INTERNATIONAL RISK GOVERNANCE COUNCIL

SURVEY ON NANOTECHNOLOGY GOVERNANCE

Volume B. The Role of Industry

IRGC WORKING GROUP ON NANOTECHNOLOGY
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Disclaimer
The contents of this working paper have been peer reviewed by the respondents to the IRGC 'Survey on Nanotechnology Governance: the role of industry' and the IRGC Nanotechnology Working Group. The IRGC does not accept responsibility for the validity of the opinions expressed within this report which are a reflection of the opinions of the survey respondents and not of IRGC itself.

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1. BACKGROUND

This survey on the role of industry in nanotechnology risk governance, conducted between September and November 2005, is the second in a series that IRGC has undertaken as part of the preparatory work for their project Nanotechnology Risk Governance ("Addressing the need for adequate risk governance approaches at the national and international levels in the development of nanotechnology and nanoscale products"). Surveys have also been undertaken amongst governments (Volume A, published on http://www.irgc.org/irgc/projects/nanotechnology/ in January 2006), research organisations (Volume C) and NGOs (Volume D). Summaries of these survey responses will be published as separate volumes in this series.

The main objective of the IRGC project is to develop frameworks for the risk governance of nanotechnology, with the intention being to provide recommendations to decision makers in government, industry, NGOs, research institutions and other organisations. Findings from these surveys, together with the outcomes of two expert workshops held in May 2005 and January 2006, and the IRGC White Paper 'Nanotechnology Risk Governance', will be used to develop initial risk governance recommendations which will be presented, discussed and enhanced at an international conference to be held in July 2006 in Zurich Switzerland. IRGC's final recommendations for appropriate risk governance strategies will be published shortly after the conference.

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

The participant organisations come from a broad international and sectoral range although it must also be taken into account that they only represent a small number of those originally surveyed, that there is no representation of developing countries, and that the largest proportion of respondents were US based. The reasons given for not being able to respond were threefold: either the organisation was already involved in the development of some form of governance strategy and did not want to replicate efforts; the focus of the survey was too broad to enable them to adequately capture their particular niche; or they did not consider that nanotechnology would require a new approach to governance strategies. Presumably, the lower rate of return in comparison to the government survey may be because of the confidentiality issue and due to the relatively early development of nanotechnology specific approaches by individual companies. That being said, should any additional organisations wish to contribute to the survey we would be pleased to update this report with their responses. We also wish to make clear that the responses are based on the personal recommendations and suggestions for risk governance of the individual respondents and should not be viewed as necessarily representative of the organisation that these respondents represent. Furthermore, the response received from Canon is attached "as received" and without review because the author was not available for editing.

The following summary represents only a sample of opinions on the industry approach to the governance of nanotechnology. The findings included are those which are most relevant to IRGC's Nanotechnology project and have been interpreted for this purpose. There has been no weighting or relative ranking of the answers, however, where there is commonality of thought or differences in opinion this has been directly stated in the text.

2. LIST OF SURVEY PARTICIPANTS

Listed in the following table are those participants who contributed to this survey report, named in country alphabetical order.

Table 1: Survey participants

Country	Respondents	Title and organisation
Chinese Taipei	Dr. HungMin Chein	Deputy Division Director, Environmental Health & Air Pollution Division, Center for Environmental Safety and Health Technology, *Industrial Technology Research Institute* http://www.itri.org.tw/eng/research/nano/index.jsp
Germany	Dr. Christoph Lauterwasser	*Allianz Zentrum für Technik GmbH* http://www.allianz.com/azcom/dp/cda/0,,796454-44,00.html
Germany	Dr. Elke Pfeffer	*NanoBioNet e.V.* http://www.nanobionet.de/eng.htm
Switzerland	Dr. Solomzi Makohliso	Chief Executive Officer, *Ayanda Biosystems* http://www.ayanda-biosys.com/
Switzerland	Dr. Thomas K. Epprecht Dr. Annabelle Hett	Chief Underwriting Office, Risk Engineering Services, *Swiss Reinsurance Company* http://www.swissre.com/
UK	Dr. Peter Hatto	Director of Research, IonBond Ltd, and Chair, Technical Committee 229 on Nanotechnologies, *International Organization for Standardization (ISO)* http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932
US	Mr. Ruben Serrato	Manager of Corporate Development, *Canon USA* (left Canon in 2006) http://www.canon.com/technology/s_labo/nano/001/03.html
US	Dr. Kenneth A. Mundt	Principal, *ENVIRON Health Sciences* http://www.environcorp.com/practices/article.php?t=Nanotechnology&id=2854&refsec=people&refid=40
US	Mr. Todd Brady	Senior Environment, Health and Safety Technologist, *Intel Corporation* http://www.intel.com/technology/silicon/nanotechnology.htm
US	Dr. Alan Rae	VP Market & Business Development, *NanoDynamics Inc.* http://www.nanodynamics.com/
US	Dr. Mostafa Analoui	Senior Director and Site Head, Global Clinical Technology, *Pfizer Global Research and Development* http://www.pfizer.com/pfizer/help/index.jsp

RESULTS OF THE SURVEY

The following summary includes selected findings which are most relevant to the IRGC project and have been interpreted for this purpose. All responses and further details can be found in the Annexes which contain the full survey responses from each participant.

3. WHAT ARE THE MAIN FINDINGS?

SUMMARY OF CURRENT GOVERNANCE STRATEGIES

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

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

A common recognition of the respondents was the need to ensure responsible development, particularly in sectors where organisations might have opportunities to act irresponsibly in order to gain competitive advantage, or where current legislation is not designed to protect against unexpected risks, for example, in the cosmetics industry. An important method of addressing this was perceived by the respondents to be through collaboration with government and academia and within industry itself. For example, the Consultative Board for Advancing Nanotechnology (CBAN), a US government and industry collaboration, has an Environmental, Health and Safety Working Group. Differences of opinion between the respondents arose with regard to when collaboration should take place. On the one hand, some participants considered that without an adequate definition of what the risks actually are it would not be possible to have an effective dialogue. On the other hand, it was felt by several participants that in order to gauge potential technical and social risks collaboration should take place now. There was greater agreement regarding the inclusion of the public in dialogue, with a clear feeling that risks should be

communicated to the public by an independent, 'trusted' source only once a rational assessment of risks and benefits has taken place. There was no mention by any respondent of the possible inclusion of the public in early dialogue.

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

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

RECOMMENDED GOVERNANCE STRATEGIES

Table 2: Risk governance recommendations (suggested in the survey)

Type of governance strategy	Recommendations, suggestions and ideas
Risk research recommendations	§ Identify deficits in research capabilities so that potential risks can be better understood, categorised and measured § Distinguish between different nanotechnologies in order to more efficiently assess risk § Establish dedicated multidisciplinary risk research centres of excellence § More aggressive risk training within R&D parameters
Stakeholder engagement recommendations	§ Collaboration between governments, industry, academia and NGOs on the establishment of best management practices § Forums for international dialogue on EHS issues § Forums for individual organisations to exchange good governance practices § Attendance at meetings by those who use the technologies, such as engineers and clinicians
Risk communication recommendations	§ Inform public with detailed scientific basics (not just hype) supported by substantial evidence § Ongoing surveys of public opinion to inform the public and other interested parties § Provision of information by independent 'trusted' organisations, such as the Royal Society and Royal Academy of Engineering in the UK § Coordinated risk communication by governments, academics and industry internationally on EHS impacts, societal impacts and overall benefits § Provision of relevant and accessible communication through the media § Serious consideration of public concerns and demonstration of an adequate response helps to gain credibility and trust
Governance approaches	***International expert bodies:*** § Determine international standards and harmonise regulatory requirements § Develop international trade agreements for certification of products and materials according to internationally established standards § Develop approval mechanisms for nanoscale materials and products as a prerequisite for best practices § Publish best practices for occupational safety § Publish best practices for a lifecycle approach towards nanoproducts

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

4. RESEARCH AND DEVELOPMENT STRATEGY

Question 1 of the survey addressed research and development programmes, including a description of the organisations focus, a list of products already on the market, or in the final phases of development, collaboration with other entities and patents owned. Optional questions were also asked regarding investment in nanotechnology R&D and any discussions with insurance companies. The following provides a summary of key points identified.

OVERALL RESEARCH AND DEVELOPMENT STRATEGY

The survey responses indicated that many of the respondents had a strong interest in the research and development (R&D) of nanotechnology. This was reflected in the potential benefits mentioned by the respondents, the extent of products in development and the number of nanotechnology specific patents already in place. With the exception of one participant, no organisation was able to share the level of investment in nanotechnology R&D nor the percentage of total R&D investment earmarked specifically for nanotechnology. No nanotechnology-specific insurance policies were identified but one company was in discussion regarding worker and researcher health insurance and another had been asked by insurance companies in the US, UK and Germany to assemble background materials on the potential risk of producing and using nanomaterials. The insurance respondents were widely involved in risk dialogue, for example, through participation at workshops and conferences, although no details of specific negotiations with individual companies were provided. The areas where the respondent organisations were focused included: drug development for developing countries, the consumer electronics industry, industrial research, nanobiotechnology, nanomaterial production, drug formulation and discovery, development of international standards, provision of adequate insurance cover, including reduction of loss potential, and consultancy work for the risks associated with environmental contamination, occupational exposures and consumer products.

One particular element that stood out was the common focus on benefits associated with immediate or near term applications**,** rather than the longer term evolving nanomaterials and systems. This might have be because the survey did not specifically ask for reference to the longer term, it might be that those organisations surveyed were not researching more long term products or, of course, it could be that organisations prefer not to advertise longer term plans for commercial reasons.

Ø Potential benefits

Many potential benefits were mentioned, some on a general level and others more product-specific. The general benefits included: lower environmental impact solutions, for example, sustainability of energy and water resources; radically new industrial processes and health solutions; cost effective, better performance products; new functions, new applications and smaller devices; and, better consumer products (e.g. in terms of efficiency, strength and durability).

The following benefits were more product-specific, although not necessarily representative of the products being produced by the organisations: more efficient energy conversion in batteries, fuel cells and photovoltaics; new and greater sensitivity in medical diagnostics, sensors and drug delivery systems; new silicon devices to drive future electronic products; environmental clean-up applications; catalysts and filters for cleaner water; biosensors to monitor water quality; and, new products such as paint, coatings and composites.

- **Specific areas of R&D focus**

  - Products in development

    Products that the respondent organisations had in development or on the market included: an HIV test, medical diagnostics, a molecular test for pneumonia, tuberculosis and influenza; screens and displays; digital cameras and printers; microprocessor with sub-100nm transistors; golf balls; solid oxide fuel cells; carbon nanotubes and metal nanopowers; carbon nanocapsules; and nano-gold masks. One respondent was also researching the potential for systems which could monitor the introduction of new nanotechnology-related occupational, environmental and consumer products.

  - Insurance

    The main focus of the insurance related respondents was the need for adequate insurance cover for nanotechnology with an emphasis on appropriate and sufficient evaluation of the potential risks and opportunities. There were differences in issue identification for insurance companies, who work directly with individual companies and face predominantly single company, industry or locality specific issues, and re-insurance companies who insure the insurance companies and need to anticipate more widespread multi-sectoral and international issues. For an insurance company the emphasis was on a detailed evaluation of the practices within individual companies, for example, product design, investment strategy, and, methods of risk control and risk management. Particular areas of R&D identified for a re-insurer included: investigation of public perception and possible regulation; consideration of corporate governance for issues with a potential for high exposure; the assessment of loss potential; and, legal initiatives.

  - Standardisation

    As part of the development of International Standards for nanotechnology the International Organization for Standardization Technical Committee 229 (ISO TC229) has a specific R&D focus on: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and, science-based health, safety, and environmental practices.

- **Collaboration with other entities**

An important R&D strategy for the respondents was strategic investment into and the formation of partnerships with start-up companies, universities, national laboratories, trade associations and consultancy experts from the areas of technology transfer, patents and finance. For example, one organisation had established joint partnership agreements with nanotechnology start-ups in medical diagnostics, displays, digital cameras and printers. An interpretation of the survey responses showed that a key element of progress in nanotechnology R&D was the development of partnerships between multinationals and organisations specialising in nanotechnology development. For example, one multinational respondent did not manufacture or produce nanoparticles itself, instead the company licensed or purchased nanoparticles for research purposes from other entities as well as funding external research making use of these materials.

