseases earlier, and, furthermore, monitor progress in fighting ailments. This holds true for a multitude of diseases, the most important ones to include cancer, neurodegenerative and heart diseases. Apart from these clear medical benefits, there are substantial socio-economic benefits. An earlier diagnosis with a non-invasive tool and an earlier treatment are less costly. In addition, economists consider living healthier, longer lives economically beneficial.

Nanomaterials and nanodevices

Nanomaterials and nanodevices are critical in nanomedicine. On the one hand, the principles of materials science may be employed to identify biological mechanisms and develop medical therapeutics. On the other hand, the opportunities of nanomedicine depend on the appropriate nanomaterials and nanodevices to realise their potentials. Nanomaterials and nanodevices for nanomedicine are produced largely based on nano-scale assemblies for targeting and ligand display. By employing underpinning technologies to enable nanomedicine, biological, biologically inspired, and utterly synthetic nanomaterials and nanodevices are all being developed, with the scales from molecule to assembly and functional device.

Drug delivery and pharmaceutical development

Drug delivery and related pharmaceutical development in the context of nanomedicine should be viewed as science and technology of nanometre-size scale, complex systems (10 – 1000 nm), consisting of at least two components, one of which is an active ingredient (Duncan, 2003). The whole system leads to a special function related to treating, preventing or diagnosing diseases which is sometimes referred to as smart-drugs or theragnostics. Depending on the origin, the materials employed include synthetic or semi-synthetic polymers and natural materials such as lipids, polymers, and proteins. The primary goals for research of nano-biotechnologies in drug delivery include: faster development of new safe medicines, more specific drug delivery and targeting, and greater safety and biocompatibility.

Currently, the development of a new drug is estimated to cost more than EUR 700 billion and the number of FDA approvals has been gradually decreasing over the past decade. It is anticipated that with the help of nanoscience, so-called orphan drugs may be further developed and drugs that were eliminated in the development of the process may be reactivated. However, the current pharmaceutical industry has shown little interest and academia has been responsible for the major developments.

Quite obvious, therefore, is that the nanomaterials segment – which includes several long-established markets such as carbon black rubber filler, catalytic converter materials and silver nanoparticles used in photographic films and papers – presently accounts for over 97.5% of global nanotechnology sales. By 2008, the nanomaterials share of the market will have shrunk to 74.7% of total sales (IBC, 2004). Nanotools will have increased their share to 4.3% (USD 1.2 billion), and nanodevices will have established a major presence in the market with a 21% share (USD 6.0 billion). The life science applications are thought to induce the latter increase.

Risks of ultrafine particles

Apart from specifically engineered nanomaterials, nano-sized particles are also being produced non-intentionally in diesel exhaust and other combustion processes. These *combustion nanoparticles* are included in particulate matter

(PM) which is measured by mass and related to adverse effects in patients with lung and cardiovascular disease. Combustion nanoparticles have also been denominated as ultrafine particles and are primary particles or agglomerates with a diameter smaller than 100 nm.

These ultrafine particles are a small mass fraction of total anthropogenic particulate emissions, described with total suspended particles (TSP), particulate matter (PM) or PM beyond a specific size in micrometres (PM10, PM2.5, PM1). It is estimated that 50,000 kg/year of nano-sized materials are being produced through these unintended anthropogenic sources. This and later studies estimate that per 10 µg/m3 increase in the concentration of PM2.5, overall mortality increases by 0.9%, while deaths from specific respiratory diseases can increase by as much as 2.7%. There is ample evidence that a small proportion of the mass, but large proportions of the number of the particles in ambient air, are ultrafine in size. Numerous toxicological studies have now forwarded that these ultrafine particles are responsible for adverse effects, but so far few human studies have been able to investigate this.

Interestingly, most of the experimental, toxicological work on nanoparticles has been generated with a small set of *bulk nanoparticles*. These nanoparticles have been found in industry for a number of decades and are produced in many tons per year, the largest production volume being in 2004 for colloidal silica, titanium dioxide, and various iron-oxides. All these bulk nanoparticles were considered to be so-called nuisance dusts until it was observed that upon prolonged exposure in rats, inflammation and lung tumors could occur (reviews: Donaldson et al, 2002; Oberdorster, 2001; Borm et al, 2004; Borm & Kreyling, 2004). In summary, these findings set the stage for the current discussion on risks of nanoparticles illustrated as a triangle in Figure 1.

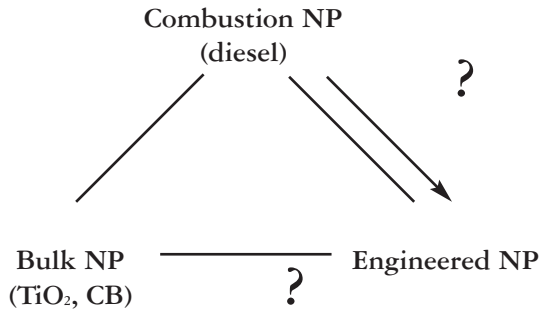

Figure 1.
Illustration of the different sources and applications of nanoparticles (NP) and the evidence for their relation with adverse effects in humans or animals. Epidemiology and toxicology have demonstrated acute effects of combustion NP in humans, as well chronic effects of NP in animals. Still an open question is whether the hazards and risks found with those types of NP can be extrapolated to engineered NP, which is illustrated by the question marks.

The key question is whether the different pieces of toxicological and epidemiological evidence on different nanoparticles can be mutually used or whether a more sophisticated approach is necessary.

A look forward

Nanotechnology has the potential to launch our current economy into a new era, much as coal mining did more then 100 years ago. Some even say, "Nanotechnology will reverse all the harm done by The Industrial Revolution". It may take at least 50 years to test these statements, but in the meantime, it may be useful to learn lessons from the development, economical impact and health implications of other technologies. Although biotechnology is most frequently mentioned for comparison, I have indicated the similarity of events to that induced by the worldwide development of coal mining (Borm, 2002). Coal mining in Europe has been at the basis of the current European Union, and its precursor ECSC starting in 1956. This consortium has stimulated and endorsed research and development programmes to ensure safe and sustainable coal mining and related industries. Research programmes on safety and health risks have led to basic understanding and pragmatic measures to reduce exposure and familiarity with the mechanisms of coal dust-related diseases. The further technological development of nanoscience requires research and regulation on safety aspects and health issues for producers, users and consumers (Colvin, 2003).

Toxicity testing of nanomaterials

While there is a considerable amount of data on the toxicity of NP, this data is mainly based on a small panel of NP (diesel, TiO_2, CB) and the assumption that a number of effects by PM are driven by the ultrafine particles in it (Donaldson et al, 2002). Due to this background of the data and the specificity of most preparations of engineered nanoparticles, a great deal of work needs to be done with regard to characterisation and biological testing of engineered NP. In this regard, it is recommended to perform testing driven by the anticipated application and classification by risk rather than by hazard.

Exposure and distribution

The ultimate risk of NP is dependent on both the hazards and the exposure. The risk is mainly driven by exposure to and uptake of NP at different routes of uptake. Different uptake routes may exist (skin, oral, lung) and NP can distribute from site of entry to other sites in the body, including the brain and placenta. Studies with NP in drug delivery have shown that NP can accumulate in areas with increased permeability and cross barriers such as the blood-brain barrier and placenta. Little is known about conditions and co-exposures that may cause increased uptake and altered distribution upon exposure to NP. In addition, there is a need for simple methods to assess airborne exposure to NP, and assess contribution to the total body burden of NP.

Consumer protection

Exposure to NP may occur in occupational and environmental sources as well as through nanomedicines, (functional) food and food chains. At the moment, there is little know-how as to how to circumvent exposure or to protect workers to NP uptake at accidental or chronic exposure to NP. Simple techniques for online measurement of NP will help to identify industrial operations and procedures that may give rise to NP emissions. Apart from incidental publications, studies on the environmental distribution and effects of NP are entirely lacking and there is considerable need for studies on the life-cycle of NP, especially in consumer product such a instruments, implants, coatings and food components.

There are, of course, potential risks and side effects from many nanomaterials applied in nanomedicine. In this respect, it is crucial to mention that those indicated in medical reports who purportedly derive the greatest benefit from nanomedicine (Buxton et al, 2003) are exactly those identified by toxicology to be at risk for the effect of inhaled nanoparticles (Seaton et al, 1995; Suwa et al, 2002; Borm & Kreyling, 2004). This underpins the importance of establishing communication among those involved in the risks and utilising the opportunities of nanomaterials. Perhaps the most challenging question about such a collaboration is the relevance of data of combustion and bulk nanoparticles for engineered nanoparticles.

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5
Could engineered nanoparticles affect our environment?

Vicki L. Colvin

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At the heart of any nanotechnology is a nanomaterial: a highly controlled, functional substance with a critical dimension under 100 nm. These engineered nanomaterials provide the unique chemical, physical and, in some cases, biological properties which make nanotechnologies so powerful and potentially valuable – whether in the electronic, medical or energy industry. As a result, while nanotechnologies will span many sectors of commerce, the production and control of high quality materials will be a shared concern.

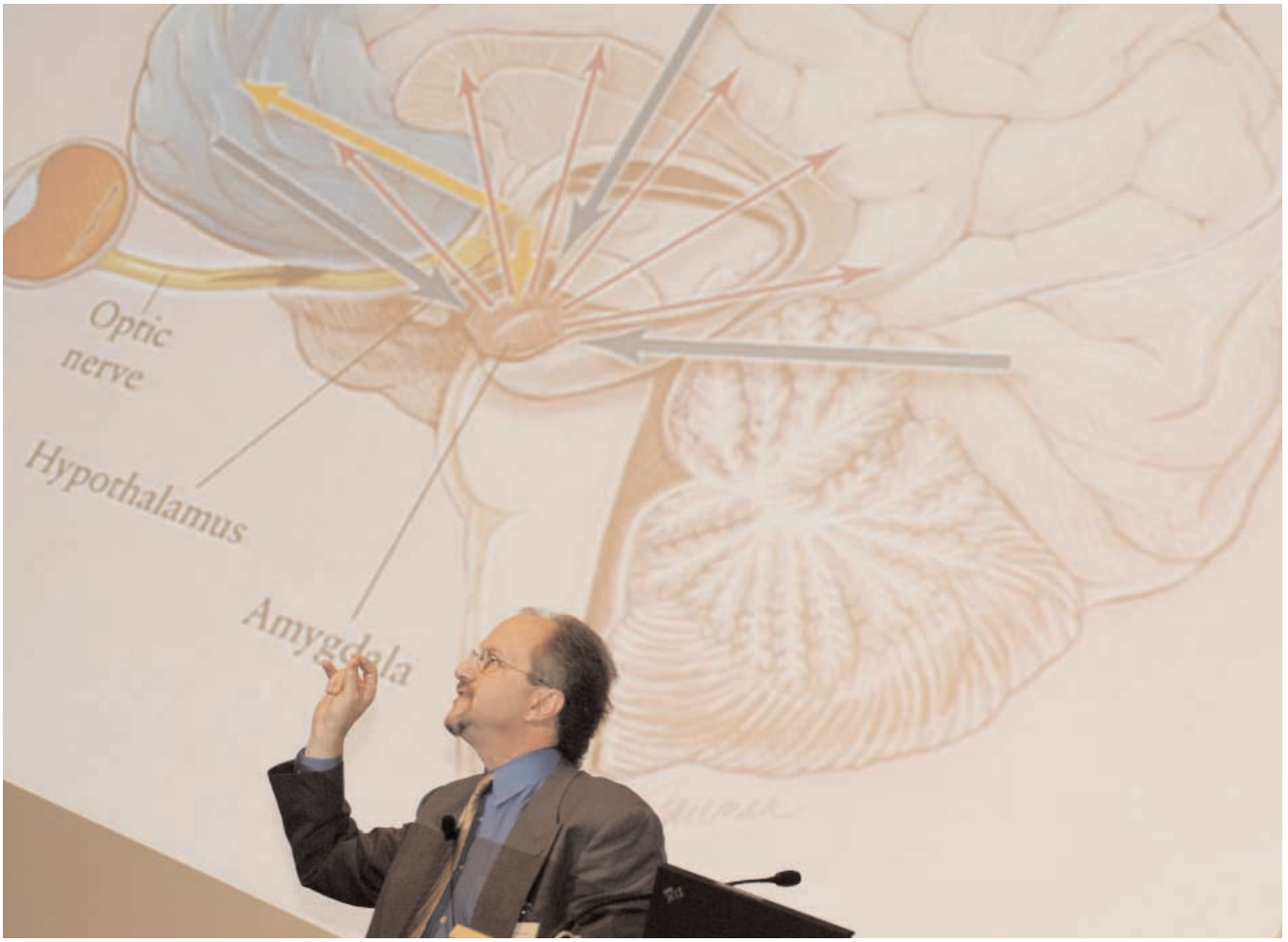
For "top-down" nanotechnologies where lithography is used to carve out ultra-small nanotransistors and sensors from bulk materials, the tools of the semiconductor processing industry will be dominant. In manufacturing these products, engineered nanostructures of one, two and three-dimensions are seamlessly integrated into larger bulk materials. Even under the most extreme end-of-use scenarios, it is highly unlikely that such systems could ever yield substantial environmental exposures of nanostructures. Instead, the environmental impact will be almost entirely defined by the by-products and sustainability of the manufacturing process itself. Because the tools used for nanolithography are not substantially different than those used for current semiconductor processing, environmental impact, both for production and product life-cycle, can be extrapolated from existing information.

By contrast, "bottom-up" nanotechnologies integrate pre-formed nanostructures into products. Bulk powders and solutions of nanotubes, nanoparticles, nanofibers and other free nanostructures are formed and packaged, and then integrated into products as diverse as solar cells, drug delivery agents, and efficient water treatment systems. Businesses marketing these engineered nanostructures will be the 21st century versions of a speciality chemical manufacturer. Thus "green manufacturing", ie best practice for waste disposal and environmental risk assessments for production processes, is central to those businesses' success. Their customers – companies which use and integrate

nanotechnologies – must also consider environmental impact issues carefully. Product lifecycle and end-of-use issues provide an important point of entry for engineered nanoparticles into the environment. Thus, both producers and users of "bottom-up" engineered nanomaterials must address the issue of their products' environmental impact. Since engineered nanomaterials differ so much from either molecular or bulk substances, extrapolation from any existing information is problematic.

The issues surrounding the environmental impacts of "bottom-up" nanomaterials are referred to here generically as "nanoparticles". Nanotechnology is too young an industry, and too little is known about its materials, to be well served by a formal risk assessment process. These quantitative measures of environmental impact require extensive and complete data on a wealth of issues ranging from nanoparticle production levels to fate and transport in aquifers to eco-toxicology. Given the wide range of nanoparticle types, sizes and formats, it is likely to be at least a decade before this information is developed, and even then, information will be highly material-specific. Until that time, the best strategy is to identify which critical parameters will determine whether certain nanoparticles are either "very safe" or "high risk". By bringing that data into focus early, we can narrow our attention to those material types and formats which could most likely affect the environment.


"Small size–large impact?"
Conference on nanotechnology


Optic nerve
Hypothalamus
Amygdala





6
Nanotechnology and the future of information technology

Paul Seidler

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Since funding agencies around the world are supporting many research institutes dedicated to the pursuit of nanotechnology and the interest shown by the press is enormous, nanotechnology has clearly become a buzzword. Scientists have been joined by analysts, planners, and strategists in a multitude of industries in their attempts to understand the implications for their businesses. As is often the case when new innovations are introduced, the emerging field of nanotechnology has also become the subject of some extreme viewpoints: hype and doomsday prophecies have come from utopian promoters and cynics.

Indeed, communication to the nonscientific community is one of the key issues scientists in the field must address. Science fiction writers are, of course, exploiting the rapid developments; books and children's cartoons feature self-replicating molecular marvels which turn into rampaging swarms or develop unexpected "emergent" collective intelligence. Further, some prominent public figures are voicing concerns over the social implications of this emerging science, perhaps opening the door to more nanomyths. It is easy for people to be confused and concerned.

Fortunately, nanotechnology research in laboratories around the world is far removed from this disturbing science fiction, and is rooted in a nanoreality which is either emerging or has emerged. In the information technology (IT) industry specifically, nanotechnology promises future innovation and growth. My intention in this article is to eliminate some confusion, first by considering a few of the widespread nanotechnology myths, and then by describing some of the challenges and opportunities nanotechnologists face today.

Opposite:
Surface of a leaf magnified
100 times
10^{-3}
1 millimeter

Myth 1: Nanotechnology is a distinct, previously unknown discipline

Nanotechnology actually embraces advancements over a wide range of scientific and technical disciplines – physics, chemistry, biology, materials science, mechanics, and electronics, to name just a few. Commonly designated as the science and technology in which at least one dimension is controlled to less than 100 nanometers, it may, in fact, be best to think of nanotechnology as an engineering discipline: its aim is to design and build structures and devices on this very small-length scale using tools from whatever field is appropriate.

Although the word is relatively new, nanotechnology has been around for some time. Chemists and biologists, for example, have long been able to design and create molecules with specific atomic structures. Typically, this could be done only in batches with relatively large collections of molecules. Over the past 20 years or so, scientists and engineers have increasingly extended the ability to view and manipulate ever smaller bits of matter – in some cases individual atoms. While nanoparticle additives to paints and clothing, molecular circuit elements and designer drugs can all be considered nanotechnologies, these applications have little in common beyond their use of materials designed and structured at the nanometer scale.

In the IT industry, semiconductor manufacturers are now producing chips with minimum lithographic dimensions which measure a mere 90 nanometers or less and feature millions of transistors. The experimental silicon transistors in our laboratories are smaller yet. A mere 6 nanometers for the critical gate length is the current frontier – the kind of innovation that IT relies upon to build devices that are ever smaller, faster and cheaper.

Myth 2: The primary goal of nanotechnololgy is to create self-assembling nanobots

Researchers today are hardly creating the self-replicating nanobots of science fiction, Instead, they are working on the so-called directed self-assembly of nanoscale materials and devices, aiming to exploit the natural tendency of atoms and molecules to orient themselves, react, and bind with each other in predictable ways under the right conditions.

Self-assembly is nothing other than exploitation of the laws of thermodynamics and kinetics which drive all natural phenomena. Consider a snowflake, which is created when water molecules floating in a cloud coalesce around a grain of dust and crystallize to create a new structure. While a snowflake may have a complex structure, it is far from *alive* and does not self-replicate. Nevertheless, when conditions are right, nature makes trillions of them quickly and cheaply.

By taking advantage of such natural forces, scientists try to discover the conditions to form technologically useful new materials and devices. They are currently exploring the directed assembly of transistors and circuits based on carbon nanotubes, semiconductor nanowires and molecular building blocks. Further, they are developing self-assembled materials for data storage and memory. In the future, processes of directed self-assembly are likely to be used increasingly in combination with today's photolithography to reduce the reliance on this ever more expensive method for semiconductor manufacturing. In this sense, the often-cited contrast between top-down (photolithography) versus bottom-up (self-assembly) approaches to device fabrication is a false dichotomy. A hybrid of the two already is – and will continue to be – employed.

Myth 3: Nanotechnology will replace microelectronics

Microelectronics is a nanotechnology, as are hard-disk drives whose giant-magnetoresistive read heads and magnetic media rely on layers of materials only a few atoms thick to give computers ever more storage capacity.

Rather than suddenly replacing today's methods for chip manufacture, it is more likely that individual nanostructures and nanodevices and new manufacturing processes will increasingly be integrated into the mainstream. Transistors made out of the new materials being considered, such as carbon nanotubes and semiconductor nanowires, might not be much smaller than that experimental 6-nanometer silicon transistor mentioned above. Silicon probably has a promising future as a nanomaterial.

That being said, there are numerous, innovative alternatives being explored to augment the capabilities of integrated circuits. Particularly interesting is the prospect of using physical phenomena other than simple manipulation of electronic charge in future computing devices, such as the spin of electrons (so-called spintronics) or even nanoscale mechanics.

Challenges and opportunities for the future of the IT industry

While nanotechnology is already contributing to the ongoing progress and extension of IT technology, the future is not without its challenges. The scaling of semiconductor technology known as Moore's Law may continue for another decade or so, allowing us to eventually fabricate transistors with critical dimensions approaching 10 nanometer. After that, a transition in technological hardware and, a long lead-time for developing new technologies can be expected. As such, the IT industry is working now on the successor to conventional CMOS semiconductor technology.

The technical challenges to be solved are numerous:

- How to cost-effectively manufacture beyond the limits of lithography?
- How to practice self-assembly such that we get the right devices at the right place with the right properties?
- How to deal with imperfections?
- With variability in device behavior?

These challenges, of course, also present opportunities. Innovation will lead to – in fact, will be essential for – business success. Sound and broad technological expertise and clever implementation will provide competitive advantage and speed to market. Development cycle times may increase for some of the more traditional technologies, but overall, the system performance experienced by the consumer will continue to improve, and nanotechnology will contribute to these improvements.

Communication: A challenge for nanotechnology in general

As mentioned at the outset, perhaps the greatest issue facing nanotechnology is the question of communicating what it is. In particular, public misconceptions may adversely affect the use or acceptance of nanotechnology.

As with any technology, one must consider the possible implications of its use. In the IT industry, further miniaturization of hardware and the commensurate lower cost of performance and functionality imply that computing will become even more pervasive. New applications, services, and business models will appear in every industry sector, and issues such as security and privacy of information will need to be taken more into account.

Scientists and engineers cannot predict all of the eventual applications of their knowledge and their designs. In the final analysis, society as a whole – of which scientists and engineers are also members – will decide on the proper applications of any new technology. While such decisions should arise through informed public debate, it is essential is that the discussion of nanotechnology focus on scientific realities rather than science fiction.

For those immersed in the science and engineering of nanotechnology, the future is exciting. It admittedly lacks the appeal of science fiction or a colorful orator in Hyde Park, but nanotechnology is here to stay in many of its manifestations, just not in a form that sells an author's books.



7
Chemical nanotechnology – challenges, opportunities and safety issues

Tilo Weiss

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Of a few megatrends in chemistry which have emerged over the last ten to fifteen years, nanotechnology is presumably the most major. A great deal of research has been conducted, and public and private bodies have invested considerable resources in nanotechnology's evolution. Now at a point where the questions related to the approach outnumber the answers and successful innovations are still few and far between, the basic questions are: what makes nanotechnology so unique and which specific issues must be targeted?

Nanotechnology is often called a "cross-sectional technology" inasmuch as the expertise of various disciplines is required for its successful development. Further, there is no common application field for products and technologies based on nanotechnology. Familiar applications range from high-volume additives for plastics, additives for paints, fillers in dental materials and coatings in biomedical products to highly sophisticated drug-targeting and drug-release technologies for cancer treatment. Obviously, research and development of chemical nanotechnology are not likely to be conducted in classical and strictly-focused research departments and specific technical strengths will determine the development objectives.

These prerequisites were accessed by SusTech Darmstadt. In 2000, leading scientists in the field of chemical nanotechnology, together with the Technical University of Darmstadt and Henkel KGaA – a leading German corporation for household goods, cosmetics, adhesives and technologies – founded a new form of public private partnership. By design, every partner contributes with the expertise or capabilities that are his own proven strength. Whereas scientists are responsible for the scientific expertise in the field of chemistry and materials, the Technical University of Darmstadt provides the necessary infrastructure. Henkel KGaA draws on its expertise in the different markets and offers support functions and services in keeping with global standards; it also covers the initial financing.

SusTech Darmstadt offers each partner an ideal platform to pursue joint efforts; as such, it is the ideal foundation for successful development in a cross-disciplinary field such as chemical nanotechnology. Given that foundation, the partners can focus on the second challenge of selecting and elaborating on the most attractive development projects. Rather than in a evolutionary, step-by-step manner, research is conducted in a highly coordinated way; all the various aspects are considered by a variety of different experts in a timely manner.

Developments in any new technology take their time; a long time-to-market can be anticipated, hence the respective activities must be separated from the usual business activities. University and research institutes' start-up companies offer the necessary expertise and perspective for such long-term activities; and the necessary seed- and venture-capital financing decreased dramatically over the past few years, particularly for activities in chemical nanotechnology.

Large investments in sophisticated research equipment can handicap young start-up companies: either supporting technology consumes all the capital gathered in the first and second financing round, or the developments are carried out ineffectively. Yet within the network of universities and research institutes, equipment and infrastructure are readily available and may indeed be working at less than capacity. Furthermore, the running costs of state-of-the-art equipment are extremely high and normally not covered by a start-up's operating budget.

As with every new kind of material, the question of manufacturing and production costs will arise sooner or later. The earlier these aspects are considered, the more likely a successful transfer of basic developments into commercial products will be. In addition to classical expertise in chemistry, physics and materials science, expert involvement in engineering, processing and formulation technology is mandatory.

Given all these parameters, chemical nanotechnology is far more than just the development of some kind of new material. Researchers must work on all the steps of the development chain and need a comprehensive overview. This challenge offers access to a broader business model where materials are an integral part of the end product, not a small item on the far end of the value chain.

Establishing an organization to cover all these of integrated development issues yields a platform which, in turn, bridges the development gap between basic research and industrial product development. For some 25 years, that gap has been widening in light of increasing sophistication in basic development and focus on very basic activities. Further, industrial product development is increasingly driven by short-term business requirements. A problem arises on both sides of this gap. Researchers at universities and institutes lose their handle on real-life applications, and experts in industry have few breakthrough innovations.

Needless to say, there are various models of cooperation between academia and industry which are well established. Ranging from direct cooperation to public funded joint activities, and the spin-off and start-up companies which may have been acquired by bigger partners and strategic venture capital over the past few years, a greater number of spin-out activities from industry are tapping into unused technologies and developments. Depending on the partners and the objectives, there will be a unique approach to organising the activities.

Within the framework of such a public-private-partnership, SusTech Darmstadt successfully develops new products and technologies based upon functional materials and/or chemical nanotechnology. It took only some four years for the company to implement a new bonding technology for the accelerated adhesion of plastic parts in the automotive industry. Actually, this step is one of the typical bottlenecks in car manufacturing; it limits the application of plastic parts and demands parallel set-ups and large investments. Developments in this field covered all the different production aspects – from materials to products, processes to technologies – and their speed and quality clearly proved the effectiveness of the partnership.

As a second example, SusTech Darmstadt also developed a class of innovative oral care products which effectively reduce the sensitivity of hypersensitive teeth caused by receding gums, a widespread problem among the ageing population of western societies. Classical treatments range from polymeric sealants applied by the dentists, to precipitation of low soluble inorganic salts or desensitizers in oral care products. Those methods promise neither durability nor convenience, and overall, the problem is treated in a less than a natural manner.

Scientists at SusTech Darmstadt developed a new material which simulates the composition of natural material such as teeth and still has the activity to induce a process called "neomineralization". Upon treatment with oral care products containing the biocomposite material Nanit®active, a natural process is induced and furthered. The resulting closure of exposed dentin tubuli leads to a remarkable reduction in hypersensitivity. Independent double blind clinical trials against a positive standard have proven its superiority, and initial products will be launched in 2005.

Clearly, the basic requirement for any of those developments is a perceivable benefit for the customer. An increased

performance, reduced number of side effects or lower costs are the driving forces for a successful roll-out. Nonetheless, for all developments in nanotechnology, safety must be considered right from the start.

Starting with initial experiments under restricted laboratory conditions, the safety of co-workers has highest priority. Laboratory practices in chemistry are well developed and the use of personal safety equipment must be made mandatory.

There is also a requirement for a continuous and independent safety assessment along the development chain. Toxicology and ecotoxicology experts must be involved in the activities from the start. Basing their approach upon a first chemical and physical analysis, these experts evaluate the possible risks connected to the materials and technologies.