- **Nanotechnology specific patents**

Only 5 of the respondents provided examples for this question, however from these it can be seen that many patents are already in place. For example, one multinational has registered hundreds of patents in core areas of reduced component size and fundamental research for the past 15 years, with patents being filed in Japan, Europe and the US. Patents were also not just in the domain of global companies as both of the start-ups who responded to the survey have separately patented their developments, for example, one company was in possession of 55 exclusively licensed or owned patents.

RESEARCH FOCUS – RISKS

The responses indicated that risk studies in industry were being focused on: environment, health and safety (EHS); and, the development of metrology and nomenclature in the form of best practices and standards. Two respondents considered it to be very important that risks were defined before governance structures could be put in place to prevent them and for many the definition and characterisation of potential risks was the main priority of risk research. One survey respondent observed that in general industry does not yet seem very knowledgeable about the potential health and environmental risks, but that they were trying to remedy this through collaborating on EHS issues, out-sourcing risk evaluation to external consultancies and working on best practice guidelines. There was no mention of specific programmes to investigate ethical, legal and social issues (ELSI), although some participants did refer to the need to engage with NGOs. The majority of risk research programmes mentioned were at industry level rather than organisational level and the following are examples of these:

- Research needs. The Consultative Board for Advancing Nanotechnology (CBAN), a collaboration of the Chemical Industry Vision 2020 Technology Partnership with the National Nanotechnology Initiative (NNI), has in place an Environmental Health and Safety Working Group. This is developing research needs statements so that potential risks can be better understood and measured (CBAN 2006).
- Best practices. The International Council on Nanotechnology (ICON) is reviewing best practices for nanomaterial safety, with the ultimate goal being a report on best practices for ensuring environmental and occupational safety when producing or using engineered nanoparticles including: an analysis of the limitations of current practices, the research needed to address these limitations and current initiatives which are seeking to develop more appropriate recommendations on the safe production and use of engineered nanomaterials (ICON 2006). In Europe, a NanoMatProd (NMP) project, a Sixth Framework Programme focused on knowledge transference in the area of nanotechnology and nanosciences has developed a good practice guide for the handling and disposal of nanomaterials which will provide guidance to its project partners (NMP 2006).
- Standards. In the US, the ASTM International Committees E56.01 and E56.02 are developing standard terminology and practices for nanotechnology (ASTM 2006). Internationally, standards are being developed by ISO TC229 on Nanotechnologies whose aim is to provide the essential foundations for naming, characterising and testing nanotechnology materials and devices (ISO 2006).

One mention was made in the survey responses of risk being addressed at organisational level and this was in relation to the employment of external consultancy agencies advising companies on concerns related to environmental and occupational exposure:

- Environmental and occupational exposure**.** Environ Health Services is an international consultancy firm focusing on providing advice for clients working with nanotechnology in the areas of toxicology, best practices in occupational safety and health, development of new quantitative risk assessment approaches and statistical models, environmental fate and transport, environmental remediation, and consumer product stewardship (Environ 2006).

As well as asking respondents to divulge current risk research, the survey also asked participants to identify the potential risks which might be created by the development of nanotechnology. One respondent commented that this question may be premature as it is not meaningful to speculate about risk and differentiate between different risks when we do not yet have any clear knowledge of what additional hazards nanotechnology might pose. Several respondents did identify risks and these are categorised below into ELSI and EHS risks:

- ELSI risks. These included the divergence in spread of technology between poor and wealthy countries, imbalance in risk management between different companies producing similar products leading to unfair competition, job losses, inappropriate banking and investment policies, insurance losses (for example: worker's compensation, general and products liability, products recall,

environmental liability and property), communication with stakeholders, and low public perception - valid or invalid - which could stem potential benefits.

- EHS risks. These included nanomaterials with deliberately engineered biological activity, products introduced into the body for long periods and which cannot be retrieved or removed, technologies involving cadmium particles (quantum dots), nanoparticles with toxic properties during manufacturing, use and at disposal, the identification and control of long term human health risks, and, freely mobile nanoscale materials with the potential to be persistent and are not able to be tracked. One respondent identified a potential highest risk case as being products that do not go through the rigorous quality control and environmental testing already required for many current materials and applications, especially if they are intended to be used commonly, for example, cosmetics.

In response to these potential risks, respondents provided us with the following recommendations for voluntary actions by industry which could be used to identify, monitor, reduce and prevent these risks occurring:

- Treat free nanoparticles as potentially hazardous materials.
- Invest in toxicological and ecotoxicological research.
- Maintain awareness of current developments in risk.
- Invest in responsible and sustainable nanotechnology and avoid hype.
- Monitor particle emissions.
- Clean work areas at the end of each shift using vacuum pickup and wet wiping methods.
- Prevent the storage and consumption of food and beverages in workplaces where nanomaterials are handled.
- Provide hand-washing facilities and encourage workers to use them before eating, smoking etc.
- Provide facilities for showering and changing clothes to prevent contamination of external areas.
- Transfer of material from primary containers to processing equipment in a fume cabinet.
- The use of filter masks, goggles and silicon rubber gloves when transferring materials, and when cleaning equipment or accidental spills.
- Implement risk management practices as early as possible and make them publicly available.
- Establish rigorous quality controls and environmental testing procedures.
- Provide guidelines for workers for understanding, measuring and managing risk at the product line.
- Develop a nano-EHS programme to implement recommended guidelines.
- Provide official support for nanoethics.
- Obtain membership of industry organisations active in nanotechnology.

5. REGULATIONS FOR NANOTECHNOLOGY

At the time of the survey there were no specific regulations for nanotechnology. For example, one participant commented that the scrutiny of the US Food and Drug Administration (FDA) had not as yet led to practices which restricted nanotechnology development (US FDA 2006). Industry is currently regulated by government agencies through legislation for environmental, health and safety risks designed to assure the quality, safety and efficacy of products This regulation also applies to nanotechnology and annex A provides an overview of those regulations mentioned by the respondents, although there was no analysis of their applicability for nanotechnology.

6. CURRENT GOVERNANCE STRUCTURES IN PLACE

At the time of the survey there were no national or international standards or best practices in place for nanotechnology although these were in the process of being developed. For example, by the National Institute for Occupational Health and Safety (NIOSH 2006) and by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECOTOC 2006). As yet however any structures mentioned as being in

place were voluntary and took place at organisational level. As a consequence of this, and due to the very different nanotechnology materials being developed, practices tended to differ substantially. Those respondents who discussed current practices mainly focused on guidelines for worker health and safety, and there were also differences in opinion as to whether or not these were necessary. For example, one respondent advised that they do not yet have a specific programme to address nanotechnology concerns, and suggested that the lead in developing this should be taken by standards bodies and not individual companies. In comparison, another respondent already has in place exposure and handling guidelines for all chemicals associated with development and manufacture of the nanoscale materials that they are researching. Three specific examples for voluntary governance structures in place at organisational level were mentioned in the responses:

- Worker safety and environment**.** One organisation has a Nanopowder Process and Working Environment Guideline and a Nanopowder Process Waste Gas Emission Protocol.
- Product safety. One multinational has a corporate global environmental promotion organisation which reviews all new products before they are approved.
- Responsible development. One organisation has in place a corporate charter which governs the approval of all projects, and ensures compliance for investors. As a matter of policy they do not invest in any technologies that are harmful to the environment or human health and they reject applications which may potentially be used for warfare or weapons.

7. COOPERATION

Question 3 considered issues of national and international cooperation in nanotechnology, including key networks, trade associations, institutions and international organisations supporting nanotechnology development. The following provides a summary of key areas in which cooperation is taking place.

COMMERCIALISATION OF APPLICATIONS

The survey responses indicated that there was a strong focus on the rapid commercialisation of nanotechnology applications in order to secure competitive advantage. Nanotechnology-specific networks, associations and initiatives were being established in many sectors to ensure that nanotechnology products could become viable as soon as possible. The main areas of collaboration for commercialisation identified in the surveys were government funded centres, government-industry initiatives, industry-academia networks and industry consortia that have a high level technical advisory board representing each participating company,

- Government funded centres. For example, Nano2Life (2006) is an EU Centre of Excellence in nanobiotechnology supported by the European Commission under the 6th Framework Programme. Its objective is to make Europe a competitive leader through the exchange of intellectual and technical resources, new education and training courses, and, the transfer of technology among its members. In the US the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), aims to establish seven Centers of Cancer Nanotechnology Excellence (CCNEs).
- Government-industry initiatives. For example, in the US, the Consultative Board for Advancing Nanotechnology (CBAN 2006) is a partnership between the US National Nanotechnology Initiative (US NNI 2006) and the electronic industry and chemical industry aiming to co-ordinate nanotechnology R&D. A Nanotechnology Research Working Group has identified R&D priorities within the following areas: understanding nanotechnology fundamentals; developing computational tools and manufacturing processes; and establishing ways to characterise nanomaterials.
- Industry-academia networks. For example, NanoBioNet e.V (2006) is a network of universities, research institutes, hospitals, private companies and experts from the fields of technology transfer, patents, industry and finance. Their common goal is R&D as well as creating marketable products and new jobs in the field of nanobiotechnology. A second example is EMPA (2006), a materials science and technology institute in Switzerland which is collaborating with industrial partners and

research organisations on three clusters of projects concerning nanocomposite coatings, nanoparticle ceramics and organic nanosystems.

- Industry consortia. For example, in the US the Nanoelectronics Research Initiative (NRI 2006) is a consortium of companies from within the Semiconductor Industry Association which aims to accelerate research into nanoelectronics for the benefit of the semiconductor industry. A second example is the NanoBusiness Alliance (2006), a nanotechnology-specific industry trade association which aims to develop initiatives that advance nanotechnology.

RESPONSIBLE DEVELOPMENT

At the time of the survey no national or international industry initiative existed to address responsible development specifically for nanotechnology. Many of the respondents had internal procedures to ensure responsible technological development in general and some were involved in collaborative forums which exclusively addressed nanotechnology. However, one survey respondent felt that the tendency of companies towards proprietary secrecy and consequential lack of cooperation in sharing risk information for new materials could hamper the ability of society to act responsibly towards potential risks. The following forms of cooperation are taking place with respect to the responsible development of nanotechnology:

- Cooperation with regulatory authorities. For example, in Chinese Taipei, the Industrial Technology Research Institute (ITRI), a non-profit R&D organisation which is engaged in applied research and technical service for industry is also an unofficial arm of the government's industrial policies. The ITRI is working closely with the national Environmental Protection Agency to set policies which are both environmentally and commercially responsible. A second example is ISO TC229 (ISO 2006) which is working with the Organisation for Economic Co-operation and Development (OECD 2006) Joint Meeting of the Chemicals Committee and the Working Group on Chemicals, Pesticides and Biotechnology subgroup on the safety of manufactured nanomaterials, with the eventual aim to establish a formal liaison between the two organisations.
- Cooperation amongst industry. For example, ISO TC229 on Nanotechnologies (ISO TC229) includes industry representatives from 24 participating countries and 8 observing countries with the explicit aim of developing test methods for applications and product standards in the field of nanotechnology.
- Cooperation between industry, academia and government. For example, the Controlled Release Society (CRS 2006) is an international organisation which serves 3,000 members from more than 50 countries. Two-thirds of the CRS membership represents industry and one-third represents academia and government. They are dedicated to improving quality of life by advancing science, technology and education in the field of controlled delivery of bioactive substances. A key element of this is their objective to ensure the minimisation of potentially adverse reactions to new drugs and devices. A second example is a project entitled ‘Dialogue on Nanoparticles: Identification and evaluation of the environmental and health hazards posed by nanoparticles’ which is being organised by several German Federal Ministries, including the Federal Environment Ministry (BMU), the Federal Environmental Agency (UBA) and the Federal Institute for Occupational Safety and Health (BAuA). Their activities include workshops with industry, insurance, administrators, scientists and NGOs amongst others (Dialogue on Nanoparticles 2006). A third example is Nanologue (2006), a European Union (EU) sixth Framework Programme project which is being led by the Wuppertal Institute in Germany. This programme aims to create dialogue among researchers, business and civil society about the benefits and potential impacts of nanoscience and nanotechnology applications.
- Cooperation with NGOs and civil organisations. For example, in the US the International Council on Nanotechnology (ICON 2006) is working to assess, communicate, and reduce environmental and health risks while maximising societal benefit. A major part of this process involves the inclusion of as many international stakeholders as possible, including NGOs, in a dialogue regarding responsible development. A second example is the consultation of consumer representation councils on issues of societal significance by ISO and the national member organisations of TC229. Other organisations identified as bringing together industry and civil society were the Royal Society and Royal Academy of Engineering in the UK (2006) and Stiftung Risiko-dialog (2006) in St. Gallen, Switzerland.