These assessments are fundamental criteria for the further elaboration and structuring of development. Even at this very early point, such a statement might lead to a "no-go" – if severe and/or chronic toxic effects are reported in literature, say. Toxicological studies are conducted and all processes, designed, such that co-workers are not exposed to the materials under development. Irrespective of whether or not the underlying materials are nanoscaled, the company marketing a new product is liable for that product's safety. Case by case, the safety chain along the whole product lifecycle has to be examined and ensured. In this respect, chemical nanotechnology is nothing new; on the contrary, it is more a problem of methods and tools in toxicology. Ongoing research and development in this area promise to fill this knowledge gap.





8
Nanotechnology business startups in AIST

Masafumi Ata

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The National Institute of Advanced Industrial Science and Technology, the new AIST, is an independent administrative institution affiliated with the Japanese Ministry of Economy, Trade and Industry (METI). In the three years since its establishment in 2001, AIST has been actively pursuing "Full Research" a comprehensive form of inquiry encompassing the wide range of fundamental to applied research. To work toward the recent global priority of sustainable development, the R&D community of Japan now needs to shift the focus of its activity from research for *science* to research for *society*. Full Research serves this purpose as a flexible and effective tool that meets specific societal needs through methodologies distinct from those used in traditional scientific basic research. Recognizing the integrative and nonlinear characteristics of R&D activities, AIST proposes an integrated research methodology incorporating Type-I Basic Research, Type-II Basic Research, and Product Realization Research.

A new methodology for AIST research

The purpose of Type-I Basic Research is to ensure and discover novel rules, laws and principles that govern natural phenomena in the many disciplines in which it is conducted. Its activities are not usually based on specific socio-economic needs, but driven by curiosity and the desire to explore unknown phenomena. Type-I Basic Research has a long history, and almost all of the research scientists who engage in it do so under the auspices of universities and public research institutes. The research methodology and performance evaluation criteria for the quality of research activity are already very well established. Type-I Basic Research is a low-risk activity for researchers.

Type-II Basic Research seeks out specific routes that can lead to universal and reproducible knowledge useful for fulfilling socio-economic needs. Its methodologies integrate theories such as natural laws, principals, and theorems with empirical and theoretical data collected through observations, experiments and calculations. The

results and outcomes are applied to the development and commercialization of new materials, new equipment, new products, new systems, new processes, and new services, or to make significant improvements of existing products. These goals are reached through the systems of multiple disciplines and the creation of methods for the use of integrated knowledge. The successful application of Type-II Basic Research requires a high level of creativity in selecting, integrating and applying knowledge and theories.

Type-II Basic Research is often a high-risk activity for researchers, as the results can easily erode with rapid changes in socio-economic needs. Yet even when R&D activities fail, they provide universal knowledge that can be applied to other projects. This underlines the importance of preserving and disseminating knowledge gained to promote natural R&D effectively; the research community must accumulate all of its R&D knowledge, including that from Type-II Basic Research, and share it publicly.

It is important that government and industries share the risks for the effective commercialization of R&D efforts. Commercial restraints limit industry involvement in Type-I Basic Research, leaving the universities as the major players in this sphere. Public institutes such as AIST should also play major roles in this field. To improve R&D activities in public institutes and contribute to future sustainable development, AIST places its highest priority on the pursuit of coherent and concurrent research series ranging from Type-I Basic Research to Product Realization Research based on intensive Type-II Basic Research. Each research unit in AIST continues to work towards the establishment of an integrated research system that enables researchers from different scientific backgrounds to participate in scenario-oriented projects that address the needs of society.

Q&A: Nanotechnology business startups in AIST

What are the business opportunities in nanotechnology for your company/industry segment?

Nanotechnology is one of the most important fields of study at AIST, together with Materials S&T and Manufacturing. Ten organizational units within the institute work closely with nanotechnology on many levels. These include:

Five research centers established within the Nanotechnology, Materials & Manufacturing unit – the Correlated Electron Research Center, Digital Manufacturing Research Center, Nanoarchitectonics Research Center, Diamond Research Center, Research Center for Advanced Carbon Materials; four research institutes – the Nanotechnology Research Institute, Materials Research Institute for Sustainable Development, Research Institute for Computational Sciences, and Advanced Manufacturing Research Institute; and one research initiative – the Micro-Space Chemistry Lab.

The development of atomic architectonics and new techniques for the extremely precise machining of solid materials now enable us to construct infinitesimally small assemblies. This innovative technology is expected to open new frontiers for development in the fields of IT, biotechnology, and environmental technology from a universal perspective. Through its development of nanotechnologies for materials and manufacturing, AIST is working to eliminate environmental abuses, improve safety and reliability, and realize digital manufacturing on a practical level.

What are the challenges in producing/marketing nanotech-products?

The AIST Innovation Center for Startups (AIST-INCS) is the key organization within AIST for nanotechnology business startups. The demand for venture startups to create new markets and industries has recently been increasing in Japan. People place especially strong hopes in fast-growing technology-based venture companies (high-tech startups) in view of their potential to create high-value-added industries and high-quality employment opportunities for the revitalization of the Japanese economy.

To establish a platform for creating high-tech startups based on the technology seeds of universities and public research institutes, AIST set up the AIST Innovation Center for Startups (AIST-INCS) in October 2002 as part of an initiative entitled “Strategic Research Base Upbringing”, a five-year project subsidized by the Ministry of Education, Culture, Sports, Science and Technology with the Special Coordination Fund for Promoting Science and Technology. AIST supports venture businesses mainly through systems for consulting, R&D, and regulation-setting for venture creation. AIST-INCS is responsible for these incubation systems within the Institute.

AIST-INCS comprises four organizations: the business development practice force, the Office of Business Development, the Research Office for Business & Innovations, and the Planning Office of Business & Innovations. Among the 15 businesses proposed in fiscal 2004, four fall within the scope of the Nanotechnology, Materials & Manufacturing field: DDS technology using liposomal nanoparticles for missile drag, Super Ink Jet Technology for a minimal manufacturing system, and GaAs/AlGaAs Quantum Wire Technology.

What types of risk assessment and management measures should be taken to ensure the successful adoption of this technology?

A brief introduction of AIST's activities relating to the societal implications of nanotechnology will be helpful here. Some months ago, Masafumi Ata and Yumi Negami organized a debate series entitled "Nanotechnology and Society." Their purpose was twofold: to provide a platform for open dialogue on societal issues related to nanotechnology and to mobilize a network among researchers and key persons working in nanotechnology-related fields. To ensure transparency, all of the debates are open to public participation and the full debate proceedings are covered on the AIST homepage. The kick-off debate was held on 5 August 2004, and four successive debates have followed since. Societal and ethical issues of nanotechnology have been integrated as themes.

Organizations from all sectors have participated in the debates, including:

- From the private sector – NanoCarbon Research Institute, Frontier Carbon Corporation, SCIVAX, Mitsubishi Research Institute, and the Nanotech Business Creation Initiative, an organization with some 320 member companies;
- From government – the Council of the Science & Technology Policy Cabinet Office, METI, the Ministry of Environment, and the Ministry of Health, Labor and Welfare (MHLW);
- Independent Administrative Institutions – the New Energy and Industrial Technology Development Organization (NEDO), the National Institute for Materials Science (NIMS), the National Institute for Environmental Studies (NIES), and the National Institute of Technology and Evaluation (NITE);
- Journalists and university professors.

Dr. Kazunobu Tanaka, Vice President of the Institute, and Masafumi Ata are also preparing a symposium entitled "Nanotechnology and Society" to be held on 1 February 2005. This will be the very first symposium co-sponsored by NIMS, NIES and AIST, and the first comprehensive symposium on the societal implication of nanotechnology in Japan. Dr. Hiroyuki Abe from the Council for Science and Technology Policy, Dr. Teruo Kishi, president of NIMS, Dr. Yoichi Goshi, president of NIES, and Dr. Hiroyuki Yoshikawa, president of AIST, will all be participating.

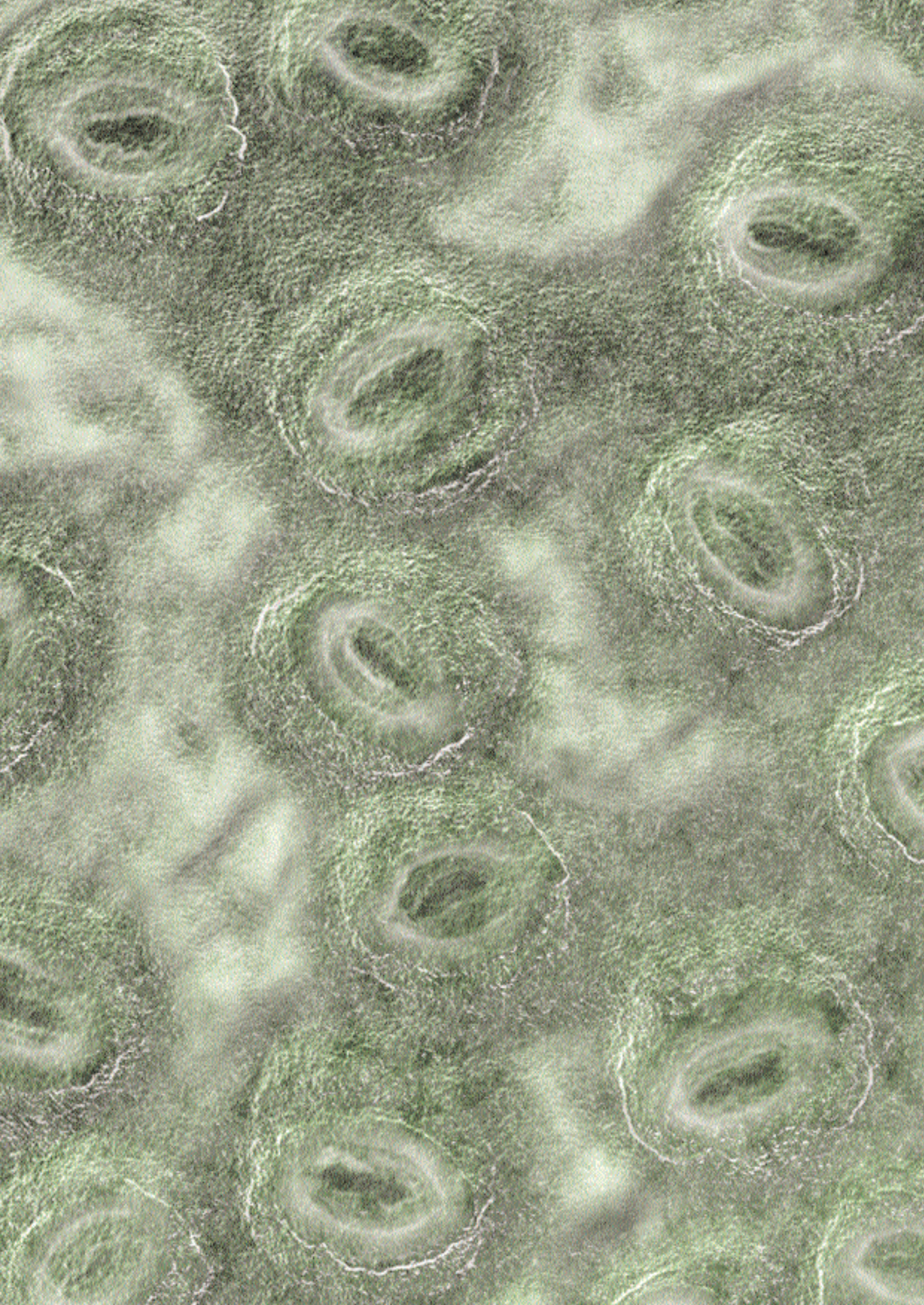
AIST is also responsible for nano-standardization in Japan. Dr. Akira Ono from AIST chairs the Japanese Standards Association (JST) newly set up for nano-standardization last month. AIST researchers from the Weights and Measures Training Institute and the National Research Laboratory of Meteorology of AIST will be playing the largest roles.

AIST also plans to set up a project on nano-risk assessment and nano-risk management in the near future. The project will be headed by Dr. Junko Nakanishi, Director of the AIST Research Center for Chemical Risk Management. These risk assessment and management activities will be closely related to nano-standardization.

Conclusion

In sum, AIST's activities in the areas of nanotechnology research and nanotechnology business startup systems have considerable potential. AIST bears responsibility for nano-standardization in Japan, and its activities on nano-risk assessment and management will be closely related to the nano-standardization procedures. These activities should speed the progress of nanotechnology and nanotechnology business startups by reducing the horizontal level of potential risks and barriers.

www.aist.go.jp/index_en.html





9
The insurability of emerging technologies

Walter R. Stahel

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Insurability could be the natural risk management borderline between Nation States and the market economy: what is insurable need not be legislated.[1]

Nanotechnology is marked by a broad diversity of applications and has been with us for a long time, a fact largely unknown to the general public.[2]

Nanotechnology is "insured" today in the sense that it is not excluded from most insurance treaties.

One conclusion drawn from the conference is that nanotechnology and nanoparticles have to be examined specifically for each application. The term "nanotechnology" should therefore be abandoned in favour of many specific terms, such as "nanotubes". Each new "nano" application could then be treated as a new chemical – this is one of the recommendations of the report by the Royal Society.[3]

From a toxicological point of view, the main hazards from nanotechnology relate to particles that are not firmly embedded in another material. This situation occurs mainly in their production and in the end-of-life phase (recycling, incineration) of the goods in which they are embedded. Only time will tell if there is a limit of bioaccumulation to certain free particles by the human body, and what that limit is. Paracelsus contended that many materials act as a medicine in a small dosage, and a poison in a large dosage.

From an insurability point of view, the question of bioaccumulation of particles could be crucial.