SUSTAINABLE DEVELOPMENT

There were very few responses relating to how nanotechnology might contribute to sustainable development and no survey respondent identified any specific nanotechnology product development taking place for the purposes of sustainable development. One participant did comment that nanotechnology could have a significant impact within the fields of sustainable energy and water but that this would only be achieved through international action, commitment by international bodies such as the United Nations and the G8, and education geared towards convincing society of the need for industries and communities to make a low energy footprint. Two specific types of industry cooperation were identified by the respondents as currently working towards sustainable development. The first of these relates to organisations actively pursuing the creation of sustainable technologies; and the second promotes the reduction of activities which may potentially harm sustainability.

- Creation of sustainable technologies. For example, the Clean Tech Venture Network (2006) provides information, advice and networking opportunities for member organisations. This organisation is US based, but its membership is international.
- Reduction of harmful activities. For example, the WasteWise Program (2006) of the US Environmental Protection Agency is a free, voluntary programme which seeks to reduce harmful wastes and to recycle where possible. There are four main benefits for member organisations: they design their own waste reduction programmes tailored to their needs; they receive free technical assistance; their participation is publicised in EPA publications; and they are able to network with other organisations.

8. RECOMMENDATIONS FOR RISK GOVERNANCE

Questions 4-14 addressed aspects of risk governance and the recommendations of the participants to address these issues. The following sections provide thoughts and suggestions made by the survey respondents; no weighting has been attributed to the answers, however where there is commonality of thought this has been directly stated.

RISK RESEARCH RECOMMENDATIONS

A common element in recommendations for risk research was the need for deficits in research capabilities to be identified so that potential risks could be better understood, categorised and measured. Several participants considered that different nanotechnologies may result in different types of risks and that to be effective risk governance processes must distinguish between these. One specific suggestion was the need for dedicated multidisciplinary risk research centres of excellence to be established, and another respondent recommended more aggressive risk training within R&D parameters. Two participants however felt that it would only be necessary to introduce new guidelines for nanotechnology in cases where no procedures existed for their bulk counterparts.

STAKEHOLDER ENGAGEMENT RECOMMENDATIONS

Many of the survey participants commented that dialogue and debate between different stakeholders should take place, particularly with respect to EHS issues. However, one participant felt that there could not be an effective debate until it is actually possible to define what the dangers and risks are. Without evidence to support the claims that are being made no practical outcomes from these dialogues could be expected. In terms of which stakeholders should be engaged, there were very varied responses. Many of the participants considered dialogue on EHS issues to be important with emphasis on the inclusion of industry, governments and academia. One respondent saw the need to include NGOs in the debate, and another to include practitioners. Inclusion of the public as stakeholders was mainly in reference to public perception of nanotechnology and the manner in which the public should be educated rather than

engaged. In terms of practical recommendations for stakeholder engagement the following strategies were suggested:

- Collaboration between Governments, industry, academia and NGOs on the establishment of best management practices.
- Forums for international dialogue on EHS issues.
- Forums for individual organisations to exchange good governance practices.
- Attendance at meetings by those who use the technologies e.g. engineers and clinicians.

RISK COMMUNICATION RECOMMENDATIONS

The majority of responses interpreted risk communication as communication to the public rather than among different stakeholders, so the focus of this section is on public communication of the potential risks. With regard to this particular aspect, many of the participants emphasised the need for risks to be properly understood before communication takes place. An important element is that the public will only really begin to understand the potential benefits once more nano-based products hit the mainstream consumer markets. As a consequence, one should be wary about raising potential risks in the public consciousness before a rational assessment of the risks and benefits can take place – especially when the risks are not well known. A second common recommendation was with regard to the source of communication: many of the respondents identified the need for information to be coordinated by an independent, 'trusted' and authoritative source in order to minimise conflicting information from too may sources. Of particular note was the reference by one participant that, in order to reach the wider public, information should be communicated through the media. The following specific risk communication strategies were suggested in the responses:

- Inform public with detailed scientific basics (not just hype) supported by substantial evidence.
- Ongoing surveys of public opinion in order to inform the public and other interested parties.
- Provision of information by independent 'trusted' organisations, such as the Royal Society and Royal Academy of Engineering in the UK (2006)
- Coordinated risk communication by governments, academics and industry internationally on EHS impacts, societal impacts and overall benefits.
- Provision of relevant and accessible communication through the media.
- Serious consideration of public concerns and demonstration of an adequate response in order to gain credibility and trust.

GOVERNANCE APPROACHES

A role for international expert bodies

The majority of survey participants agreed that international expert bodies should act as neutral resources through which different sources of information can be coordinated and published. In particular these types of bodies were seen to have a key role in ensuring that firms do not have the incentive to play different countries off against each other in terms of who has the lowest threshold for environmental protection, for example, through the determination of internationally applicable standards. One respondent commented that as yet governance at a global level is insufficient and that more work needs to take place especially within the areas of standardisation and trade. The following suggestions for international bodies were made in the responses:

- Determine international standards and harmonise regulatory requirements.
- Develop international trade agreements for certification of products and materials according to internationally established standards.
- Develop approval mechanisms for nanoscale materials and products as a prerequisite for best practices.
- Publish best practices for occupational safety.

- Publish best practices for a lifecycle approach towards nanoproducts.
- Collaboration between multinational organisations (such as the European Commission (EC), Organisation for Economic Co-operation and Development (OECD), World Health Organisation (WHO) and the United Nations (UN)) and consultation with national bodies.
- Provide advice which is independent of national legal environments.

A role for self regulation (for industry, NGOs and research organizations)

Many of the respondents agreed that self-regulation by industry was an important aspect of any risk governance process for nanotechnology and the largest number of risk governance recommendations were provided in this area. In terms of who should take the lead, one survey participant felt that it was not an appropriate role for individual companies to define risk governance strategies and that this should be undertaken by standards bodies and industry organisations with access to a wider range of information, and the ability to define more fully informed practices. There were however differences in responses regarding whether any changes would be necessary, for example one respondent felt that normal precautionary chemical/biological laboratory practices should be adequate, and another that, based on the evidence from nanoproducts that have been used for years (e.g. carbon black and fumed silica), additional voluntary practices would not be necessary. Other respondents however indicated that they had already put specific guidelines in place, with one participant in particular adopting a precautionary approach to worker exposure and another suggesting that possible nanotechnological risks could not be adequately managed if similarity with their bulk counterparts was assumed. The following specific suggestions were made by the participants with respect to self-regulation:

- Introduce voluntary programmes for best practices and guidelines in laboratories in order that researchers are better informed regarding the potential risks.
- Standards bodies and industry organisations to take the lead in defining risk governance practices.
- Industry and trade associations to lead self-regulation of different sectors and international cohesiveness.
- Judge nanomaterials on a case-by-case basis rather than using a generic approach and characterise using multidisciplinary teams.
- Develop best practices that screen new materials for potentially high risk nanotechnological properties and for approval procedures to take this information into account.
- Develop training and certification schemes with respect to nanotechnological advice provided by consultancy agencies.
- Document products in the process of being developed and currently on the market to provide an information source for occupational and environmental safety agencies.
- Develop informal approaches in the areas of both EHS and ELSI, for example, traditional cost-benefit analysis should include the positive and negative consequences for society.
- Shareholder oversight (through corporate charter) to prevent investment in technologies harmful to the environment or human health, and may lead to applications in warfare.

A role for government in governance approaches

Many of the survey participants felt that government should be directive rather than restrictive and that, whilst risk governance should be cautious, it should also be the result of reasonable judgement. For many of the respondents it was not clear yet whether changes in / or new regulation will be needed and there were a variety of responses regarding the implementation of regulation. One respondent suggested that government should monitor the situation closely and put in place regulatory changes only if there were signs of irresponsible use, another commented that informal approaches should be sufficient where competitive advantage issues do not play a role, another felt that the standards being developed by ISO would be sufficient to close any gaps, and one survey respondent felt that entirely new regulations would not be needed, although it may be necessary to adjust existing legislation.

There seemed to be three common perceptions amongst the participants, the first being that the current state of knowledge is insufficient to set entirely new regulations, the second that any changes made to

regulatory policy should be designed to restrict irresponsible behaviour rather than restrict innovation, and the third that there should not be a long period of regulatory uncertainty The following specific suggestions were made by the respondents with regard to a role for government:

- Steer research direction through funding of key strategic pre-commercial areas.
- Support and guide independent research on nanotechnology related risks.
- Provide transparent and open access to the results of government supported research.
- Provide education, awareness, guidelines, and effective but not over-restrictive legislation.
- Standardise and harmonise risk assessment processes and regulations nationally.
- Instigate a transparent review of existing legislation and assess risk governance gaps related to the specific properties of nanotechnology.

9. REFERENCES

All references are internet sites last accessed in April 2006.

ASTM International – an open forum for the development of international standards http://www.astm.org/cgi-bin/SoftCart.exe/index.shtml?E+mystore

Center for Biological and Environmental Nanotechnology (CBEN) - a National Science Foundation funded Nanoscale Science and Engineering Center focusing on research at the interface between "dry" nanomaterials and aqueous media such as biology and the environment http://cben.rice.edu/

Centers of Cancer Nanotechnology Excellence (CCNE) – to develop and apply nanotechnology and nanoscience solutions to the diagnosis and treatment of cancer http://nano.cancer.gov/funding/nanotech_centers_of_excellence.asp

Chinese Taipei Environmental Protection Agency (EPA) http://www.epa.gov.tw/english/webezA-1/code/main.asp

Cleantech Venture Network - a membership organisation which aims to bring together investors, entrepreneurs and service providers interested in clean technology http://cleantech.com/

Consultative Board for Advancing Nanotechnology (CBAN) - A partnership between the National Nanotechnology Initiative and the chemical industry to promote, plan, coordinate, and expand nanotechnology R&D. CBAN has prepared a document on research needs for EHS which is now available on the website. http://www.chemicalvision2020.org/nanotechnology.html#nano

Dialogue on Nanoparticles – a German Federal Government project to initiate dialogue with other stakeholders in order to debate the impact of synthetic nanoparticles on health and the environment http://www.dialog-nanopartikel.de/index_en.html

EMPA – a Swiss materials research institute http://www.empa.ch/plugin/template/empa/32/*/---/l=2

European Centre for Ecotoxicology and Toxicology of Chemicals (ECOTOC) – A company funded organisation whose mission is to support the safe manufacturing and use of chemicals, pharmaceuticals and biomaterials through sound science http://www.ecetoc.org/Content/Default.asp?PageID=32

International Council on Nanotechnology (ICON) – an international organisation whose mission is to assess, communicate, and reduce the environmental and health risks of nanotechnology while maximizing its societal benefit http://icon.rice.edu/

International Organization of Standardization (ISO) Technical Committee 229 on Nanotechnologies http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932

Nano2Life – a European Centre of Excellence in Nanobiotechnology http://www.nano2life.org/

Nanologue – a European dialogue on the social, ethical and legal implications of nanotechnology http://www.nanologue.net/

NanoBusiness Alliance – A nanotechnology trade association for over 40 member companies http://nanobusiness.org/

National Cancer Institute - the US Federal Government's principal agency for cancer research and training http://www.cancer.gov/
National Nanotechnology Initiative (US NNI) – a federal R&D program established to coordinate the US multiagency efforts in nanoscale science, engineering, and technology http://www.nano.gov/html/about/home_about.html

Nanoelectronics Research Initiative - Nanoelectronics Research Corporation (NERC) programme to demonstrate novel computing devices with critical dimensions below 10 nanometers in simple computer circuits http://www.src.org/nri/default.asp?bhcp=1

NanoMatProd (NMP) – an FP6 programme which supports research projects in the area of "Nanotechnology and nanosciences, knowledge-based multifunctional materials and new production processes and devices" http://www.cordis.lu/nmp/home.html

National Institute for Occupational Safety and Health (NIOSH) - the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. http://www.cdc.gov/niosh/topics/nanotech/

National Institutes of Health (NIH) - the primary Federal agency for conducting and supporting medical research http://www.nih.gov/

Organisation for Economic Co-operation and Development (OECD) Joint Meeting of the Chemicals Committee and the Working Group on Chemicals, Pesticides and Biotechnology subgroup on the safety of manufactured nanomaterials http://www.oecd.org/department/0,2688,en_2649_34365_1_1_1_1_1,00.html

Royal Society and Royal Academy of Engineering (2006) – the UK national academy of science, and the UK national academy of engineering http://www.nanotec.org.uk/

Stiftung Risiko-Dialogue http://www.risiko-dialog.ch/overview.htm#expertises

US Food and Drug Administration (FDA) - responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation http://www.fda.gov/nanotechnology/

WasteWise Program of the US Environmental Protection Agency - a free, voluntary program through which organizations eliminate municipal solid waste and select industrial wastes http://www.epa.gov/epaoswer/non-hw/reduce/wstewise/about/index.htm

10. ANNEXES

ANNEX A – ABOUT THE IRGC

The International Risk Governance Council (IRGC) was founded in 2003 at the initiative of the Swiss government. IRGC is an independent foundation, a public-private partnership enjoying the financial support and participation of public and private sector organisations from several European, North American and Asian countries.