Opposite:
Individual leaf cells
10^{-5}
10 micrometers

An issue of knowledge – the fear of phantom risks

According to a report by the Royal Society[3], there are three main areas where nano can be found today in large quantities:

- Ubiquitous particles in pollution
- Particles in consumption goods
- Particles in durable goods

Ubiquitous particles can be found in air and water pollution, but also in anti-fungal sprays, for example. Million of nanoparticles inhaled daily by humans should be tested for toxicity, in keeping with the recommendations of the report by the Royal Society. Most of these particles today come from diesel engines and other combustion equipment. Since they are not recognisable as a health hazard by the human body, they are not of general concern. Standard filters will not eliminate them.

The only viable way to limit ubiquitous particles is probably to prevent their emission from technological sources. The German government has already asked that the Euro-5-Standard for diesel engines of the EU[4] should include a limit for nanoparticles, which would impose special filters on all new diesel engines. This, however, is still the old end-of-pipe approach to the problem. A more intelligent solution would be changing to an inherently clean technology.

Particles in consumption goods are those such as in food and cosmetics which are consumed or absorbed by the human body.

If labelled accordingly, *consumers* can chose to buy or avoid the products containing nanoparticles, just as they do bio-products. Besides the manufacturer, distributor and the consumers, there are no other parties involved. Thanks to global commerce, consumption could take place anywhere. Safety, Health and Environment issues affecting the *workers* and the stakeholders around the production sites can be controlled. It can be expected that nano-science knowledge is available to identify and mitigate these production hazards.

The same issues apply to the transport of particles. The hazards in this case should be of limited scale for technical reasons; nanoparticles cannot be transported easily, as they cannot be separated if intermingled.

Particles in durable goods include stain repellent and waterproof textiles, ubiquitous computing fabrics, computer disk drives, and automobile paint. In the incineration, recycling or breaking up of these goods or their components, nanoparticles may be released into the environment in an uncontrolled way.

This closely resembles a modern Steptoe & Son situation. In many cases, the knowledge about nano will neither be available to protect the safety and health of workers nor of stakeholders living around the sites. Given global commerce, this situation could arise anywhere in the world.

These durable goods are thus both an occupational hazard and a general pollution issue similar to that of the particles emitted by diesel engines. In order to reduce the possible negative effects, the manufacturer – as recommended by the report of the Royal Society – should do a complete life cycle analysis (LCA) before the commercialisation of these particles.

The legislators of most European countries have already imposed a recall on some types of used goods using particles, such as automobiles (EU end-of-life vehicles directive) and used electronic and electrical equipment (EU WEEE directive). Including the particle issues in waste management and recycling activities covered by this legislation should, therefore, not be too demanding a task.

An issue of loving it or "what is in it for me?"

That scientific innovations have both positive and negative impacts on society was clearly formulated by C.P. Snow as "the two faces of science and technology". Professor Richard Jones stressed this same point in the report by the Royal Society: "The debate now needs to move on to some bigger, longer term, questions: How can we use nano to overcome the world's pressing environmental and health problems while staying alert for the new ethical issues that such a powerful technology will potentially raise?"

The main applications of nano in consumer products today are linked to the concept of beauty: sun creams that enhance attractiveness, and car paints that resist scratching. Nano applications in medical sciences are less well known despite the fact that medical life science in itself – molecular biology and molecular medicine, for example – is nano-driven.

Patients suffering from real medical problems do not normally question the side-effects of a treatment; they can weigh the benefits and the side-effects and change medications accordingly if they prefer. Insurability questions may, however, arise in the context of nano in life-style treatments that promise "beauty and happiness".

Is there a parallel between nanotechnology and the role of windmills in the sustainable energy discussion of the 1990s? Building windmills used to be a business marked by many uncertainties: farmers were reluctant to have such equipment on their land, and charged

high land rents fearing negative influences on their cattle. Ecologists claimed that windmills would destroy the beauty of the countryside, and investors could not know if the future revenues from selling the generated electricity to the grid would cover their costs.

The German law on energy production (*Energie-Einspeise-Gesetz*) stated the political priority to promote renewable energies and introduced fixed prices, which the grid will have to pay to producers of green energy for the coming decade. This has opened the possibility of financing windmills through "wind funds". The windmill producer is responsible for building and operating the equipment for ten years. Instead of the farmer or landowner receiving rent, the property of the windmill on his land is transferred to him after ten years. He thus becomes one of the beneficiaries of the new technology. Interestingly, Germany has become the world's largest market for windmills.

[1] Dahlström, Kristina, Skea Jim, and Stahel, Walter R (2003), "Innovation, Insurability and Sustainable Development: Sharing Risk Management between Insurers and the State": Geneva Papers, Vol. 27, No.7, July 2003 (pp. 394–412). ISSN 1018-5895. This paper is a summary of the research project "Interest – 'Insurance, Technological Risk and Emerging Science and Technology Policies" conducted between Sep 2001 and Nov 2002 for the EU Commission in Brussels. The project consortium included representatives from academia, the insurance sector and the technology consultancy sector, including The Geneva Association.

[2] See among others: "Nanotechnology – small matter, many unknowns", Swiss Re, Zürich, 2004.

[3] "Nanoscience and nanotechnologies: opportunities and uncertainties"; The Royal Society and The Royal Academy of Engineering, RS Policy document 19/04, July 2004, ISBN 0 85403 604 0.

This report can be found at www.royalsoc.ac.uk and www.raeng.org.uk.

[4] the introduction of which is planned for 2010.



10
Dealing with risks and opportunities of new technologies
Christoph Lauterwasser

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"So close to heaven, so near to hell", as one researcher quipped at a conference recently, the discussion on nanotechnology today combines hopes for major technological progress and economic prosperity with fears of new risks. Generally, the double-edged sword seems to be an inherent feature of new technologies. For where new frontiers are explored, new risk scenarios will invariably arise. Somewhat like the yin and yang of Chinese philosophy, one can hardly exist without the other.

It is widely accepted that nanotechnologies will have a significant impact on the global economy over the next 10 – 15 years. This is reflected in the market expectations of various organisations (eg Nation Science Foundation, Sal. Oppenheim), as well as in trends in public spending on research. While in 2003, the overall levels of public expenditure in nanotechnology for Europe, for example, reached around EUR 1,150 million, the EU Commission has called upon its member states to increase public investment in nanosciences and nanotechnologies by a factor of three by 2010. Science and technology have reached a degree of miniaturisation which makes the exploitation of the sub-100 nm range the next logical step. The novel potential arising from the ability to manipulate and engineer nanomaterials at this scale will enable companies to create new qualities in multiple applications and industry sectors. This, in turn, will lead to the creation of more and more marketable products.

Many business activities of financial service providers such as the Allianz Group, are likely to be confronted with these changes over the next few years. While the internal and external discussion of emerging risks will be strongly geared towards questions of risk assessment and insurance, the overall view also has to include the banking side (eg credits), investments and risk communication with various stakeholders. In the investment portfolio, major technological trends can lead to new success stories, but may also mean that "old technologies" are phased out. New targets might arise on the investment horizon.

To evaluate such broad trends and to generate a common evidence base, the Allianz Group has established a Trend Assessment Committee. The committee serves both as platform and forum to feed ideas on business opportunities and risks into the various organisational units and to the management board. Studies and trend assessments are performed by Group Economic Research, by the Allianz Center for Technology and by external partners. The Trend Assessment Committee is asked to review many aspects of modern life; technology-related questions such as the reliability of the power grid, genetic testing and carbon markets are but a few of the topics examined.

What are the implications of nanotechnology for the insurance industry? The commercialisation of products either containing nanoparticles or using nanotechnologies is an ongoing process. There are already hundreds of products on the market that make use of the unique properties. Since nanotechnology is an enabling technology, applications range across all types of industries – from sporting goods, such as tennis balls and ski wax, to cosmetics and hardware components in the semiconductor industry. As such, the insurer's risk portfolio contains an increasing number of nanotechnology-related risks.

At the same time, there is a great degree of uncertainty regarding emerging risks associated with these technologies. There is sufficient evidence to say that at least some manufactured nanoparticles have greater toxicity than the same chemicals in bulk form. Given that little is known about acute or chronic toxicity of nanoparticles in general and the effects of determining factors, such as surface area and shape, chemical composition and particle concentrations are also still subject to discussion, it will take years for studies about exposure routes, the effects on human health and the environment to reach conclusive results.

Further, there are no specific policy exclusions for nanotechnology-related risks; the insurance industry in general may face the scenario that multiple lines of business could potentially see claims. The potentially affected areas range from general and product liability to product recall, workers compensation or D&O. Multiple classes of insured could be affected: from small to large companies in a wide range of industry sectors in various countries. Perhaps more importantly, the risk management practices in these companies will range from very basic to highly sophisticated. The last point is of key importance: even if a certain technology creates new risks, the quality of risk management practices will determine whether these hazards will actually materialise.

By carrying these risks, the insurance industry is already contributing to the early commercial phase of nanotechnologies, since especially for small- and medium-sized enterprises, adequate insurance cover is an important prerequisite for entrepreneurial activity.

This approach is reasonable and has been typical of the insurance industry in the early phase of many new technologies. With an increasing proportion of nanotechnology risks in the portfolio, the question of the insurability of these risks and Allianz's own risk management become more and more relevant. Given the knowledge gap about risks outlined above, it is a matter of debate whether one main criterion of insurability – namely the assessability of risks with respect to probability and severity – is or can be fulfilled. The combination of limited evidence regarding the hazards and potential latency claims warrants close monitoring of the risk. On the other hand, the multitude of different applications and/or substances and industry segments has a positive diversification effect. While it is still too early to make conclusive statements, our own risk management will have to "put its feelers out" on the subject.

The first step in a risk management toolbox is to create risk awareness and an understanding of the hazards involved. The next step is to identify and evaluate the risks – an ongoing process which, in the case of new technologies, must compromise scientific, technical, legal and regulatory aspects. Public opinion has a strong bearing on the risk evaluation process because it affects many political, industrial – and legal – decisions. Yet close scrutiny of the individual risk, often with support from the decentralised risk-consulting units, is a prerequisite to taking economically sustainable decisions. Similarly, the insurer can handle and optimally manage the risk by employing a wide range of measures to help "sculpt" a portfolio. The risk appetite for certain classes of risks can be defined, the allocation of limits, wordings, and a number of reinsurance options, tailored, to meet the demands of the clients while protecting the enterprise's assets in a prudent manner.

While this may appear simple in principle, the process of adapting to new technologies is, in fact, a balancing act of risk-taking by limiting transaction costs, improving the evidence base and coping with a degree of uncertainty.

The Allianz Center for Technology believes that to help establish a sustainable and mutually beneficial approach to the insurance of nanotechnologies, several steps should get high priority in the next few years. These include:

- Independent research about risks of nanoparticles, exposure routes and the effects on humans and the environment. Strengthening of the evidence base.

- Bringing an understanding of nanotechnology to the front line of insurance, ie to underwriting and risk engineering.
- Developing comparative risk classification schemes.
- Focusing attention on critical issues within this broad field (eg direct exposure to nanoparticles or release into the environment).
- Fostering – from an early phase – a dialogue-oriented approach which is neither burdened nor dominated by ideology, and making good use of reviews by independent organisations.
- Using sustainability as a vision and success criterion for these developments.





11
Liability regimes in a changing risk landscape
Richard H. Murray

Richard H. Murray *is Chief Claims Strategist, Swiss Re, Switzerland*

My remarks today will focus on the dynamics of liability systems: How risk events are processed and determined, and the proceeds of awards distributed by liability regimes.

The risk events will be viewed from the perspective of emerging technologies. Principal focus will be on the liability regimes of the US and Europe. The scope will include the actual unanticipated adverse consequences of products and their applications, and the "phantom risk" concerns spurred by those new technologies that generate social anxieties.

We will discuss the current conditions in liability regimes. Those conditions are sometimes so bizarre that one could well wonder how they got that way – but this is a subject for another day. We will address current and prospective conditions affecting nanotechnology. Many of the examples used will be taken from lessons learned in asbestos and pharmaceutical litigation. These are current and highly illustrative models, since those products, like nanotechnology, provide great social benefits with occasional serious liability exposures. Finally, I will conclude with some observations about the possibility for mitigating techniques to be applied in reduction of liability risks.

The nanotechnology industry is conducting its research, development and marketing practices in a reasonable and cautious manner. You are entitled to apply the same reasonable world hypotheses to the unanticipated risks associated with your activities. I begin with summarizing what those reasonable expectations might include.

First, you could reasonably expect to establish a valuable and protective developmental partnership with governments and regulators. In the developmental and pre-application stages of your initiatives in particular, you should expect: a responsible partnership for stimulating innovation; a partnership for sharing the responsibility of making risk and reward assessments about products deserving approval and distribution; and the support of governments and regulators in providing a liability

safe haven for those in the private sector who comply responsibly with the requirements of policymakers.

The safe havens could consist of full protection from liability, or second, you should expect a civil justice system for determining tort liability consequences. A civil justice system should seek to consistently provide justice, usually manifested by: reliance upon established standards for performance, breach of duty and causation; respect for an adherence to establish precedent; and, reasonable measures of recovery, designed to achieve an equitable balance between fault and recoveries.

Third, you should expect a coherent global liability environment. This would be consistent with the borderless nature of nanotech development and distribution. You could reasonably expect to operate in a borderless environment like that which seems to be enjoyed by the internet and telecommunications world, though, in truth, national boundaries and restrictions are beginning to appear in that environment.

While these are conditions you should reasonably expect to encounter as you pursue your developmental and commercial opportunities, there are not in fact the real world in which we operate.

Nanotechnology (and similar controversial technologies and innovations) will actually experience a very ambivalent relationship with governments and regulators. You will receive entrepreneurial encouragement and often funding support as well, because you provide policymakers with economic growth, new employment and solutions to vexing problems.

You will find, however, that the risk and reward assessments designed to provide societal protection will involve very ambivalent and often politically fraught relationships. Consider the difficulties regularly encountered by those involved in stem cell research and genetic engineering.

And, you will encounter resistance to the provision of safe havens. In order to get new products and applications through approval processes and into the marketplace, you will need to demonstrate that you have no basis for anticipating known risks or adverse consequences. You will also need to prove that your products provide strong societal and consumer benefits.