IRGC's purpose is to help to reduce risk on a global basis. We do so by providing both general and policy recommendations to those individuals and organisations in government and industry that make the decisions on those risks that impact on human health and safety, the environment, the economy and society at large.

In achieving our mission we will seek to work with governments, industry, NGOs and other organisations and, with them, foster public confidence in risk governance and other related decision taking by:

- reflecting different views and practices and providing independent, authoritative information
- improving the understanding and assessment of major risks and ambiguities involved
- studying the future evolution of global risk governance
- designing innovative governance strategies

IRGC's project methodology involves leading and participating in collaborative research efforts ('expertise collégiale') as well as providing a platform for global dialogue focusing on risk assessment and governance. IRGC works and communicates in ways that account for the needs of both developed and developing countries.

The IRGC creates value by offering a unique platform for global debate and as a source of compiled and, if possible, unified scientific knowledge. From this base, IRGC elaborates generic recommendations and guidelines for risk identification, assessment and management on a global basis, as well as recommendations for their implementation. Its working approach is international, trans-sectoral and multidisciplinary.

Members of the IRGC Working Group on Nanotechnology (the Group's Chairman is Mihail Roco and Project Manager is Emily Litten):

- Dr. Lutz Cleemann, Director of the Allianz Technology Center, Germany

- Dr. Thomas K. Epprecht, Chief Underwriting Office, Risk Engineering Services, Swiss Reinsurance Company

- Dr. Jeff McNeely, Chief Scientist, World Conservation Union, seated in Switzerland

- Prof. Nick Pidgeon, Director of the Centre for Environmental Risk, School of Environmental Sciences, University of East Anglia

- Prof. Dr. Ortwin Renn, Professor of Environmental Sociology, University of Stuttgart, and Director of the non-profit Research Institute "DIALOGIK", Germany

- Dr. Mihail Roco, Member of the National Science and Technology Council's Subcommittee on Nanoscale Science, Engineering and Technology and Senior Advisor for Nanotechnology at the National Science Foundation, US

- Dr. Joyce Tait, Professor and Director of Innogen, the ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh, UK

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

ANNEX B – A DEFINITION OF 'RISK GOVERNANCE'

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

ANNEX C – ACKNOWLEDGEMENTS

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IRGC would like to thank all of those who contributed their valuable time to participating in the survey.

ANNEX D - OVERVIEW OF CURRENT REGULATIONS MENTIONED IN THE SURVEY

Table 3: Current regulations in place

Name of Act or Regulation		Overview
Toxic Substances Control Act (TSCA)	**US**	'The Toxic Substances Control Act (TSCA) of 1976 was enacted by Congress to give EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the United States. EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk. Also, EPA has mechanisms in place to track the thousands of new chemicals that industry develops each year with either unknown or dangerous characteristics. EPA then can control these chemicals as necessary to protect human health and the environment.' **Source of information:** **http://www.epa.gov/region5/defs/html/tsca.htm**
Resource Conservation and Recovery Act (RCRA)	**US**	'RCRA gave EPA the authority to control hazardous waste from the "cradle-to-grave." This includes the generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA also set forth a framework for the management of non-hazardous wastes. The 1986 amendments to RCRA enabled EPA to address environmental problems that could result from underground tanks storing petroleum and other hazardous substances. RCRA focuses only on active and future facilities and does not address abandoned or historical sites (see CERCLA). HSWA —The Federal Hazardous and Solid Waste Amendments are the 1984 amendments to RCRA that required phasing out land disposal of hazardous waste. Some of the other mandates of this strict law include increased enforcement authority for EPA, more stringent hazardous waste management standards, and a comprehensive underground storage tank program.' **Source of information:** **http://www.epa.gov/region5/defs/html/rcra.htm**
Clean Air Act	**US**	'The Clean Air Act is the comprehensive Federal law that regulates air emissions from area, stationary, and mobile sources. This law authorizes the U.S. Environmental Protection Agency to establish National Ambient Air Quality Standards (NAAQS) to protect public health and the environment. The goal of the Act was to set and achieve NAAQS in every state by 1975. The setting of maximum pollutant standards was coupled with directing the states to develop state implementation plans (SIP's) applicable to appropriate industrial sources in the state. The Act was amended in 1977 primarily to set new goals (dates) for achieving attainment of NAAQS since many areas of the country had failed to meet the deadlines. The 1990 amendments to the Clean Air Act in large part were intended to meet unaddressed or insufficiently addressed problems such as acid rain, ground-level ozone, stratospheric ozone depletion, and air toxics. ' **Source of information:** **http://www.epa.gov/region5/defs/html/caa.htm**

Name of Act or Regulation		Overview
Clean Water Act	**US**	'The Act established the basic structure for regulating discharges of pollutants into the waters of the United States. It gave EPA the authority to implement pollution control programs such as setting wastewater standards for industry. The Clean Water Act also continued requirements to set water quality standards for all contaminants in surface waters. The Act made it unlawful for any person to discharge any pollutant from a point source into navigable waters, unless a permit was obtained under its provisions. It also funded the construction of sewage treatment plants under the construction grants program and recognized the need for planning to address the critical problems posed by nonpoint source pollution. Subsequent enactments modified some of the earlier Clean Water Act provisions. Revisions in 1981 streamlined the municipal construction grants process, improving the capabilities of treatment plants built under the program. Changes in 1987 phased out the construction grants program, replacing it with the State Water Pollution Control Revolving Fund, more commonly known as the Clean Water State Revolving Fund. This new funding strategy addressed water quality needs by building on EPA-State partnerships.' **Source of information:** **http://www.epa.gov/region5/water/cwa.htm**
Occupational Safety and Health Act (OSHA)	**US**	'Congress passed the Occupational Safety and Health Act to ensure worker and workplace safety. Their Goal was to make sure employers provide their workers a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions. In order to establish standards for workplace health and safety, the Act also created the National Institute for Occupational Safety and Health (NIOSH) as the research institution for the Occupational Safety and Health Administration (OSHA). OSHA is a division of the U.S. Department of Labor that oversees the administration of the Act and enforces standards in all 50 states.' **Source of information:** **http://www.epa.gov/region5/defs/html/osha.htm**
CE Marking	**EU**	'The CE mark is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. The letters 'CE' are an abbreviation of Conformité Européenne, French for European conformity. The CE mark must be affixed to a product if it falls under the scope of the approx. 20 so called 'New Approach' Directives. Without the CE marking, and thus without complying with the provisions of the Directives, the product may not be placed in the market or put into service in the twenty five member states of the European Union and Norway, Iceland and Liechtenstein. However, if the product meets the provisions of the applicable European Directives, and the CE mark is affixed to a product, these countries may not prohibit, restrict or impede the placing in the market or putting into service of the product. Thus, CE marking can be regarded as the products trade passport for Europe.' **Source of information:** **http://www.cemarking.net/#what**

Name of Act or Regulation		Overview
Registration, Evaluation and Authorisation of CHemicals (REACH)	**EU**	'Under the proposed new Registration, Evaluation and Authorisation of CHemicals (REACH) system, enterprises that manufacture or import more than one tone of a chemical substance per year would be required to register it in a central database. Besides improving protection of human health and the environment, this system, which would replace over 40 EU directives and regulations, aims to maintain the competitiveness and enhance the innovative capability of the EU chemicals industry, by, inter alia: Ø focusing on substances of high concern, Ø requiring only essential safety and use information for low-volume chemicals, Ø raising the registration threshold from 10 kg to one tonne, Ø extending the exemption period for research and development from 6 years to 10 years (and up to 15 years for pharmaceutical research) Ø simplifying rules for downstream users, and Ø using existing Safety Data Sheets (SDS) as the main tool for hazard and risk communication. REACH would give industry greater responsibility for managing risks and providing safety information on chemicals, in effect shifting the burden of proof from public authorities to industry. Some groups of substances would not have to be registered (such as certain intermediates, polymers and some chemicals managed under other EU legislation).' 'A new European Chemicals Agency would manage the registration database and provide non-confidential information to the public. It would also be responsible for taking decisions requiring further information from industry, managing the Committees that will provide opinions to the Commission, and for ensuring the consistency and coherence of the new system.' ^'Where there is reason to suspect that a substance may pose a threat to human health or the environment, it may be evaluated by a Member State competent authority, under priority-setting criteria drawn up by the agency. Substances of very high concern, e.g. carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative and toxic (PBTs) or very persistent and very bio-accumulative (vPvBs), would require specific-use authorisations from the Commission. ' **Source of information: http://www.food-mac.com/lib_reg_Chemicals_REACH.htm**

ANNEX E – THE IRGC QUESTIONNAIRE TO INDUSTRY

Questions 1-4

1. *Briefly describe your organisation's* ***nanotechnology research and development programmes*** *and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
- A list of products containing nanotechnology already on the market, or in the final phases of development.
- Collaboration with other entities i.e. universities, regulators, trade associations
- Patents owned

The following optional details may also be provided if available:

- The investment amount, from your organisation and other collaborators, and the proportion of total R&D investment spent on nanotechnology. (Please provide information which is publicly available and refer to the confidentiality section on P.2 of the Information booklet).
- Discussions/agreements with liability insurance companies regarding potential risk issues.
- Any other information you would like to provide.

2. *Please provide an overview of your* ***industry's laws, regulations, standards and best practices*** *which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*

Please provide the following details:

- The name of the regulatory instrument, standard or best practice.
- Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, ethical, trading etc.) and how it applies to your organisation and to nanotechnology.
- Any voluntary practices which your organisation elects to follow e.g. full body protection for workers.

The following optional details may also be provided if available:

- Knowledge of any developments with implications for the regulation of nanotechnology practices.
- If, in your opinion, there are any governance gaps which need to be filled.
- Any other information you would like to provide.

3. *Please describe the* ***key networks, trade associations, institutions and international organisations which support nanotechnology*** *in your industry.*

Please provide the following details:

- The name(s) of organisation(s) involved
- A brief description of the networks etc. focus and scope, how it works and your participation in it.

- Ø The name(s) of any agreements and/or advisory body(s) (both formal and informal)

The following optional details may also be provided if available:

- Ø Description of how you, and/or, they are able to influence policies and decisions in your industry
- Ø Any other information you would like to provide.

4. *Please provide information on **reports and communications concerning nanotechnology** which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*

***Measures needed to address nanotechnology risk** (please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*

10. *In your opinion what are the potential risk prevention approaches?*

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*

ANNEX F – QUESTIONNAIRE RESPONSES

(only the questions with answers are given below for each respondent)

F1. QUESTIONNAIRE RESPONSES FROM ALLIANZ, GERMANY

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's interest in nanotechnology research and any particular issues / areas which you are investigating. The following are examples of programmes which you may be investigating: toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk, health benefit and risk, public perception, international trade, the north-south divide and knowledge transfer etc..*

   It is widely accepted, that nanotechnologies will have a significant impact on the world-wide economy over the next 10 – 15 years. For the Allianz Group as a financial service provider many business activities are likely to be confronted with these changes in our business environment over the next years. While the internal and external discussion of new risks will be strongly geared towards questions of risk assessment and insurance, the overall view also has to include the banking side (e.g. credits), investments and our communication with various stakeholders. In the investment portfolio, major technological trends can lead to new success stories, but also to the phase out of "old technologies". New targets might arise on the investment horizon.