Even when you achieve these two significant milestones, it is unlikely that your success will be rewarded with safe haven protections. One need look no further than the current pharmaceutical relationship with the US Food and Drug Administration (FDA). The FDA requires product safety and efficacy to be demonstrated prior to obtaining marketing approval. That approval is often narrowly defined, specifically limited and subject to labeling and promotional controls. Yet, the FDA approval provides no protection from unanticipated adverse consequences. As we note almost weekly in the media, the pharmaceutical industry enjoys no safe havens.

The civil justice system is no longer dedicated to achieving justice. Rather, in the US the tort system, the judicial process by which claims are adjudicated, has in fact become a wealth transfer system.

We have reached a state where the goal seems to be achievement of the maximum size of assets transferred through the tort system. The phrase, "tort tax," is often and accurately applied. Obvious illustrations of these conditions can be found in respect of liability litigation, where the latest phase of claims involve, for all practical purposes, the ability to be held liable without fault and recover damages without harm.

One could be forgiven for believing that the inmates have taken over the institution of the civil justice system. Currently 54% of the sums paid into the system remain there, in the form of attorneys' fees and expenses, with only 46% being paid to claimants – and more than half of that is recovered for non-economic injuries in the nature of "pain and suffering" and punitive damages. The very small community of successful specialist plaintiffs' counsel in the US has learned, through the long struggle to break through recoveries in asbestos and tobacco litigation, to use their tools and skills in generating total annual revenues of between USD 40 – 50 billion – this for at best a universe of a few hundred people.

Your efforts to establish responsible risk management systems will not always avoid liability. You will still be confronted with irrational triggers to risk. Societal fear alone can drive liability conditions. The decline of governmental ability to finance social welfare systems subjects the controversial elements of the private sector to make up the difference, as we have seen with respect to environmental cleanup costs. Perhaps most unexpected is the extent to which waves of publicity create liability conditions that turnout to lack substance. One need look no further than the silicone gel mania even though the related breast implants were ultimately determined to be essentially harmless.

The situation in Europe is not as dire as that in the US. However, Europe has its own form of liability excess arising from the activity and attitudes of regulatory bodies. The EU regulators have, for example, adopted regulations dealing with genetic engineering which are designed to control the behavior of the private sector by imposing strict liability for adverse consequences. Similarly, Brussels has undertaken to protect the



environment by requiring anyone charged with environmental damage by reversing the traditional burden of proof and requiring those charged with environmental damage to establish that they are without fault – a daunting requirement. Further, the regulatory requirements of Europe are not isolated. At any given time, the various commissions in Brussels will be considering between 50 – 100 initiatives designed to protect various elements of society by imposing liability responsibilities and often mandating the use of third party liability insurance as a funding mechanism.

This last element – the reliance on insurance as the financial lubricant for social legislation by the courts or regulators, is the most important common thread between conditions in the US and those in Europe. It is, however, a mistaken and naïve view of the economics of insurance.

Even otherwise sophisticated judges and regulators often assume that insurance provides an endlessly elastic ability to spread risk over time and space.

In fact, this is a dangerously mistaken perception. Buyers of insurance will not routinely pay more for their protection in order to spread risks from other industries, locations and technologies. Equally important, insurance companies, like all businesses, must generate a reasonable return of investment capital in order to continue attracting that capital as the platform from which underwriting risks.

This common thread potentially puts the commercial lubricant of insurance at risk, particularly in high volatility and emerging risk environments such as those that will be encountered by nanotechnology.

Finally, I turn to the reasonable expectation that might be given its best chance of success: The existence of a coherent global environment in which liability and risks will be adjusted. Regrettably, this too is not reality.

Liability is still a national issue, and one in which the varied influences and conditions are highly vulcanized. This stands in sharp contrast to other seemingly similar conditions where collective behaviors are emerging across national boundaries.

In securities regulation, IOSCO (International Organization of Securities Commissions) is rapidly developing global consistency of financial reporting standards and enforcement behaviors.

The influence of the Basle Conventions in banking regulations are self-evident examples of the benefits of voluntary transnational cooperation. Even in the

long overlooked field of insolvency regimes, global coordination is beginning to produce beneficial effects.

But there are no signs of such movements with respect to liability regimes. The differentials of national procedures and standards remain highly vulcanized – indeed, those of us who monitor global litigation could be forgiven for perceiving a trend toward the increasing nationalization of liability regimes.

The situation is compounded by rules which permit the same claim to be brought in a variety of locations, such as the country of origin of the developer and/or manufacturer, the country of sale, the country of injury, or (the most popular) the country of easiest recovery.

Since the US is ordinarily and correctly viewed as the country of easiest recovery, the US is every claimant's favorite liability regime. Commercial interests in the US have, in consequence, begun to invest substantial sums in resisting global forum shopping. But, the real impact of these conditions is the fact that a company wholly domiciled in Europe or elsewhere that develops, distributes or markets high risks products can be virtually as seriously exposed to US liability as a competitor domiciled in the US.

One need look no farther than the current Vioxx trauma to understand the difficulty. In one of a multitude of advertisements placed by US lawyers on the internet and in global media, the attorney's claim was that over 85 million people were Vioxx users – a global claim if there ever was one since only 10 million are known to be users in the US. Using the privilege of US attorneys to openly advertise, and global communications technology, seeking to tempt claimants into US litigation by declaring that simply by being a user of Vioxx, "you may be entitled to a minimum cash settlement between USD 100,000 and USD 300,000". These are the conditions that nanotech practitioners need to be prepared to deal with in the future.

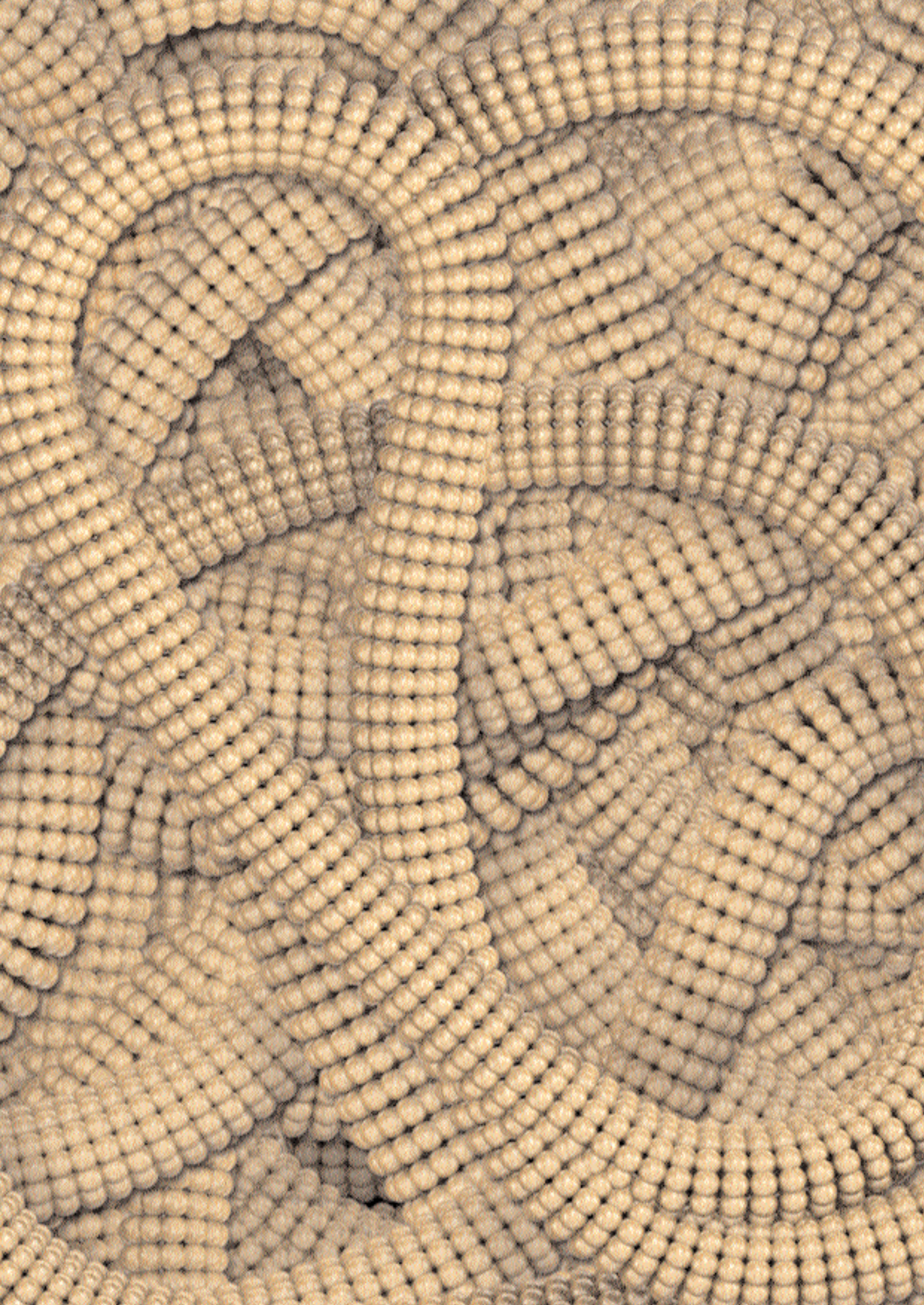
Which brings me to my final topic: Is there anyway in which the nanotechnology industry might mitigate the uncertainties and risks faced in an unfair world of liability and regulatory regimes? I am fundamentally an optimist, believe that conditions run in cycles and that pendulums tend to return from their excesses. I urge that the nanotechnology industry not retreat from the opportunities and responsibilities that lie ahead. While I do not have a prescription that will provide safety and security, I offer a few observations that I hope you find useful.

First, it is imperative that you understand the enemy (and recognize that there is one) and the processes by which the enemy operates (and that they can be abusive). Do not assume that what is reasonable will occur and for you to incorporate that understanding in your business plans and business structures. Simple but powerful illustrations from current headlines include the lessons Dow is learning after acquiring Union Carbide in the belief that the Bhopal was settled and closed long ago, and the struggles of ABB for having acquired a US asbestos manufacturer. Business plans must take great care with merger and acquisition decisions that may have such consequences.

Second, when the early phase of risk and claims activity emerges, do not take the easy route of compromising and settling uncertain exposures. While it is tempting to view each individual case as one that could be more economically resolved through settlement than litigation, the momentum and growing expectations created by such behavior can be extraordinary. Consider that asbestos liability litigation is currently expected to cost the industry collectively more than USD 300 billion. Had the industry, and its insurers, understood this a few decades ago and refused to compromise itself into more exposed positions and higher expectations, it is doubtful that asbestos litigation would have cost even one-third that amount.

Third, focus early attention on building better understanding and stronger relationships with regulators. Demand realistic safe haven protection as a condition of your continued contribution of your entrepreneurial skills and investment. Only by negotiating your way to constructive partnerships with policymakers can some of the current political opportunism be controlled.







12
The International Risk Governance Council (IRGC)
Christopher Bunting

Christopher Bunting
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Opposite:
Chromatin in the leaf cell nucleus
10^{-7}
100 nanometers

"People are interested in the nanoscale (which we define to be from 100nm down to the size of atoms) because it is at this scale that the properties of materials can be very different from those at a larger scale."
The Royal Society

"By tailoring the structure of materials at the nanoscale, it is possible to engineer novel materials that have entirely new properties. With only a reduction in size and no change in substance, fundamental characteristics such as electrical conductivity, colour, strength, and melting point – the properties we usually consider constant for a given material – can all change."
VDI Technologiezentrum

I would like to begin by thanking Swiss Re, both for their invitation to participate in this excellent conference and for their many other contributions to IRGC, which include hosting – in this very building – the Round Table meeting in early 2002 at which the key decisions were made regarding the mission, activities and organisation of what became, at its foundation in June 2003, the International Risk Governance Council.

I have been asked to address three issues in a short time. These are: firstly, to inform you of IRGC and its purpose; secondly, to summarise why we are interested in nanotechnology; and, thirdly, to say something of what we intend to do.

IRGC's foundation has its origins in the 1999 Forum Engelberg. Delegates attending that year's conference agreed on the need to create a new, independent organisation that could make a significant and unique contribution to alleviating many of the problems faced by those responsible for risk-related decision making. These problems included the increasing pace of technological change (linked with the sheer pace of scientific discovery), the changing nature of many of the new and changing traditional risks, and many changes to how the responsibility for risk governance is allocated. In the years between 1999 and the present day, considerable thought and effort was contributed by individuals and institutions from governments, business, academia and the NGO sector, from many countries, so that the new organisation's mission and organisational structure would be appropriate to its delivery of a valid and valued contribution to risk-related decision making.

Our aims are to improve the capability of governments, business and other organisations to handle traditional changing and emerging human-induced risk and uncertainty/ambiguity in a more efficient, fair, balanced and anticipatory way. We do this by adding a global view to disciplinary, national and sectorial approaches. We undertake projects and arrange conferences through which we compile knowledge that

encompasses both a range of scientific disciplines and each of the several sectors responsible for risk governance (government, business, academia, NGOs, etc). We seek to do so by complementing other, existing organisations and their efforts, and will deliberately not duplicate work that others undertake – indeed, we would be delighted to collaborate with them.

IRGC's work is undertaken primarily in the form of projects, which are led by sub-groups of our Scientific and Technical Council. Projects are either focused on a specific problem field or are cross-cutting in nature. We currently have two in progress. The first of these is a study of the technical and socio-economic structure of the European electricity supply system; in it, we are identifying risks both within the system and caused to other vital services which depend on electricity. Our intention is to propose possible solutions for each of the risks we identify.

The second project, which we call Basic Concepts of Risk Characterisation and Risk Governance, is developing a comprehensive framework for risk governance. This framework takes as its starting point the many challenges faced by those responsible for establishing and implementing risk governance strategies. Among those challenges are the insularity and fragmentation which hinders the development of broad-based strategies; the ambiguity and uncertainties affecting the risks themselves; and many confusing aspects, including the specific problems of language and terminology.