   What are the implications of nanotechnology on the insurance side? The commercialisation of products that contain nanoparticles or use nanotechnologies is an ongoing process. Today, there are already hundreds of products on the market that make use of the unique properties. Since nanotechnology is an enabling technology, the applications range across all types of industries. From sporting goods like tennis balls and ski wax to cosmetics to hardware components in the semiconductor industry, there exits a long list. For the insurance, this means that our risk portfolio is containing more and more nanotechnology related risks over time.

   At the same time there are many unknowns regarding emerging risks of these technologies. There is sufficient evidence to say that at least some manufactured nanoparticles are more toxic than the same chemicals in larger form. There is little knowledge about acute or chronic toxicity of nanoparticles in general, and the determining factors like surface area and shape, chemical composition, particle concentrations etc. It will take years until studies about exposure routes, about the effects on human health and the environment will reach conclusive results. Looking at these open questions, there is clearly a knowledge gap and it will be here for a considerable period of time.

   The insurance industry is going to have to live with the uncertainties of nanotechnology related risks for a longer period of time and it will not be able to quantify the probability of potential losses occurring and their possible extent. In principle, many lines of business are considered to be potentially affected, including:

   - Workers' compensation,
   - General and products liability
   - Products recall,
   - Environmental liability,
   - Property (dust cloud explosion).

   For a successful risk management of nanotechnologies from our perspective, the following approach to research is needed:

- sufficient funding of independent research on nanotechnology related risks in all areas (workers safety / product safety / environmental protection / ...) with active steering by governments,
- transparency about and open access to the results of research activities,
- ongoing dialogue between all stakeholders about the results of research.

The role of Allianz with respect to nanotechnology research is to timely monitor trends and to evaluate their consequences for Allianz, including

- products design
- risk controlling and risk management
- steering of insurance portfolio
- investment strategy
- consulting of clients.

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of investigation and any results (if available, links to published results)
  - See attached document: "Small sizes that matter: Opportunities and risks of Nanotechnologies"
  - Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
  - Report in co-operation with the OECD International Futures Programme

- Patents owned
  - None

2. *Please provide an overview of international laws, regulations, standards and best practices which apply directly, or could be applied, to nanotechnology research and development*

   Do you really mean "nanotechnology research and development" or rather "products and processes based on nanotechnology"? Generally I think this question should best be answered by national and international regulators and multinational organisations such as OECD.

   - If, in your opinion, there are any governance gaps which need to be filled.
     - To establish risk assessment schemes for nanoparticles, products and processes using nanotechnologies
     - To make the results of risk assessments available to the public
     - To review the existing legislation (national / international)
     - To publish and discuss the results thereof with all stakeholders
     - To address any gaps related to the specific properties of nanotechnologies (e.g. in material safety data sheets).

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*
   - Co-operation with OECD (see above) in 2005
   - Workshop on synthetic nanoparticles organised by several Federal Ministries in October 2005 with contacts to major German stakeholders (NGO, Industry, Insurance, Administrators, Scientists). http://www.dialog-nanopartikel.de/
   - IGRC

Please provide the following details:

- Brief description of their focus and scope, how the 'horizontal' connections work and your participation in it

  Allianz is participating in a general dialogue via
  - press conferences (London, Madrid, Vienna, Munich)
  - participation at conferences and workshop (e.g. Swiss Re Centre for Global Dialogue December 2004)
  - publications (Report with OECD, client magazins, internet)

- The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).
  - IRGC Technical Committee (Lutz Cleemann)
  - WBCSD
  - OECD
  - UNEP

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*

   See Attachments

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Based on the equation Risk= Hazard X Exposure:
   - Applications that lead to an exposure to free persistent nanoparticles with toxic properties in manufacturing, during use or at the end-of-life.

   It seems to early to pick examples at this stage. Fundamental questions regarding toxicology, translocation and relevant parameters like size, shape, chemical composition, surface coatings, agglomeration etc. are still open. Specific nanoparticles in conjunction with specific applications will have to be judged on a case by case basis. Evidence for safety or risks should be presented to the public.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - See our report on opportunities and risks.

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   One major possibility is to foster research in areas, where solutions for these fundamental problems can be expected: e.g.

- efficient production, storage and conversion of energy,
- catalysts and filters for clean water

For an analysis also see:
Michael Steinfeldt, Arnim von Gleich, Ulrich Petschow, Rüdiger Haum, Thomas Chudoba, Stephan Haubold: "Nachhaltigkeitseffekte durch Herstellung und Anwendung nanotechnologischer Produkte" Schriftenreihe des IÖW 177/04
(http://www.bmbf.de/pub/nano_nachhaltigkeit_ioew_endbericht.pdf)

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

10. *In your opinion what are the potential risk prevention approaches?*
    For a successful risk management of nanotechnologies from our perspective, the following framework is needed:
    - sufficient funding of independent research on nanotechnology related risks with active steering by governments,
    - transparency about and open access to the results of research activities,
    - ongoing dialogue stakeholders
    - international standards and nomenclature,
    - adequate regulation of risk issues,
    - a global risk governance approach.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - See questions related to governance gaps.

Nanotechnology at the international level

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - To establish dedicated multidisciplinary research centers (e.g. on a European Level) as centers of excellence for risk research in parallel to research in existing structures (private, universities etc.).

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - Mainly via multinational organisations like the EU, OECD, IGRC, WHO or the UN in co-operation with local governments. The processes should be transparent to the public.

F2. QUESTIONNAIRE RESPONSES FROM AYANDA BIOSYSTEMS, SWITZERLAND

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's* ***nanotechnology research and development programmes*** *and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*

   - A list of products containing nanotechnology already on the market, or in the final phases of development. (Both test are under development using our proprietary SLIC™ nanotechnology platform.
     - SLIC™ HIV Test
     - SLIC™ Molecular Test for Pneumonia, Tuberculosis & Influenza

   - Collaboration with other entities i.e. universities, regulators, trade associations
     - Both products above are developed in collaboration with a variety of universities, medical centres and a government lab. (exact names confidential for now).

   - Patents owned
     - SLICTM nanotechnology platform (US Patent pending)
     - Cell-based biosensors (PCT patent)

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*

Please provide the following details:

   - The name of the regulatory instrument, standard or best practice.
     - CE Markiing.

   - Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, ethical, trading etc.) and how it applies to your organisation and to nanotechnology.
     - Human health safety.

   - Any voluntary practices which your organisation elects to follow e.g. full body protection for workers.
     - No, not necessary.

The following optional details may also be provided if available:

   - Knowledge of any developments with implications for the regulation of nanotechnology practices.
     - No

3. *Please describe the key networks, trade associations, institutions and international organisations which support nanotechnology in your industry.*

Please provide the following details:

- Ø The name(s) of organisation(s) involved
  - o Nano2Life,
- Ø A brief description of the networks etc. focus and scope, how it works and your participation in it.
  - o A network of excellence supported by the EU research initiative foccusing on applications of nanotechnology applicatications in life sciences and health.

The following optional details may also be provided if available:

- Ø Description of how you, and/or they, are able to influence policies and decisions in your industry
  - o Primarily through participation in the definition of strategy for networks of excellence supported by the EU organizations or locally national government bodies such as OFES in Switzerland.

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*
   - o MicroNews: A free monthly newsletter devoted to micro & nanotechnologies (www.yole.fr).
   - o Smalltimes.com: A weekly free online newsletter on emerging nanoteechlogy industries & markets (www.smalltimes.com).

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - o Perhaps, products that are introduced into the body for long periods that we cannot subsequently retrieve or remove in case of an undesired response.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - o More cost-effective but better performance products. May lead to job losses in some cases.

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - o Biosensors to monitor water quality. Cost efficient renewable energy sources, e.g. photovoltaic solar cells based on nanocrystals. Materials coatings with intelligent nano-based surface coatings, e.g. self-cleaning surfaces.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - By first defining clearly what nanotechnology risk is exactly (i.e. if it really exists???). then it might be possible to develop strategies to deal with it.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Again, the risk part can be best communicated only after we have understood what they are exactly. The benefits: we need a bit more time for more nano-based products to hit the mainstream consumer markets, and then it will be easier to communicate what nanotech is and its benefits etc.

10. *In your opinion what are the potential risk prevention approaches?*
    - See response to no. 8 above.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - Until we define what the dangers & risks are, it may be pointless to engage in serious discussion about regulation etc. For example, in the case of cloning, stem cells etc, these issues are clear, ad hence easier to devise regulatory policies.

Nanotechnology at the international level

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Nanotechnology is a very high-tech science, and is typically practised by highly trained scientists & engineers (i.e. with post-graduate education). Therefore, I do not see much room or possibility for (informal) nanotech practice outside of labs or institutions with appropriate expertise and equipment. Perhaps, I'm not certain I understand what informal R&D means in the context of technology.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - We will have to watch closely for any initial signs of its irresponsible use (not yet known), and then put in place regulatory policies that discourage such practises.

F3. QUESTIONNAIRE RESPONSES FROM CANON, US

This response is provided "as received" because the author left Canon in 2006 and was not available for editing.

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's* ***nanotechnology research and development programmes*** *and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc.*
   - ***We have established hundreds of patents in core nanotechnology areas for the past 15 years. Much of this work was part of our general effort to reduce component size and conduct fundamental research. It has been conducted out of Japan and patents have been filed there, in Europe and in the United States. These patents were originally developed internally and not through university or other external research sponsorships.***
   - For the past 3 years, in this US, we have sought to complement our core patent position by seeking strategic investments and partnerships with US universities, national laboratories and startup companies. We have executed joint partnership agreements with numerous nanotechnology companies whose technology can help us launch or grow businesses in specific vertical markets, especially medical diagnostics, displays, digital cameras and printers. We also sponsor university research and fund some work at government laboratories. Some of this work is limited due to US export restrictions. We also invest in 2 venture capital funds in order to expand our exposure to new technologies being developed.
   - As a matter of policy, we do not invest in any technologies that are harmful to the environment, such as cadmium related technologies. We also automatically reject any applications used for weapons or warfare. This is part of our corporate charter. From a public relations standpoint, we have no specific program designed to address concerns related to nanotechnology and maintain no specific nanotechnology-related insurance policies to my knowledge.

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*
   - We operate in a number of different industries (digital cameras, semiconductors, office products, and medical equipment among others) that could broadly be characterized as the consumer electronics industry. It would be inappropriate for me to try to assess all of the relevant laws which govern our activities in these broad areas. With respect to our work in nanotechnology, we do not manufacture or produce nanoparticles. We also do not license or invest in new technologies we believe to have adverse health consequences. Finally, we would not consider an investment in areas we deemed risky to health and the environment, no matter what the return potential.
   - Currently, we do license or purchase nanoparticles for research and we fund research that uses these materials. However, since these projects are still in the research stage it is likely that future specific toxicology questions will need to be addressed in the event we decide to go to market. However, it should be noted that since we are focused on US markets, those are the laws we focus on adhering to for now. The US Food and Drug Administration and Environmental Protection Agency scrutiny applied to nanoparticles have not been a deterrent to our investment in this area to date. We also have a global environmental promotion organization dedicated to reviewing all new projects. Their report is reviewed along with other relevant material for approval

of new projects. Finally, we adhere to all ISO14001 standards. This might be considered the primary driver of international adherence to environmental standards.

3. *Please describe the key networks, trade associations, institutions and international organisations which support nanotechnology in your industry.*
   - We are a member of the Clean Tech Venture Network, dedicated to pursuing technologies useful in sustainable development. Many of these are new materials, such as those related to alternative energy where nanomaterials and systems will be critical for next generation energy sources.
   - We actively participate in the WasteWise program of the US Environmental Protection Agency. This affiliation requires active analysis on ways to reduce harmful wastes and to recycle where possible. All nanotechnology related projects fall under the same rubric.
   - Finally, at the center of our corporate charter is a philosophy known as Kyosei, which means "To achieve corporate growth and development while contributing to the prosperity of the world and the happeness of humankind." This charter governs approval of all projects and is a critical part of corporate compliance as investors on behalf of Canon.

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*
   - Unfortunately, none of the reports we have prepared for use in this area have been done for outside use.

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - We have avoided the pharmaceutical applications, drug delivery applications, anything that goes into the body, products where nanoparticles would be inhaled, and all technologies involving cadmium nanoparticles. We have also been generally conservative in terms of the specific areas of research we explore. Quite often our interest lies in miniaturization and this makes no difference whether at the micro or nanoscale. Since we are not developing new materials per se, but are interested in applying existing materials to products, we feel we lie less on the "cutting edge" and thus lower on the risk threshold than other companies in this area.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - We see alternative energy as an area of enormous potential, both environmentally and in terms of the market. In addition, greater sensitivity in medical diagnostics through nanoscale control also offers potential huge benefits for human health.

Nanotechnology at the international level

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*

- It seems that standards bodies need to more directly address nanotechnology related issues so that firms do not have incentives to play countries off of each other in terms of who has the lowest threshold for environmental protection. I believe this should be easier to do than in past technology development waves, because many lessons have been learned.

F4. QUESTIONNAIRE RESPONSES FROM ENVIRON, US

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's* ***nanotechnology research and development programmes*** *and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc.*

We are a diversified international consultancy with a special theme of identifying, evaluating, managing and/or controlling risks associated with environmental contamination and occupational exposures, as well as consumer products. In this context we invest in the preparation of our professional staff in areas of toxicology, best practices in occupational safety and health, development of new quantitative risk assessment approaches and statistical models, environmental fate and transport, environmental remediation, consumer product stewardship, all as they pertain to the production and use of nanomaterials and nanostructures. We also have begun tracking relevant scientific, regulatory and policy developments. The new emphasis on nanomaterials and nanostructures is an extension of similar skills routinely applied in analogous situations dealing with various chemicals and other agents that have unknown but potentially serious risks to human health and the environment (such as potent compounds, pharmaceuticals, products of biotechnology, radiation, etc.).

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
  - No primary research on the potential adverse health effects of nanoscale materials has yet begun. It is anticipated that we will be establishing occupational, environmental and consumer product surveillance systems that may be used for conducting research in the future (i.e., monitoring of trends in health indicators as they may pertain to related changes in exposures to nanomaterials).

- Collaboration with other entities i.e. universities, regulators, trade associations
  - We have entered collaborative relationships with several organizations including two University-based Nanoscale Science and Engineering Centers (NSECs) (specifically manufacturing), and have discussed collaborative and/or client relationships with several trade groups. Additionally, parts of our nanotechnology team have begun to develop a network of law firms specializing in complementary legal aspects pertaining to nanomaterials and nanostructures, such as product liability, environmental law and support of legislative development.

The following optional details may also be provided if available:

- Discussions/agreements with liability insurance companies regarding potential risk issues.
  - We have been asked by insurance companies in the US, UK and Germany to assemble background materials on potential risk associated with producing and using nanomaterials and nanostructures. No formal agreements for providing services have been entered yet.

- Any other information you would like to provide.
  - Clients and potential clients do not appear to be well versed on potential human health (occupational and consumer) and environmental risks associated with nanomaterials and nanostructures; however, they appear to recognize the potential marketing, product and business advantages that these materials may provide. Therefore the majority of requests

for consulting services have consisted of either providing syntheses/overviews of potential health issues, or evaluating current workplace safety and health procedures and generating best practice guidelines for occupational and environmental safety and health.

2. *Please provide an overview of your **industry's laws, regulations, standards and best practices** which apply directly, or could be applied to nanotechnology research and development within your organisation**.** These should include both national and international regulation and agreements which oversee your industry.*
   - Rightly or wrongly, the consulting industry generally is not regulated. With respect to services provided to nanotechnology interests there is likely to be a lack of standardization of procedures and recommendations, and no obvious mechanism for assuring the value and quality of such services. Training and certification programs might be helpful in this respect.

The following optional details may also be provided if available:

- If, in your opinion, there are any governance gaps which need to be filled.
  - What companies producing or using nanoscale materials feel obligated to provide with respect to environment, safety and health information varies dramatically. Some entities proceed with new technologies without consideration of potential risks, while others forego the financial and marketing benefits of using nanotechnologies until such risks (if any) are determined. The imbalance across companies producing similar product lines could become much greater, and, in the long run, fair competition may be compromised. This, as with other environmental or occupational regulations, clearly will be seen (if not already) at the international level.

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Because the cosmetics and consumer products industry has enjoyed a low level of regulation, a potential exists for various hazardous nanoscale materials to enter the market in these products, with a parallel difficulty in tracking users and directly associating risks to the products.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - Potential benefits include vast improvements in the performance (including energy efficiency, strength and durability, speed and complexity of electronics) for a variety of consumer products. Long-term human health risks (not limited to what might be identified toxicologically) may be the most challenging to identify, and if present, to control.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - Risks associated with nanotechnology are not necessarily different from those associated with other new products and materials; however, our ability to address potential risks associated with them is hampered by the inherent (proprietary) secrecy surrounding the development and application of these materials. Organizations will be better equipped to manage risks if they document now what is being used/developed and by whom and communicate this information to

those responsible for protecting environmental and occupational health. This information will be helpful in the future either to demonstrate safety or to provide evidence of potential risks. Where we today lack good historical records of chemical use (or contamination), exposures to workers (or community members) and disease patterns (registration), large gaps exist in identifying and controlling risk. Many of these limitations may be prevented with good planning and the collection of reasonable and informative data.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Clear and simple communications from respected and authoritative organizations are important. Overload and conflicting information from too many groups (including governments) will be likely if flow of information is not checked and content validated.

10. *In your opinion what are the potential risk prevention approaches?*
    - Careful characterization of new materials by multidisciplinary teams. Some classes of materials may be predicted to carry greater risk, others less. Approaches to screen for potentially high-risk properties are urgently needed.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - R&D activities are notoriously difficult to identify and influence (or regulate) due to their widespread distribution, often small size of operations, lack of understanding of potential risk problems at the management/administrative level, and complete inability to enforce regulations. At the core of changing this is aggressive training and on-going risk communication coupled with appropriate (and relevant) regulations.

Nanotechnology at the international level

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*

Possibly by using multi-pronged approaches that combine the establishment of international quality and performance standards within international scientific bodies with promulgation of supportive international trade agreements that require certification of products and materials according to agreed-upon standards.

F5. QUESTIONNAIRE RESPONSES FROM INDUSTRIAL TECHNOLOGY RESEARCH INSTITUTE (ITRI), CHINESE TAIPEI

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's nanotechnology research and development programmes and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*

New materials and applications, risk to workers, best practices, environmental benefit and risk.

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
  - Nanotechnology Development and Application, especially industrial production.
- A list of products containing nanotechnology already on the market, or in the final phases of development.
  - ZnO nanopowder, Carbon nanocapsule, nano-Gold mask
- Collaboration with other entities i.e. universities, regulators, trade associations
  - Government, Universities, Trade associations.
- Patents owned
  - Many. Ex. ZnO nanopowder production, Carbon nanocapusle preparation

The following optional details may also be provided if available:

- The investment amount, from your organisation and other collaborators, and the proportion of total R&D investment spent on nanotechnology. (Please provide information which is publicly available and refer to the confidentiality section on P.2 of the Information booklet).
  - The total R&D investment in nanotechnology is US$ 60 millions.
- Discussions/agreements with liability insurance companies regarding potential risk issues.
  - Worker or Researcher health insurance.
- Any other information you would like to provide.
  - Major Industrial Research Institute in Taiwan.

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*
   - We have nanopowder production and handling guideline and waste gas emission protocol for worker or researcher.

Please provide the following details:

- The name of the regulatory instrument, standard or best practice.
  - Nanopowder process and working environment guideline.

- Nanopowder process waste gas emission protocol.

- Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, ethical, trading etc.) and how it applies to your organisation and to nanotechnology.
  - Environmental impacts, worker safety.

- Any voluntary practices which your organisation elects to follow e.g. full body protection for workers.
  - Particle monitoring.

The following optional details may also be provided if available:

- Knowledge of any developments with implications for the regulation of nanotechnology practices.
  - It is still too far away from setting the regulation based on current knowledge.

- If, in your opinion, there are any governance gaps which need to be filled.
  - Risk communication.

- Any other information you would like to provide.
  - I already sent ISEN2004 proceeding to you.

3. *Please describe the key networks, trade associations, institutions and international organisations which support nanotechnology in your industry.*
   - Industrial Technology Research Institute (ITRI)
   - National Science Council (NSC)

Please provide the following details:

- The name(s) of organisation(s) involved
  - ITRI and Major Universities in Taiwan

- A brief description of the networks etc. focus and scope, how it works and your participation in it.
  - ITRI focus on Industrial Application. Universities focus on fundmental science
  - I am involving in ESH technology development.

The following optional details may also be provided if available:

- Description of how you, and/or, they are able to influence policies and decisions in your industry
  - We are working closely with Taiwan EPA to set the related policies.

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Nanoparticle Production and Application. Especially free nanoparticles.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*

- New function. New application. Smaller devices

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - International Dialogue and Standards for ESH issues.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - Send professional engineers to attend ESH forum.
   - Develop a nano-ESH program to implement the guidelines.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Forum and Media.

10. *In your opinion what are the potential risk prevention approaches?*
    - Treat potential free nanoparticles as hazardous materials.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - Best Practices or guideline. Voluntary program.

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - Publish best practices or international regulations.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Forum and Dialogue.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - International Standards or Regulations.

F6. QUESTIONNAIRE RESPONSES FROM INTEL, US

Questions 1-4

Please provide answers electronically beneath the questions.

1 *Briefly describe your organisation's nanotechnology research and development programmes and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
  - Our company engages in R&D on the physical, thermal and electrical properties of nanostructures used in the fabrication of integrated circuits.
    http://www.intel.com/technology/silicon/nanotechnology.htm
    http://www.intel.com/pressroom/archive/releases/20010611tech.htm
  - In addition, we set a priority to proactively identify and address environmental, health and safety (EHS) aspects of the new technology.

- A list of products containing nanotechnology already on the market, or in the final phases of development.
  - Our company began selling microprocessor with sub-100nm transistors in high volume in the summer of 2001.

- Collaboration with other entities i.e. universities, regulators, trade associations
  - Our company collaborates with many universities, government laboratories and research consortia such as SRC and IMEC. The main trade association is the SIA,

The following optional details may also be provided if available:

- The investment amount, from your organisation and other collaborators, and the proportion of total R&D investment spent on nanotechnology. (Please provide information which is publicly available and refer to the confidentiality section on P.2 of the Information booklet).
  - Nanotechnology is not tracked as a separate R&D function, it is distributed among several R&D groups

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*

Please provide the following details:

- The name of the regulatory instrument, standard or best practice.
  - U.S. environmental, health, and safety regulatory programs (e.g., TSCA, RCRA, Clean Air Act, Clean Water Act, OSHA) and similar environmental, health, and safety regulatory programs around the world, already generally apply to the manufacture of nanoelectronics devices. Future regulations such as the E.U. REACH regulation, also could apply.
  - In addition to these regulatory programs, we are involved in setting industry standards for best practices for handling nanoscale particles, including work in ASTM and ICON.

- Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, ethical, trading etc.) and how it applies to your organisation and to nanotechnology.
  - Environment, health, and safety aspects are all currently regulated in the development, and manufacture of nanoelectronic devices.

- Any voluntary practices which your organisation elects to follow e.g. full body protection for workers.
  - Our company has set robust exposure and handling guidelines for all chemicals associated with the development and manufacture of nanoelectronic devices and has a world class safety performance as a result. In addition, we have set health and safety guidelines to minimize exposure to nanoscale materials that are being researched for future nanoelectronic applications.

The following optional details may also be provided if available:

- Knowledge of any developments with implications for the regulation of nanotechnology practices.
  - In our opinion, "new" regulations are not required to regulate nanoscale materials. It may be necessary however to adjust existing regulatory programs to comprehend the novel properties that some nanoscale materials exhibit.

3. *Please describe the key networks, trade associations, institutions and international organisations which support nanotechnology in your industry.*

Please provide the following details:

- The name(s) of organisation(s) involved
  - Semiconductor Research Corporation (SRC), IMEC (Belgium), Sematech, Semiconductor Research Corporation (SIA), Nanoelectronics Research Initiative (NRI), International Council on Nanotechnology (ICON), Standards organizations - ASTM, ANSI, and ISO.

- A brief description of the networks etc. focus and scope, how it works and your participation in it.
  - The above are industry consortia that have high level technical advisory boards representing each participating company.