The project seeks to create a framework which links the key components of effective governance, namely the characteristics of the risk and the means by which and by whom it is assessed, managed and communicated. Our work has included looking at a number of existing governance approaches and we are applying learning from this review to ensure that what we develop has validity across a range of risk types and can, after initial testing within one of our problem field projects, be accepted by others seeking help in developing their own governance approach. We also hope that we can do so with a consensus agreement from potential stakeholders, primarily governments and the business community, worldwide.

One of the existing works we have studied is the 1998 report by the German Advisory Committee on Global Change entitled *Strategies for Managing Global Environmental Risks*. It was subsequent to this report that Renn and Klinke developed their nine criteria for evaluating risk and, using that set of criteria, it is clear that what we are calling "nanotechnology" today, though I agree with those who have expressed the need for more precise definitions of the various technologies covered by this word, presents everyone with responsibility for nanotechnology-related risk governance with a considerable problem. Indeed, for none of the nine criteria we have at the present time, is there clear factual knowledge on which to base an appropriate risk governance approach.

For example, we do not know what potential damage, if any, may be caused by the absorption of nanoparticles into the human body or by their release into the environment. With no definite consequence, we cannot assess the probability of it, not state whether any potential consequence is immediate or takes time to happen. Indeed, although it is possible to buy products containing nanoscale materials, such as sunscreen, today, there is no way a purchaser can know if the product contains a nanoscale ingredient. The risk governance of nanotechnology, therefore, offers considerable potential to IRGC as a subject where our competences can make a positive contribution to the issues we have been discussing over the last two days.

I cite a paper by Nick Pidgeon of the University of East Anglia by suggesting there are three streams which should drive the development of policy. These are economics, science and public debate. The economics tests are cost/benefit and utility, although there are occasions when it may be preferable to think in terms of relative utility, particularly when a "new" product is no more than a replacement for an existing item. I think we can be sure that no commercial enterprise will launch new products if these economic tests are not met.

Regarding science, it is for the scientific community to provide the evidence of safety (and, in support of the economic stream, utility). My understanding from this conference is that we have some progress to make here. Indeed, we should beware of the possibility that, in Europe at least, the absence of scientific evidence of the safety of nanoscale materials could trigger the application of the Precautionary Principle, which would be in no one's best interest.

The triggering of the use of the Precautionary Principle is also a possible outcome of engaging the public. The recent evidence of the development and use in Europe of GMOs, particularly in food, suggests that there are lessons to learn, both in accepting the need to engage the public at an earlier stage in the development of a new technology and in ensuring that such engagement deals with the public's perception of the new technology and the associated risks; it is not enough to use facts to overcome intuitive perceptions. Getting the public involved will need care, particularly if nanotechnology is to be welcomed rather than feared.

IRGC has identified a particular area where we believe we can play a positive role, which is to help develop an appropriate risk governance approach for nanotechnology. We have already received verbal

confirmation of an award from the US Environmental Protection Agency for a project with three complementary stages. First, we wish to assemble a comprehensive review of the governance approaches – including regulation and communication – in use in all those countries actively researching nanotechnology and developing products using it. The output of this stage will be a valuable reference tool, as well as learning about common approaches and differences.

The second stage will see IRGC apply its own governance model, which I referred to earlier, to one or two nanoscale technologies. We have yet to select these, but I would suggest it would be appropriate to take two distinctive fields, perhaps the nano-chip and nanotubes. Thus, our project would both test the efficacy of our governance model and, we hope, provide substance for developing a governance approach appropriate to meeting the twin objectives of substantiating the safety of nanotechnology and, thereby, ensuring that research and development can continue.

The final element of our project will be a conference in late 2005, where key players from governments and the business community can meet and agree a risk governance approach that is recognised as appropriate to addressing the many needs that have been raised during this dialogue.

This is an ambitious project, and we already know that we cannot achieve these goals alone. I am particularly pleased that my participation in this conference has enabled me to meet with representatives of the International Council on Nanotechnology and the Meridian Institute, because our three organisations have complementary goals and we would be wise to ensure we avoid duplications of effort.

We will also work with other partners, exploiting IRGC's links with, for example, the World Business Council for Sustainable Development and the OECD. Finally, I hope we will be able to count on support from the many organisations present here at this dialogue, as I am already convinced that we have, between us, agreed that there are sound reasons for assuring the economic and other benefits offered by nanotechnology by devising and implementing a risk governance approach which ensures that those benefits are not accompanied by unacceptable hazards.



13
The Meridian Institute
Tim Mealey

Tim Mealey *is a co-founder and Senior Partner of the Meridian Institute, United States of America*

With support from the Rockefeller Foundation (US) and the International Development Research Centre (Canada), the Meridian Institute is convening the "Global Dialogue on Nanotechnology and the Poor: Opportunities and Risks" (hereafter referred to as the GDNP). The goals of this global scale multi-stakeholder dialogue are to: raise awareness about the importance of examining both potential benefits and risks of nanotechnology to meet the needs of the poor in developing countries; to close the gaps within and between sectors of society to develop an action plan for addressing opportunities and risks in an open and transparent manner; and to identify the elements of a model for the role of science and technology in development.

Meridian Institute developed a Paper to raise awareness about the implications of nanotechnology for poor people, both the potential opportunities and risks. To solicit views on the issues raised in the paper, Meridian Institute sponsored an on-line consultation between 24 January and 1 March, 2005. The consultation process enabled anyone to submit their responses to a set of questions related to the Paper. More than 280 people registered for the on-line consultation process; approximately 600 individual comments were submitted.

Meridian Institute is organizing a small steering group meeting in June 2005 to refine and further develop the specific details of a multi-stakeholder dialogue process that will focus on the implications of nanotechnology for poor people in developing countries. Meridian Institute anticipates organizing one or more multi-stakeholder meetings during 2005. Although the focus of these meetings will be discussed with and developed by the steering group, it is likely that multi-stakeholder dialogue meetings will initially focus on both opportunities and risks associated with a limited number of tangible issues such as nanotechnology and water, energy, and/or health.



Meridian Institute will engage a diverse group of stakeholders with expertise and experience relevant to the broad set of issues encompassed by topics of nanotechnology and poverty. Participants will, for example, have experience in fields encompassed by the terms nanoscience and nanotechnology, such as materials science, chemistry, biology, and engineering, as well as experience with technology introduction, poverty reduction and disciplines such as public policy, risk assessment and risk management, and regulation. In doing so, Meridian will seek a balance among the different types of organizations, including industry, government, academia and NGOs, from both developed and developing countries.

For more detailed information about this and other Meridian projects regarding nanotechnology, including a copy of the Paper and results of the on-line dialogue, please visit: www.nanoandthepoor.org. For more information about Meridian Institute, please visit: www.merid.org.



50 Mark Lanfranconi, *Proctor & Gamble, represented ICON, the International Council on Nanotechnology*

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International Council on Nanotechnology (ICON)
Mark Lafranconi

The International Council on Nanotechnology (ICON) was formed in the fall of 2004 to assess, reduce, and communicate the environmental and health risks of nanotechnology. ICON was constructed as a multi-stakeholder group to bring together the interests of government officials, industrialists, academicians and civil society organizations at a shared table for dialogue and action. The council will undertake projects in three areas: research on nanotechnology and risk, policy guidance through product stewardship and the formation of global standards, and communication to and with a variety of audiences. The council is administered within the National Science Foundation Center for Biological and Environmental Nanotechnology at Rice University in Houston, Texas, US.

Strengths of the council include an in-depth technical understanding of and capability in nanomaterial production and characterization, an inclusive approach to dialogues that involves the voices of a variety of stakeholder groups, an international basis and an ability to respond quickly to emerging needs. As a novel organization seeking to create a new paradigm for emerging technology stewardship, the council faces some challenges in managing the needs of diverse participants, bridging international boundaries and creating a unique identity.

To meet these challenges, a core group of initial participants met in October 2004 at Rice University. Out of this meeting came a commitment by the group to perform a gap analysis to identify needs that may be addressed with council resources, work toward developing a standard of care for industry as well as globally adopted standards for terminology and nomenclature of nanomaterials, and create a communication plan that will provide science-based information on nanomaterial risk to a variety of audiences.







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Nanotechnology and risk perception

David Ropeik

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Nanotechnology, the capacity to manipulate materials at atomic and molecular scales, holds promise bounded only by the human imagination. But if this promise is to be fully realized in ways that respect potential harms to human and environmental health and safety, serious and ongoing consideration needs to be given to the way the public will react to nanotechnology and all its specific applications. For despite its benefits, if public apprehension builds, the potential of nanotechnology could be severely limited. The findings of the field of research known as risk perception offer valuable insights into what that public reaction might be. Understanding those potential reactions will allow proponents of nanotechnology to respect public concerns and address them through more effective risk communication, and advance the prospects of the entire field.

The Greek Stoic philosopher Epictetus observed, "People are disturbed, not by things, but by the view they take of them." Indeed, researchers including Paul Slovic, Amos Tversky, Baruch Fischoff, Sarah Lichtenstein, and others, have found that risks seem to have shared characteristics which, quite apart from the scientific facts and statistical probabilities, play a key role in making us more or less afraid. These affective/emotional characteristics are a fundamental part of how we frame our worries. They essentially form the subconscious backdrop by which we "decide" what to be afraid of and how afraid to be.

Perhaps the most important of these characteristics is the matter of trust. As Ragnar Lofstedt, Ortwin Renn, and other leaders in the field of risk communication have found, the more we trust – the less we fear. And the less we trust – the more afraid we are likely to be. Trust will almost certainly play a key role in the acceptance of, or resistance to, nanotechnologies.

Opposite:
DNA nucleotide building blocks
10^{-9}
1 nanometer

Trust is determined by many factors. It is determined in part by who does the communicating. The facts being presented could be the same, but the trustworthiness of the communicator will help determine how worried the audience will feel. For example, people who learn about nanotechnology from the chemical industry, which is less trusted according to many polls, are more likely to worry than people who learn about it from healthcare professionals such as doctors or nurses, more trusted professions.

Trust is also established through honesty. BSE affords a good example. In Japan, after the first indigenous infected cow was found, the government promised there would be no more. A second cow was found just days later. The government then said they had created a ban on feeding ruminant protein back to healthy cows – which is how the disease spreads – only to have the press learn and report that the "ban" was only voluntary. The press also reported that the government had kept secret an EU report rating Japan at high risk for BSE.

These less-than-honest statements by the government badly damaged trust and fueled much greater fear in Japan than in Germany, where, within about a month of the discovery of the first indigenous infected cow, two cabinet ministers were sacked and changes were proposed to make agricultural practices more natural and less mechanical. Beef sales rebounded in Germany quickly, unlike Japan, partly because of the different degrees of honesty on the part of the government.

Trust also grows from an organization's actions. Again, BSE affords an example. In Canada and the US, after the first infected cows were found, the governments were able to point out that they had long ago instituted a feed ban and other restrictions to keep the risk low. As much as citizens might not have trusted the government in general, in this matter the responsible agencies had demonstrated their competence in keeping the risk low. This demonstration of competence probably played a role in the relatively minimal impact on consumer beef sales experienced within each country.

Trust is also established when an organization respects the reality of the public's fears, even though there may be no scientific basis for those fears. In the US, authorities withdrew muscle meat from the market that had come from the slaughterhouse that processed the BSE-infected cow. This despite the scientific consensus that muscle meat is not a vector for BSE. The US Department of Agriculture said it was acting "out of an abundance of caution…". In other words, they were acknowledging and responding to the reality of the public's fear and doing something that did not reduce the physical risk, but reduced public apprehension. The implicit message in such actions is that the agency was not being defensive, but was being responsive to public concern. That kind of action encourages people to trust such an agency, more than when the message is, "There are no scientific reasons for your fears. The facts as we see them says there is no risk. So we are not going to act." This potentially damaging message has already been heard from a small number of scientists in the area of nanotechnology.

Trust is also established by sharing control. In the case of nanotechnologies, this could include shared control over the writing of public health and environmental risk regulations, or shared control over the development of societal and ethical guidelines. The more people feel they have some control over their own health and future, the less afraid they will be. The same risk will evoke more worry if people feel they have less control.

Trust is also built by openness. In the development of nanotechnologies, this should include dialogue with various stakeholders, a fully open exchange of scientific data, open government regulatory development, and open discussion of societal and ethical issues, among other areas. The more that people feel they are being deceived, lied to, or manipulated, the more afraid of a risk they are likely to be. Openness reassures them that they can know what they need to know to keep themselves safe. An open process is inherently trust-building.

Trust will be difficult to establish as nanotechnologies develop, because the driving forces behind such development will be principally commercial, industrial, corporate, and government, and the politically and profit-driven sectors of society are, *de facto,* perceived to be out for their own good more than they are out to serve the common good. So special attention and effort must be paid to establishing trust in everything that a government, a business, or a scientist does while working on nanotechnological research, development or application.

But there are other risk perception characteristics that could bear on public acceptance of or resistance to nanotechnologies.

People tend to be more afraid of risks that are human-made than risks that are natural. Nano is almost certainly going to perceived as a human-made technology.

We tend to worry more about risks like nanotechnology that are hard to comprehend because they are scientifically complex, invisible, and not yet completely studied and understood. This could well invoke calls for a stringent application of the Precautionary Principle, and proponents of nanotechnology would be well advised to give serious consideration to such calls until

a reasonable amount of safety data is developed. We tend to worry more about risks that are imposed on us than risks we knowingly choose to take. Nanotechnologies will provide finished materials in some cases, which could appear in the label of a package to alert the consumer and give them choice. But in many cases, nano-substances will serve as intermediates or raw materials or catalysts, substances which cannot be labeled, and which therefore could evoke concern because people are going to be exposed to them without any choice.

We worry more about risks that are new than the same risk after we have lived with it for a while. While carbon black and some nano-materials have been around for a while, many nano-materials and products are new, with different behavioral characteristics than anything we've ever known. And of course the precise ability to manipulate things on a nano-scale is new. This too could feed greater public apprehension about this technology.