The following optional details may also be provided if available:

- Description of how you, and/or, they are able to influence policies and decisions in your industry
  - Our company and the organizations listed above have regular contact and interaction with policy makers. For example, ICON is a consortia that consists of industry, government, academia, and NGOs. The forum provides the opportunity to discuss policies and research needs in the area of EHS and nanotechnology. Likewise the SRC has formed a Consulatative Board for Advancing Nanotechnology (CBAN) with the US National Nanotechnology Initiative (NNI).

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*

   http://www.intel.com/technology/silicon/nanotechnology.htm
   http://www.ti.com/research/docs/Nanotechnology.pdf
   http://www.imec.be/essderc/papers-97/311.pdf
   http://public.itrs.net/Files/2003ITRS/LinkedFiles/ERD/NanoeletronicsRdmp.pdf

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Nanotechnology is a very broad classification of products and must be distinquished to assess risk. For example, there is a fundamental difference between nano-sized features such as the transistors found in electronics and nanoscale materials which may be used in products. Nano-sized features in electronic products do not pose environmental, health and safety risks.
   - Likewise, not all nanoscale materials should be treated the same. "Unbound" or freely mobile nanoscale materials will logically pose a higher risk due to exposure possibilities than "bound" or fixed nanoscale materials.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - Benefits:
     - new silicon devices to drive future electronic products – unlimited applications
     - new medical diagnostic, treatment and drug delivery mechanisms
     - environmentally friendly applications – clean energy, pollution abatement and clean-up
     - new products – paints, coatings, composites, etc as well as many unseen applications and products.
   - Risks:
     - Public perception, valid or invalid, could stem potential benefits
     - Toxicity and environmental implications of unbound or freely mobile nanoscale materials.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - ICON represents an excellent model – create forums that involve government, academics, NGOs (public) and industry.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Coordinated communication for EHS impacts, societal impacts and overall benefits of nanotechnologies by governments, academics and industry.
   - Coordinated communication cross geographies – US, EU, Asia, etc.
   - Ongoing surveying of public opinion, focus groups, etc.
   - A research needs paper is being developed by the SRC/Chemical Industry CBAN EHS working group. The paper will be finalized and distributed by the end of October.

10. *In your opinion what are the potential risk prevention approaches?*
    - Establishment of best management practices. Such practices do not formally exist today. Ideally, governments, industry, academia, and NGOs will work together to set these management practices. ASTM and ISO are setting up committees to develop such management practices.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - More data. Need to better understand the potential risks and how to measure them. This is another area where the SRC/Chemical Industry CBAN EHS working group is developing research need statements.

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - International standards and harmonization of regulatory requirements.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Yes, particularly in the area of EHS and societal concerns where competitive advantage issues should not play a role.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - International standards and harmonization of regulatory requirements would be an excellent first step.

F7. QUESTIONNAIRE RESPONSES FROM CHAIR OF THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) TECHNICAL COMMITTEE 229, UK

Questions 1-4

Please provide answers electronically beneath the questions.

Although I am completing this survey in my capacity as Chairman of ISO TC 229 – Nanotechnologies, the answers given are my own and should not be construed as being the official position of the International Organization for Standardization

1. *Briefly describe your organisation's* ***interest in nanotechnology research and*** *any particular issues / areas which you are investigating. The following are examples of programmes which you may be investigating: toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk, health benefit and risk, public perception, international trade, the north-south divide and knowledge transfer etc.*

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of investigation and any results (if available, links to published results)
  - ISO TC 229 will develop International Standards and other standardization instruments to support technological, product and market development, and regulatory needs by providing the essential foundations for naming, characterizing and testing nanotechnology materials and devices. The scope of the TC was defined at the first meeting and comprises the following statement:
    "Standardization in the field of nanotechnologies that includes <u>either or both</u> of the following:
    Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,
    Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties
  - Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices.

- Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
  - Besides the collaborations implicit in the constitution of the national delegations (24 "P" members and 8 "O" members) and the national committees that they represent (including all of the above entities in these different countries), TC 229 will be establishing internal liaison with a significant number of ISO and IEC TC's with interests in the area of nanotechnologies, and is currently working closely with the OECD Joint Meeting of the Chemicals Committee and the Working Group on Chemicals, Pesticides and Biotechology subgroup on the safety of manufactured nanomaterials with the view to establishing a formal liaison between the two. External liasions have been established with the European Union DG JRC, specifically with the Institute for Health and Consumer Protection and the Institute for Reference Materials and Measurement. Other external liaisons will be established in due course.

- Patents owned
  - None

2. *Please provide an overview of international laws, regulations, standards and best practices which apply directly, or could be applied, to nanotechnology research and development*
   - The OECD Joint Meeting referred to above has recently undertaken a comprehensive survey of members and I would refer IRGC to this document. Contact Mar.GONZALEZ@oecd.org in the first instance. There are currently no international standards specifically developed for nanotechnologies, although there are a number of published standard that have application at the nanoscale, e.g

     ISO 13321:1996 Particle size analysis -- Photon correlation spectroscopy

     And

     ISO/TS 13762:2001 Particle size analysis -- Small angle X-ray scattering method
   - ISO TC 229 will be undertaking a survey of current standards relevant to nanotechnologies and is prepared to make appropriate information available to IRGC when this has been completed.
   - NIOSH in the US has recently issued a document "Approaches to Safe Nanotechnology", which is available for free download from the www.
   - Another useful reference document is "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy." Available at www.particleandfibretoxicology.com/content/2/1/8

Please provide the following details:

- A description of any practices which you would recommend e.g. full body protection for workers, fair trading, development of particular technologies etc.
  - In the context of a European FP6 NMP project, in which my company IonBond is involved, a good practice guide to the handling and disposal of the specific nanomaterials that will be used in the project has been produced to provide guidance to project partners. Its recommendations are as follows (but it is emphasized that these are only relevant in the context of the project, which itself is confidential):

    Work Practices

    The incorporation of good work practices in a risk management program can help to minimize worker exposure to nanomaterials. Examples of good practices include the following (attachment 1, page 22):
    - Cleaning work areas at the end of each work shift (at a minimum) using HEPA vacuum pickup and wet wiping methods. Dry sweeping or air hoses should not be used to clean work areas. Cleanup and disposal should be conducted in a manner that prevents worker contact with wastes and complies with all applicable local regulations.
    - Preventing the storage and consumption of food or beverages in workplaces where nanomaterials are handled.
    - Providing hand-washing facilities and encouraging workers to use them before eating, smoking, or leaving the worksite.
    - Providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas (including take-home) caused by the transfer of nanoparticles on clothing and skin – not considered necessary in the present case in view of the small quantities of materials that will be handled.

    In the present case, the material will be under the control of competent personnel and its use can be expected to be restricted to areas such as laboratories and small test facilities. Hence there is unlikely to be a specific need for routine clean up procedures, though procedures for cleaning up accidental spills and removing waste or unutilised material from equipment will be required. It is emphasized that all accidental spills should be cleaned up immediately they occur.

    Personal protective clothing

    Again, given the small volumes and restricted access to material, it is considered that specific protective clothing will be unnecessary. However, the following are recommended:
    - Transfer of material from primary containers to processing equipment should, where possible be undertaken in a fume cabinet

- § The use of HEPA filter half-masks and goggles, or full-masks (using P3 filters), and silicon rubber (surgical) gloves when transferring material from containers to processing equipment and when cleaning processing equipment or clearing up accidental spills;
- § The use of either or both HEPA filtered vacuum cleaners or wiping-up with dampened cloths for cleaning processing equipment or clearing up accidental spills.

The following optional details may also be provided if available:

- Ø Knowledge of any developments with implications for the regulation of nanotechnology practices
  - o This is being actively reviewed by the OECD joint meeting referred to above, as well as by regulatory agencies of various of the member countries

- Ø If, in your opinion, there are any governance gaps which need to be filled.
  - o Not until further work on health and environmental impact has been done.

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*

Discussed above

- Ø The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).
  - o In the UK some members of the ISO/TC 229 mirror committee, NTI/1, are also members of the Nanotechnology Issues Dialogue Group and of the Nanotechnology Research Coordination Group, both of which have an advisory role. It is known that the US TAG to 229 has members from NIOSH, EPA and OSHA. A similar situation probably applies to most of the other members of TC 229, although no details are available.

    It is expected that a formal liaison will be established between 229 and the OECD Joint Meeting referred to above

The following optional details may also be provided if available:

- Ø Description of how you, and/or they, are able to influence national and international policies, decisions and agreements
  - o The close association with Government departments in all member countries provides an important 2 way communication channel ensuring that national and international issues can be efficiently articulated and addressed.

- Ø Description of how the public are able to participate in and influence your organisation.
  - o ISO and the national member organisations of TC 229 have consumer representation panels that are consulted on issues of societal significance. In addition, the ISO Code of Ethics requires members to take "appropriate measures to facilitate the participation of consumers and other affected parties from civil society, SMEs and public authorities".

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*
   - o No reports specifically produced about standardization but virtually all reports of significance identify the need for standards in this area, particularly for terminology.

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Until the nature of the hazard is known it is not meaningful to attempt to evaluate risk. Risk is a combination of hazard and exposure, hence if there is no exposure the only risk is from accidental exposure, but again unless the hazard has been identified and quantified it is not appropriate to attempt to differentiate between levels of risk. We do not yet know what additional hazards nanomaterials pose over and above those posed by conventional materials.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - There are significant potential benefits, the most significant being in the area of sustainability, particularly energy and water resources.

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - This can only be achieved through international action on the part of bodies such as the UN, EU, G8, etc. with the support of NGO's. I believe that the potential for sustainable energy and water are the two critical areas that must be addressed and where nanotechnology can have a major and lasting impact. Success will require a significant commitment to technological development but a much bigger commitment to education to convince society that industries and communities must move to a low energy footprint

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - See above. We do not yet know what if any risk exists (except for investors!).

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - In my opinion it is important to identify risk in a proactive manner rather than discuss potential risk, which may have little substance in practice. I believe it is important to give factual information to society and not to get bogged down in talking about something for which we have, as yet, no evidence. I am convinced that if there is a risk it will come from a direction that no one is predicting – cf thalidomide! The danger of talking about risk of nanotechnologies is that it implies that what we currently have is risk free, which is patently not the case. Society has, in general, a very poor appreciation of the concept of risk. I believe the IRGC could make a major contribution to educating the public about this issue.

10. *In your opinion what are the potential risk prevention approaches?*
    - Back to the issue of risk and hazard – there is no risk identification without hazard identification and we do not yet have the latter.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - It is not clear at this juncture that regulation is needed!

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - Make sure the advice is couched in such a way that it can be understood by those using the recommendations!! However, it must be recognised that in a highly technical area, such as nanotechnologies, the advice may need to be complemented by substantial supporting/background information.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - I don't understand what "informal approaches for research and development" are! It seems unlikely that, in a costly field of endeavour, which nanotechnology undoubtedly is, any work will be undertaken without careful consideration of the implications.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - In my opinion the responsible development of nanotechnology means focusing development on socially beneficial activities and not on consumer applications unless these have a measurable benefit in terms of reduced energy and/or raw material consumption, i.e. a proper and comprehensive cost benefit analysis needs to be undertaken, including societal aspects.

F8. QUESTIONNAIRE RESPONSES FROM NANOBIONET, GERMANY

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's* ***nanotechnology research and development programmes*** *and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*
   - NanoBioNet e.V. is a network of universities, research institutes, hospitals, private companies and experts from the fields of technology transfer, patents, industry and finance. Their common goal is the research and development as well as the practical application of nano- and biotechnology in order to create marketable products and new jobs.

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
  NanoBioNet e.V. has the following focus:
  - national and international positioning of the region Saarland/Rheinhessen-Pfalz as a competitive centre of excellence in the field of nanobiotechnology
  - supporting companies with identifying and implementing nanotechnology developments
  - consistent development of nanobiotechnology expertise in order to create qualified jobs
  - promoting research and development
  - supporting initial and advanced training in the field of nanobiotechnology
  - active public relations work relating to opportunities, applications and reliability of nano- and biotechnology

- Collaboration with other entities i.e. universities, regulators, trade associations
  - Members and Partners of NanoBioNet you find on www.nanobionet.de

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*
   - Competence networking in Nanobiotechnology
   - Nanotechnology and Life Science – Initial and advanced training
   - Demonstration Centre – innovations from the fields of nano- and biotechnology
   - Nanobiotechnology Lab Association
   - Presentations and In-House Seminars

For further information see www.nanobionet.de

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - e.g. nanoparticles, nanotubes

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - high toxicological risk to humans and environment.
   - divergence in the spreading of the technology in the poor and wealthy countries

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - It is important to provide an official support for nanoethics.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - You need more detailed scientific basics and the inform the public in a very serious way.