And we tend to worry more about risks from which we personally derive less benefit, and vice versa. For some nanotechnologies, for some people, the personal benefits may well outweigh the risks. But when they don't – when the benefits accrue to someone else – fear and resistance could rise.

It is important to respect the reality and the fundamental roots of these perception factors. They cannot not be manipulated away or circumvented with a clever press release, website, or a few open public meetings and dialogue. Human biology has found that the brain is constructed in such a way that external information is sent to the subcortical organs that generate a fear response *before* that information gets to the part of the brain that reasons and thinks "rationally". In short, we fear first and think second. No press release can undo that biology.

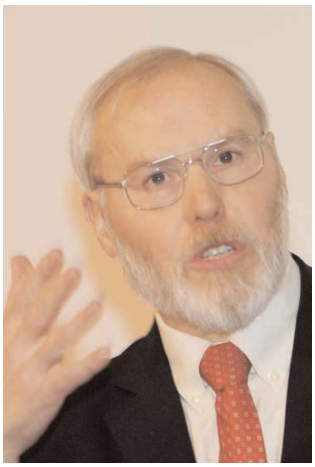
It is quite likely that, because of some of the characteristics of nanotechnology listed above (human-made, hard to understand, imposed, new, lack of trust in industry), that the first reaction many people have when they learn about it will be worry and concern.

Moreover, the brain is constructed such that circuits stimulating a "fear" response are more numerous than those bringing rationality and reason into the cognitive process of risk perception. In short, not only do we fear first and think second, we fear more, and think less.

Again, this suggests the likelihood that first impressions many people will have of nanotechnology will be predominated by caution and concern.

Fortunately, both the biology and psychology of risk perception have been fairly well characterized. Insights from those fields can guide the design of research to find out how people are likely to react to nanotechnology as it becomes more common, is introduced into their lives, and as it gets more and more attention in the press, a trend already beginning in many places. Research that understands how people are likely to react is the first step toward designing risk management strategies, including risk communication, to address public concerns.

It is imperative that such research be done soon, so it can be used to develop risk management and risk communication strategies that will maximize public understanding of nanotechnology, and public participation in the process of its development and implementation. With these steps, the potentials of this remarkable field can be more fully realized while respecting public concerns and insuring public and environmental health and safety.



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Regulatory challenges with emerging technologies
Paul Davies

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The Health and Safety Executive (HSE), is responsible for regulating almost all the risks to health and safety arising from work activity in Great Britain. The HSE and its predecessors have been doing this for the last 170 years – a lot of technologies have emerged (and disappeared) in that time! Based on this experience, I believe we can make a useful contribution to the issue of how to handle the regulatory challenges arising with emerging technologies in the world of work.

In considering a wider picture, it is not just the regulation of health and safety at work that is challenged by emerging technologies but regulation in the round: financial, environmental, product liability, etc. It might be useful to approach the issues from this general perspective, to examine what makes for better regulation, how this might be upset by an emerging technology and how to counter such an upset, and then to look at HSE's particular experience in this area.

Better regulation

Several years ago, its Better Regulation Task Force advised the UK Government on how to improve government regulation. The Task Force identified the following characteristics of better regulation:

- proportionality – requiring action that is commensurate to the risks;
- targeting – focusing on the most serious risks or where there is a need for greater controls;
- consistency – adopting a similar approach in similar circumstances to achieve similar ends;
- transparency – being open on how decisions were arrived at and what their implications are;
- and accountability – making clear, for all to see, who are accountable when things go wrong.

Of those characteristics, emerging technology presents a challenge to "proportionality" and "targeting" in particular. In both cases, to have those characteristics, the regulation of an emerging technology requires a good estimate of the risks posed by that technology – and that is often just what we do not have; not enough is known about the technology to be clear about the harm it could cause – especially in the long term.

Precaution

The response of regulators to this lack of knowledge is, generally speaking, to adopt a precautionary approach – to regulate for the worst case risk (one that is credible), undertake research to fill critical knowledge gaps[1], and be prepared to ease regulatory controls if and when research and experience prove the emerging technology to be a lesser risk.

Taking a precautionary approach does not mean abandoning rationality and an evidence/risk-based approach. Constructing the "worst case" involves using the available scientific evidence – together with expert judgement and experience – to formulate credible scenarios on how harm might be realised, test these via peer review, and thereby make assumptions about consequence and likelihood so as to enable a risk assessment.

Critics also express concern that a precautionary approach inhibits innovation and the take-up of emerging technology. While there clearly is a cost to the approach, I believe experience shows these concerns to be unfounded. In fact, there is substantial evidence to show that tight regulation can stimulate innovation, though it might involve some pain in the short term; there are good examples of this in the area of occupational health and safety.

Furthermore, by providing reassurance to the public, tight regulation helps establish an environment in which the emerging technology can move forward and flourish. There is a cost to precaution, but too little precaution can also prove extremely costly: while generally precautionary in its approach, the pharmaceutical industry has provided a number of examples over the years where, for some, the cost of insufficient initial precaution has had tragic consequences. We cannot ignore the potential for adverse effects from a precautionary approach, but what we must strive to do is strike a balance between the need for – and extent of – precaution and the need for innovation.

Globalisation

Another challenging aspect of emerging technology for better regulation is that it can emerge in several global locations at once or be shifted easily from one place to another – gene technology provides a topical example: the trade-off between the costs and benefits of a technology can be perceived very differently by different societies. This global aspect can make it difficult for the national regulator, given its restricted locus, to ensure proper accountability. We can look only to international cooperation to overcome this particular problem.

Stakeholder engagement

In the past, the regulator is likely to have been concerned only with engaging stakeholders "downstream", when the regulatory regime, already fully formed, was ready to be put into operation. Engagement was necessary if the regulation was to be effective in changing behaviour in the way intended. If the regime was not understood and/or ignored by stakeholders, it would almost certainly fail.

More recently, the importance of engagement "upstream" has been realised[2], ie involving stakeholders in actually forming the regulatory regime. At the very least, it allows account to be taken of stakeholder experience, gives them a sense of ownership, and makes it much more likely that stakeholders will "buy-in" to the new arrangements such that the desired behavioural change is achieved.

More importantly, engagement "upstream" provides the opportunity to reflect stakeholder concerns and values in the nature and scope of the regime. This is particularly significant where the public are stakeholders and the regime is intended to control a hazardous activity which engenders significant societal concern – often the case with an emerging technology. If the regulatory regime fails to deal with those concerns, the public is likely to be opposed to that hazardous activity and its continuance will be jeopardised.

Some would argue that the public is not capable of understanding the technical matters often driving the risk and therefore what is required from regulation. However, experience in the UK has shown that public engagement and expert advice can be integrated to provide lay audiences with sufficient technical understanding to enable them to develop informed views on regulatory issues. Examples of such recent debates in the UK concerned the introduction of new medical[3] and improved train safety technologies[4].

As it happens, the UK Government has identified "nanotechnology" as a priority area in its new public engagement grants scheme *Sciencewise*, and its Engineering and Science Research Council is funding a project *Nanotechnology, Risk and Sustainability*[5] to encourage early public engagement with nanotechnologies. These projects consider how dialogue between scientists and the public can be improved so that public responses are integrated into both the innovation process and the development of regulatory frameworks around nanotechnologies.

Justification

By "justification", I am referring to such matters as whether the purported benefits are really worth the cost and whether the benefits add to the stock of human well-being or are already widely available elsewhere. Are the costs and benefits of the emerging technology evenly, or unevenly, distributed in society? Some of the objection of Europeans to GM crops, for example, seems to have concerned their belief that the benefits from the crops (in terms of revenue) were accrued by the seed and pesticide suppliers whilst they, the public, incurred much of the costs (in terms of environmental damage, harm to health).

Thus, the question which concerns the public is not, "should the emerging technology be regulated" but, rather, "should the technology be allowed to emerge at all"? The question of regulation is a second-level consideration which can be tackled once there is first-level agreement that proceeding with the new technology can be justified.

Much of the discussion around "justification" may well depend on people's perceptions of the risks, costs and benefits – perceptions which, in turn, depend on people's beliefs, interests and values. This sometimes results in accusations of irrationality in decision-making from those who want to see only hard scientific facts used to make decisions. As technical experts, we have a role in informing the public and therefore challenging some of its perceptions. Some differences between the expert and lay view are just that: a matter of viewpoint depending on the beliefs, interests and values of the respective parties. In which case, the lay view must also be given proper consideration and taken into account in regulatory decisions.

Regulation

This difference in viewpoint can pose challenges for the regulator in the governance of the engagement process[6]. Where the viewpoints have a strongly ideological perspective, the process may become strongly polarised with little prospect of agreement between the different parties because of a lack of trust in what the other side has to offer in the way of information, compensation and negotiation. Much of the past engagement over the issue of GM crops can be characterised in this way.

Whatever the difficulties, however, the bottom line must be that public engagement is what is owed to the democratic process and the nature and scope of regulation should flow from public consultation. Provided regulators are transparent in their regulatory decision-making, public debate follows naturally and any reluctance organisations may feel to sharing their "secrets" with other stakeholders is more likely to be overcome. However, it may be that the greatest challenge regulators face in practice is to get the public actually involved, and not just the major players such as employers organisations, trade unions and pressure groups. Since, in the UK, the Government's traditional methods of engagement, consultation documents and the like, succeed only in engaging those "usual suspects", we have been resorting increasingly to more novel approaches such as focus groups, consensus conferences and the like, to engage the public more effectively[7].

Staying ahead of the game

Regulators often find themselves in the position of having to "catch up" with a technology that is already widespread and developing rapidly. As a result, they may find their ability to regulate compromised by the existence of already well-established practices, some of which may be unacceptable from the regulator's perspective. They may also be subject to public and political pressure to regulate in a hurry, and without taking the time to engage stakeholders fully.

Horizon-scanning may help, by ensuring that the regulator is aware of changes in the medium to long-term future that could have an impact on its ability to act effectively and allow it to take the initiative. The process must be systematic in anticipating and identifying new regulatory challenges, and should bring together back-room policy-makers and frontline operational experts, both in-house and external, to identify emerging issues and evaluate their likely impact.

In the UK, a number of government departments operate horizon-scanning programmes. For example, the Department of Trade and Industry runs its Foresight Programme which in its present round operates through a fluid, rolling programme that looks at three or four areas at any one time; it is currently considering such issues as "Intelligent Infrastructure Systems", "Brain Science, Addiction and Drugs". Other UK departments run programmes dedicated to health, food and environmental issues. My organisation, the HSE, has commenced a programme for a more structured approach to horizon scanning for health and safety at work.

The challenge of horizon-scanning is to spot the "runners", the technologies which will prove to have a long-term future rather than be technological dead-ends. Conversely, the regulator must be able to recognise when some catching up is required because the emergence of a technology "runner" has not been detected and is developing at pace and unregulated, and have the necessary organisational arrangements in place to ensure that catching-up can be achieved.

The HSE experience

As I commented at the start, the HSE has been faced over many years with the challenge of regulating emerging technologies. An early example is "electricity"; regulations were introduced in 1908, however, this was clearly a case of retrofit since by the end of the 19th century there were

already hundreds of power generating stations in the UK. Nevertheless, it is a tribute to the perspicacity and expertise of the author of the regulations that they lasted 81 years, being replaced only 1989, in spite of all the intervening technological change.

One reason for this longevity was the fact that the regulations lay down general safety requirements which were to be met "so far as is reasonably practicable" – an approach to health and safety regulation which was not adopted generally in the UK until the arrival of the Health and Safety at Work Act in 1974, and which provides the current regulatory architecture. A goal-setting approach to regulation such as this allows for a greater degree of flexibility than prescriptive approaches and thus is more likely to be resilient to changes in technology. Further, it facilitates the catching-up necessary when the horizon-scanning "radar" fails to detect an emerging technology in time.

A less happy story can be told about the challenge posed by the emergence of asbestos as a binding agent and fire resistor. In the 1930s, the use of asbestos took off in the UK; the first set of regulations were enacted in 1931 and the current UK regulations were introduced in 2002. The intervening years were characterised by the regulatory regime catching-up, progressively tightening as the full extent of the harmful effects of asbestos were understood. We can only speculate as to how many lives would have been saved had a more precautionary approach been taken early on; the difference such an approach might have made to the risk carried and the financial losses incurred by the insurance industry is also worth considering.

I am confident that the plethora of asbestos substitutes we have nowadays, produced in response to the current prohibition on asbestos use, would have been with us much earlier had a more precautionary approach been adopted. There is, as I mentioned, considerable experience[8] suggesting that tight regulation is often a stimulus to innovation; another example is the proliferation of substitutes for CFCs following the Montreal Protocol.

In the case of work with GMOs, initial health and safety regulation was characterised by a precautionary approach – in response to uncertainty about the risk and the effectiveness of control measures, and to the high degree of societal concerns. Since those early days, the resultant tight regulation has in some cases been relaxed as more knowledge has been gained about the risks and the effectiveness of control.

For example, pioneering research in the 1960s and 1970s identified plasmids as potential gene delivery tools for the manipulation of DNA and production of recombinant proteins. In those early days, such DNA technology was undertaken at the highest laboratory containment level (glove boxes, etc); indeed there was a moratorium on such "hazardous" research. Subsequent scientific research and comprehensive risk assessment showed that such measures were over-precautious; it has since been possible to relax controls and undertake such work safely at the lowest laboratory containment level.

Conclusion

To summarise, I would suggest that in regulating emerging new technology we need to:

- aspire to the characteristics of better regulation;
- be goal-setting rather than prescriptive;
- be precautionary in the face of uncertainty about the risk, with a view to easing controls if knowledge of the risk gained subsequently supports this;
- engage stakeholders, including the public, in constructing the regulatory regime;
- and "keep ahead of the game" by adopting a structured approach to horizon-scanning.

Nanotechnologies offer the prospect of great benefits for societies the world over. But those societies will need to manage the tension between the need for innovation/wealth creation and the protection of the public/workers. I believe regulation along the lines I have suggested will enable the tension to be resolved satisfactorily.

[1] For details of the knowledge gaps in the health and safety risks of nanotechnology, see "Nanoscience and nanotechnologies: opportunities and uncertainties", Royal Society and Royal Academy of Engineering, July 2004 (www.royalsoc.ac.uk). Also "Nanomaterials – a risk to health at work?": First International Symposium on Occupational Health Implications of Nanomaterials", October 2004 (www.hsl.gov.uk).

[2] See, for example, Wilsdon J. and Willis R. 'See-through science – why public engagement needs to move upstream", (London: Demos, www.demos.co.uk, 2004)

[3] See, for example, Eames et al, "Deliberative Mapping: Integrating Citizens and Specialists Appraisals in a Transparent and Inclusive Participatory Process", Paper presented at FRONTIERS 2: European Applications in Ecological Economics, February 2003, Tenerife Spain, Fifth International Conference of the European Society of Ecological Economics.

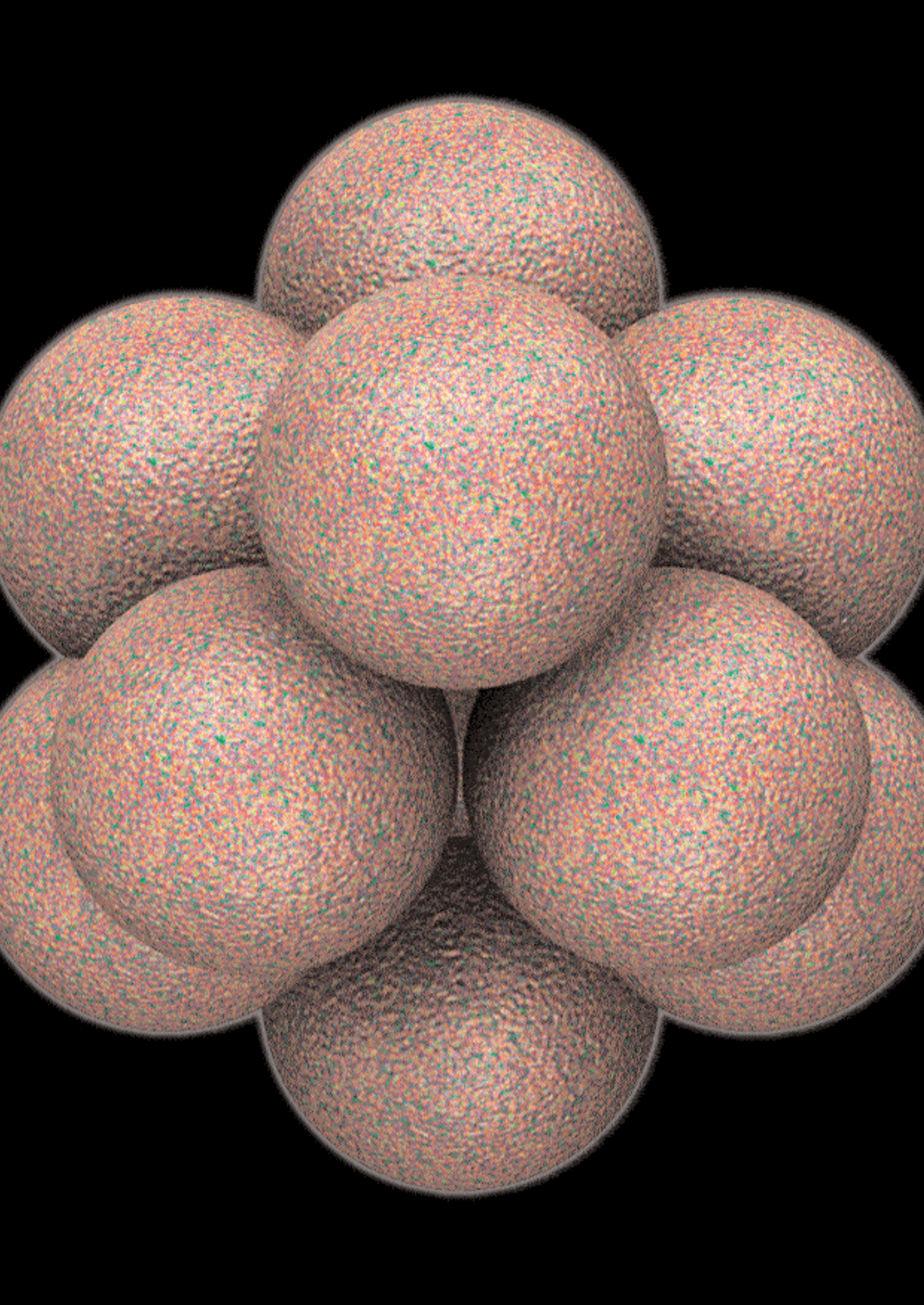
[4] "Public dialogue on train protection", HSE Research Report 055, (London: www.hse.gov.uk/research/rrhtm/rr055.htm, 2004)

[5] "Nanotechnology, Risk and Sustainability: Moving Public Engagement Upstream", Institute for Environment, Philosophy & Public Policy (domino.lancs.ac.uk/ieppp/Home.nsf/)

[6] See the discussion in Tait J. and Cleemanns L., "An Overall Framework for Risk Governance" (prepared for the IRGC Scientific and Technical Council Meeting, Geneva, 5 – 6 November 2004)

[7] See, for example, ref. 4

[8] See, for example, Porter M., "The Competitive Advantage of Nations" (The Free Press, 1990, ISBN 0 684 841 47 9)



Conclusion

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A summary of the 6 – 7 December 2004 nanotechnology conference

Small size – large impact

The conference on nanotechnology that took place on 6 – 7 December 2004 was the first event on the subject to be held at the Centre for Global Dialogue in Rüschlikon. Opening the conference, Annabelle Hett, Risk Expert, Risk Engineering Services, Chief Underwriting Office, Swiss Re expressed her satisfaction that the event was taking place at this relatively early stage in the development of the technology. She emphasised the need for cross-sectoral international dialogue to ensure the sustainable introduction of nanotechnology across a broad spectrum of industries, and to address its potential risks.

Insuring the unknown

Nanotechnology presents a variety of challenges to the insurance and reinsurance industry, and several Swiss Re executives were present at the conference to give their perspective on these challenges.

Insurance acts as a pooling mechanism, a pricing mechanism and a volatility absorption mechanism for risk, but there are certain guiding principles determining whether or not a given risk is insurable. John Coomber, CEO, Swiss Re explained how new technologies present a particular challenge to the insurance and reinsurance industry in terms of assessability. He stressed the need for openness, transparency and honesty among the various stakeholders to ensure that the insurance industry can play a positive role in the future development of nanotechnology.

Later in the conference, Bruno Porro, Member of the Executive Board and former Chief Risk Officer, Swiss Re reiterated the challenge presented by nanotechnology to risk assessment, explaining that this process usually involves knowledge about both the hazard and exposure. In the case of nanotechnology, knowledge about both is severely limited, and it is not even certain whether in the long term, it could prove to

Opposite:
Nucleus of the carbon atom
10^{-14}
10 femtometers



be a phantom risk. Given that nanotechnology is a swiftly growing field that could potentially impact a number of business areas within the insurance industry, he stressed the need for insurers to proactively learn more about its production and distribution mechanisms in order to be able to effectively quantify the risks it presents.

Focusing in on the area of product liability, Andreas Schraft, Head of Risk Engineering and Training and Member of the Chief Underwriting Office Executive Team, Swiss Re emphasised the threat posed to insurers by the potential gap between the introduction of the technology and the manifestation of any damage that may occur. He also stressed nanotechnology's challenge to the principles of causation and economic feasibility in the area of product liability.

The conference did not focus solely on the role of the insurance industry in the development of nanotechnology. One of its main purposes was to initiate a multi-stakeholder dialogue that would bring together many different perspectives in a way that could be mutually beneficial to the development of nanotechnology as a whole.

Developing a vocabulary

One of the first issues to emerge was the fact that nanotechnology is a broad term covering a great variety of different applications. As Professor Mark Welland, Head of the Nanoscience Centre, University of Cambridge pointed out, it is an enabling technology that covers many disciplines, and there is no reason to choose any one area to which it may be applied. Subsequent speakers took this point further, and several participants questioned the utility of the term itself, suggesting that it was too general to be of real use in communicating either within the scientific community or to the public.

In a similar vein, the need for a coherent global nomenclature was reiterated many times, and there was a general feeling that without this tool, meaningful communication about substances, methodologies and standards would be severely hampered.

Recognising the risks

Nanotechnology is currently enjoying ever-increasing levels of both public and private investment, and it has been declared a public research priority in both the US and Japan. However, it is not without its risks, and the conference made it clear that while we are aware of some of these risks, our level of actual knowledge about the effects of nanomaterials on the environment and human health is still low.

Although the quantities of nanoparticles being released into the environment are still small by weight, environmental reactions are often triggered by numbers,



not weight, and this should be borne in mind when assessing the environmental risks associated with nanotechnology. In addition, the increased surface area to mass ratio that such particles possess makes them potentially more reactive. One major risk to the environment is the possible accumulation of nanoparticles within living organisms, making the detoxification of certain nanoparticles before their release into the environment essential.

When it comes to human health, nanotechnology has a significant and exciting potential to improve healthcare in fields including imaging and microscopy, diagnostics, and transport and dosing of drugs to name but a few. But there are still many unknowns, including what happens to nanoparticles after the release of drugs and coatings: are they degraded, accumulated or excreted? If they are accumulated, are they potentially carcinogenic?

Presentations from representatives of the industries involved in developing nanomaterials led to discussion of a possible re-examination of toxicology methods used to study nanoparticles, moving away from classical toxicology methods and taking into account their unusual properties and the diverse ways in which they are being used – an idea that met with some opposition from certain industry representatives. During this debate, it became clear that there is currently some discrepancy in risk perception between the nanotechnology industry and insurers and the public.

On the other side of the coin, Richard Murray, Chief Claims Strategist, Swiss Re presented some of the risks that nanotechnolgy itself faces in the form of liability claims. While urging participants not to be put off by the challenging liability regimes that are prevalent today, especially in the US, Murray urged that they should be aware of potential pitfalls, and accept that the industry will undoubtedly face challenging liability conditions in the future.

Communicating risk and building trust

Such a challenging liability regime underlines the need to communicate risks effectively and build trust. Nor is this the only reason that the nanotechnology industry needs to cultivate a positive public image – a public that feels threatened by a new technology can in turn threaten that technology's very survival. Participants agreed that for nanotechnology to succeed it is vital that it does not fall into the trap of alienating public opinion.

For Paul Davies, Chief Scientist and Director of Corporate Science and Analytical Services, Health and Safety Executive, UK, appropriate and consistent regulation is one way of raising the level of public trust.

In a different vein, it was also suggested that nano-scientists should become more proactive in their relationship with the media, endeavouring to communicate these complex concepts in a language that is comprehensible to non-experts.

However, it is not enough simply to communicate the positive aspects of a new technology. For David Ropeik, Director of Risk Communication, Harvard Center for Risk Analysis, Harvard University, one of the keys to successfully communicating with the public is to respect their concerns, and allow an open discussion of fears, real and imagined.

According to Ropeik, nanotechnology bears all the hallmarks of the risks that make us most afraid: it is hard to detect, we cannot control our level of exposure to it, it is new. Fear is an instinctive reaction that is largely beyond our control; for nano-scientists to dismiss it as irrational would therefore be both arrogant and unwise. Instead, Ropeik recommended that the nanotechnology industry should show respect for the public's fear, avoid manipulation or over-reassurance, share control by empowering stakeholders, and demonstrate competence and responsibility in protecting the public from potential risks.

Looking to the future

Designed to provide a broad overview of the subject, the conference initiated a dialogue among the many stakeholders, which it is hoped can be meaningfully continued into the future. Swiss Re looks forward to ongoing involvement in promoting this dialogue and working towards greater cohesion in risk perception in years to come. This will ensure that nanotechnology has the greatest chance to sustainably and successfully fulfil the enormous potential it offers.





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Conclusion
Annabelle Hett

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To reduce uncertainties and ensure a sustainable introduction of the technology, efforts clearly must be made to establish a common discussion platform facilitating an open dialogue on risk analysis, risk management and options for acceptable risk transfer. Our two-day nanotechnology conference at Swiss Re's Centre for Global Dialogue in Rüschlikon offered an overview of the topic and addressed a broad scope of potential risks and inherent opportunities. One concrete result of the meeting was that for as many stakeholders represented – participants from science, business, the insurance sector, and regulatory bodies – there were fundamentally different perceptions of nanotechnology as a potential risk. Clearly, it is up to these very stakeholders to decide how to minimise those gaps in perception. Doing so will not be without its challenges, however: the risk perception environment is increasingly complex and demanding, and our information age gives ample room and channels to many voices.

As the nanotechnology conference organiser, I also took the following key messages from our early December meeting; as concerns nanotechnology: specifying standards and nomenclature is a foremost priority; stakeholder groups must define and communicate their concrete requirements more effectively; more risk research is urgently needed so as to lay a sound, objective basis for discussion, and stakeholders need to find a common ground to benefit from that exchange; the experts were concerned as much with the concept of "phantom" risk – where no scientifically demonstrable cause-effect relationship can be established as yet – as they were with potential "real" risk, and for that reason, they weighed the importance of risk communication heavily; the public's fear should be taken seriously, and the public must be included in the dialogue to a greater extent to build trust.

In conclusion, I wish to thank all the speakers for their valuable contributions. I look forward to an ongoing dialogue on this topic, which will have a tremendous impact on society and our future risk landscape. In the meantime, if this first conference 9on nanotechnology organised by Swiss Re helped in some way to effectively foster exchange among the stakeholders, we can all join in counting it a success.

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Further reading: "Nanotechnology – Small matter, many unknowns". Zurich: Swiss Re, 2004

Opposite:
Examining quarks
10^{-16}
100 attometers