10. *In your opinion what are the potential risk prevention approaches?*
    - Make a good technology risk management as early as possible

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - All information should be circulated in a very serious way.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - In all parts of the value chain beginning with basic research to the products you need further public financial support.

F9. QUESTIONNAIRE RESPONSES FROM NANODYNAMICS, US

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's nanotechnology research and development programmes and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of research and any results (if available, links to published results)
  - Production of nanomaterials: nano metals and oxides by solution processes and controlled deformation; nanocoatings by gel coating and vapour deposition; carbon nanotubes by vapour processing and polymer nanotubes by solution processing; modification of thr above e.g. plating, impregnation, surface modification; application development e.g. metals and cnannotubes in polymer composites; integration into systems e.g.solid oxide fuel cells.

- A list of products containing nanotechnology already on the market, or in the final phases of development.
  - Cu, Ag, Ni, Ag-Pd powder; golf ball; solid oxide fuel cell; carbon nanotubes.

- Collaboration with other entities i.e. universities, regulators, trade associations
  - Electronics – SEMI, iNEMI, IPC
  - Controlled Release Society
  - Universities – include Clarkson, Purdue, Penn State, Rutgers, Penn State, Oxford (UK), Christchurch (NZ)

- Patents owned
  - 55 exclusively licensed or owned

The following optional details may also be provided if available:

- Any other information you would like to provide.
  - We are proactively working with ANSI, ISO and the NNI-CBAN group to help develop standards and guidelines.

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*

   - Most regulations will be unchanged – the nanomaterials will just provide better performance e.g. longer lasting tires

Please provide the following details:

- The name of the regulatory instrument, standard or best practice.
  - ISO TC 229 is formulating nano standards.

- Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, ethical, trading etc.) and how it applies to your organisation and to nanotechnology.
  - All aspects

- Any voluntary practices which your organisation elects to follow e.g. full body protection for workers.
  - We follow a precautionary approach to ensure our workers receive minimal exposure.

The following optional details may also be provided if available:

- If, in your opinion, there are any governance gaps which need to be filled.
  - ISO TC 229 should cover them

3. *Please describe the key networks, trade associations, institutions and international organisations which support nanotechnology in your industry.*

Please provide the following details:

- The name(s) of organisation(s) involved
  - SEMI and SRC – semiconductor industry
  - iNEMI – the rest of the electronics supply chain

- A brief description of the networks etc. focus and scope, how it works and your participation in it.
  - SEMI – standards, lobbying
  - SRC – sponsored research
  - iNEMI – roadmapping, member funded research

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Those with deliberately engineered biological activity

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - To some extent the cat is already out of the bag – many nano products e.g. carbon black, fumed silica or nano clays have been used for years. That doesn't mean we shouldn't be cautious but we need to exercise reasonable judgements. The benefits include more efficient energy conversion in batteries, fuel cells and photovoltaics, new medical sensors and drug delivery systems as well as lower environmental impact products e.g. additive rather than additive-subtractive processes for making circuit boards.

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - Government direction by funding key strategic pre-commercial areas is extremely helpful.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - Current awareness and membership of active industry organisations.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - We have seen excellent documents from the National Nanotechnology Initiative in the USA, the Royal Society in the UK, and the EC.

10. *In your opinion what are the potential risk prevention approaches?*
    - Develop appropriate guidelines and screening tests

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - In the US we have OSHA covering workers health; NIOSH developing test and analysis protocols and EPA covering environmental considerations.

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - Through involvement and consultation with national bodies.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Normal precautionary chemical / biological lab practices should be adequate.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - Education, awareness, guidelines, effective but not over restrictive legislation.

F10. QUESTIONNAIRE RESPONSES FROM PFIZER, US

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's nanotechnology research and development programmes and other investment programmes on nanotechnology research and / or development. The following are examples of programmes in which you may be investing: new materials and applications, nanodevices and nanosystems, toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk and public perception etc..*
   My organization is a pharmaceutical company. Nanotech is one of many technologies being considered and utilized in drug development, manufacturing. Current investments are limited in drug discovery and formulation. Future uses may include diagnostics and devices.

The following optional details may also be provided if available:

- Ø The investment amount, from your organisation and other collaborators, and the proportion of total R&D investment spent on nanotechnology. (Please provide information which is publicly available and refer to the confidentiality section on P.2 of the Information booklet).
  - o Most investment in this area is confidential.

2. *Please provide an overview of your industry's laws, regulations, standards and best practices which apply directly, or could be applied to nanotechnology research and development within your organisation. These should include both national and international regulation and agreements which oversee your industry.*
   - o This industry is regulated by government agencies assuring quality, safety and efficacy of products. At this point there is no specific regulation about nanotech in this line of business.

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).*
   - o Lux Report by Lux Research

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - o All products that do not go through rigorous quality control and environmental testing, specially if used very commonly

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - o Potential risk is unknown health hazard and benefit would radically new industrial and health solutions

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - Focused investment and avoind hypes

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - Understand, measure and manage the risk for product line

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Public education backed by substantial evidence

10. *In your opinion what are the potential risk prevention approaches?*
    - Quality control

F11. QUESTIONNAIRE RESPONSES FROM SWISS RE, SWITZERLAND

Questions 1-4

Please provide answers electronically beneath the questions.

1. *Briefly describe your organisation's* ***interest in nanotechnology research and*** *any particular issues / areas which you are investigating. The following are examples of programmes which you may be investigating: toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk, health benefit and risk, public perception, international trade, the north-south divide and knowledge transfer etc..*
   - As an observer, we are interested in toxicological risk, risk to workers, best practices, societal benefit and risk, environmental benefit and risk, health benefit and risk. We are investigating in particular public perception and the resulting regulation, since we need to identify, assess and evaluate risks and opportunities associated with nanotechnology in order to offer adequate insurance cover for this emerging technology.

Please provide the following details:

- A brief description of the organisation's focus i.e. scope, type of investigation and any results (if available, links to published results)
  - We are focussing on client related risk assessment and have given nanotechnology the status of a 'top topic' with dedicated human and financial resources. 'Top topics' serve corporate governance for issues with a potential for elevated exposure. Top topic managers play a connective role and support the business functions. They are Swiss Re's appointed contact (ext.), and provide technical guidance and expertise (int.)
  - The bottom line is integrated management of issues, risk and opportunities.
  - See Swiss Re reports on www.swissre.com
- Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
  - Collaboration with ICON (Int. Council On Nanotechnology), Member of the Expert Group of the EU
- Patents owned
  - None. Indirectly related patent owned for early risk identification system SONAR.

2. *Please provide an overview of international laws, regulations, standards and best practices which apply directly, or could be applied, to nanotechnology research and development*
   - TOSCA in the US, REACH in the EU as a basic regulatory framework that can be modified for nanotechnology
   - To our knowledge no best practice documents are published to date but a number of organizations are working on it (NIOSH, ICON, ECETOC etc).
   - On a national level many countries (US, DE, UK, F, CAN, JAP etc) are creating standards. ICON tries to bring the individual models together to foster discussions around an international standard.

Please provide the following details:

- A description of any practices which you would recommend e.g. full body protection for workers, fair trading, development of particular technologies etc.
  - Best practice for occupational safety is a priority, and then best practice in formulating and distributing nanocomposed goods against the background of life cycle assessments is needed. Approval mechanisms for nanoscale materials and products are a prerequisit. This in turn requires a nanospecific terminology.

The following optional details may also be provided if available:

- Knowledge of any developments with implications for the regulation of nanotechnology practices
  - see above

- If, in your opinion, there are any governance gaps which need to be filled.
  - The global perspective is missing. On the other hand, not enough differentiations are made in the broad field of nanatechnology. So far missing is also a risk assessment approach (eg in toxicology) which is addressing specifically enough the nanoscale properties of novel compounds.

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*

Please provide the following details:

- The name(s) of the organisation(s) involved.
  - ICON
  - EC (DG SAENCO & DG Research)
  - US Admin (NSF, NNI)
  - Royal Society
  - FDA/EPA
  - EMPA/ETH/
  - Stiftung Risikodialog St. Gallen
  - NanoBusiness Alliance
  - IRGON Kings College London
  - NanoLogue Wuppertal Institute

- Brief description of their focus and scope, how the 'horizontal' connections work and your participation in it
  - Focus is risk identification and assessment of loss potential (with regard to insurance cover), as well as legal initiatives. Collaboration with experts from various organisations.

- The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).
  - ICON
  - IRGC
  - EC Expert group

The following optional details may also be provided if available:

- Description of how you, and/or they, are able to influence national and international policies, decisions and agreements
  - We are experts in risk management and bring this perspective to the table to find solutions for adequate risk assessment and transfer together with regulatory (and other) representatives. Since we are enabling risk taking, we are interested in knowing and influencing the borderline between societally acceptable and inacceptable risks.

- Description of how the public are able to participate in and influence your organisation.
  - Via the insurance market and regulation.

4. *Please provide information on reports and communications concerning nanotechnology which have been produced by your company or industry, or in relation to your industry and which you would*

recommend for our purposes. Please provide the name of the report(s) and producing organisation(s).

- Nanotechniology – Small matter, many unknowns. Swiss Re Risk perception Series 2003
- Nanotechnology "Small size – large impact", Swiss Re Centre for Global Dialogue, Risk Dialogue Series 2005
- "Technologiedebatten und Versicherung, oder die Macht der öffentlichen Wahrnehmung" in: Mitteilungen für die Aerzteschaft 2005/1, Schweizerischer Versicherungsverband SVV.

Questions 5-14

For the following set of questions please provide your opinion. These are all optional and represent your opinion and not that of your organisation (please see No.4 on P.2 of the information booklet)

Note: Opinions provided by T. Epprecht, questions 5 and 7 by A. Hett and T. Epprecht

Benefits and risks associated with nanotechnology

5. *In your opinion which nanotechnology products have the potential to lead to the highest risk in application? Please also indicate what are the risks specific to these applications (See P.4 of the information booklet)*
   - Any application with free floating passive or active nanoscale materials that come in close contact with the worker or consumer (inhalation > blood via injection > digestive system > skin etc.). Reactive or accumulating nanoscale materials which are released to the environment are highly exposed, too.

6. *In your opinion what are the potential risks and benefits of nanotechnology in general (e.g. increase in localised production, cheaper, more environmentally friendly energy, high toxicological risk to humans and environment, etc.)*
   - Risks see 5.
   - Benefits: more targeted or novel product applications, maybe produced in a more environmentally friendly way of energy and raw material consumption.

7. *Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.*
   - By addreassing potential risks and developing proper risk management procedures early in the development to ensure the sustainable development of nanotechnology.
   - By doing a good job in risk communication and public outreach early on.

Measures needed to address nanotechnology risk *(please address either specific applications or provide an overview)*

8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*
   - product stewardship: investment in tox. and envir. risk research

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - for being perceived as viable: demonstrate the benefits
   - manifest precautionary approach: toxicity and exposition
   - adequate responses to (future) concerns in order to gain credibility and trust

10. *In your opinion what are the potential risk prevention approaches?*
    - see 11.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*

- Technology specific laws inadequate. However, internationally standartised, nano-specific adoption and extention of approval procedures needed. Substantial equivalence as sole key criterion inadequate. Precautionary principle which takes into consideration also application, distribution and life cycle more adequate. But precautionary principle should be understood as a measure to manage risk and not as a means to prevent from any risk.

Nanotechnology at the international level

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide in a manner that satisfies the needs of those using any recommendations?*
    - Advice needs to be practical and applicable independant of local legal environment.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - I do not know how to interpret “formal” and “informal” approaches. Question needs to be reformulated.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - Most quickly by international industry and trade associations, which self regulate the respective sectors. Politics (which is slower) – maybe institutionalised as an international clearing house - should provide the framework for basic safety requirements for nano-goods which are shipped internationally. This results indirectly in standardised safety requirements on the national levels. Thus, an iterative process is required where the staring point should be built on the most advanced knowledge in terms of risk and safety management, wherever it comes from. A possible backlash of this approach is a period of regulatory uncertainty, which should be kept as short as possible.