INTERNATIONAL RISK GOVERNANCE COUNCIL

SURVEY ON NANOTECHNOLOGY GOVERNANCE

Volume D. The Role of NGOs

IRGC WORKING GROUP ON NANOTECHNOLOGY
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On the cover page: A viral molecular motor, composed of
RNA and a protein connector, drives DNA through a channel within a cell.
Courtesy of Purdue University

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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 NGOs 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), industry (Volume B) and research organisations (Volume C). 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 on 6 and 7 July 2006 in Zurich Switzerland. IRGC's final recommendations for appropriate risk governance strategies will be published shortly after the conference.

The survey was originally sent to 25 potential participants (see Annex E for the IRGC Questionnaire to NGOs). During the relevant time period 9 responses were received from ETC Group (Canada), Demos, The Forum for the Future, Greenpeace (UK), the Center for Responsible Nanotechnology (CRN), Environmental Defense, Foresight Nanotech Institute, the National Resources Defense Council and Sciencecorps (US). These respondents represented NGOs with a broad range of activities and focus, for example: the conservation and sustainable advancement of cultural, human and ecological diversity, accountable and effective public policy, sustainable development, environmental protection, the environmental and societal implications of nanotechnology, public education, and, the right to live and work in a healthy environment. Nevertheless it must be taken into account that the survey respondents were not representative of a broad international cross-section of NGOs and all of the respondent organisations were based in the industrial west, predominantly the US. The reason for the concentration of responses in this area was because IRGC could not identify NGOs involved with nanotechnology based in other regions. 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.

The following summary represents only a sample of opinions on the NGO 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. Full responses from each of the respondents can be found in Annex E.

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
Canada	Dr. Kathy Jo Wetter	Researcher, *ETC Group* http://www.etcgroup.org/
UK	Dr. James Wilsdon	Head of Science and Innovation, *Demos* www.demos.co.uk
UK	Mr. Hugh Knowles	Senior Sustainability Advisor, *The Forum for the Future* http://www.forumforthefuture.org.uk/Default.aspx
UK	Dr. Douglas Parr	Chief Scientist, *Greenpeace* http://www.greenpeace.org.uk/
US	Mr. Mike Treder	Executive Director, *Center for Responsible Nanotechnology* http://www.crnano.org/index.html
US	Dr. Richard Denison Mr. Scott Walsh	Senior Scientist Project Manager, Corporate Partnerships *Environmental Defense* http://www.environmentaldefense.org/home.cfm
US	Ms. Christine Peterson	Founder and Vice President, Public Policy, *Foresight Nanotech Institute* http://www.foresight.org/
US	Dr. Jennifer Sass	Senior Scientist, Health and Environment, *Natural Resources Defence Council* http://www.nrdc.org/
US	Dr. Kathleen Burns	*Sciencecorps.org* http://www.sciencecorps.org/org/

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. These answers are not inclusive of 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

NGOs have significant involvement with nanotechnology

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

respondents were split between those who were concentrating on ethical, legal and social issues (ELSI) and those who were concerned with environment, health and safety (EHS):

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

A focus on identifying current gaps

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

A focus on engagement of stakeholders

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

Considering regulation

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

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

RECOMMENDED GOVERNANCE STRATEGIES

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

Type of governance strategy	Recommendations, suggestions and ideas (to industry and government unless otherwise stated)
Risk research recommendations	§ Develop the methods, protocols and tools needed to characterise nanomaterials or to monitor and measure their presence. § Identify and understand the critical characteristics of nanotechnology, including toxicity and eco-toxicity, and biological and environmental fate and transport. § Determine whether existing testing and assessment methods and protocols need to be modified to allow for the particular characteristics if nanotechnology. § Ensure coordination between different agencies involved in risk research to ensure that all needs are being addressed and that sufficient resources are available. § Consider the social and ethical aspects of scientific training and how this influences the culture and practice of research. § Study the potential (positive and negative) issues of molecular manufacturing.
Stakeholder engagement recommendations	§ Identify R&D priorities and agendas through upstream public engagement, with wider dialogue between scientists, policymakers and publics. § Government to initiate and adequately fund public dialogue. § Include civil society in discussion of risk assessment and management strategies.
Risk communication recommendations	§ Develop standards of care in a transparent and accountable manner. § Make research and development funding transparent, including assessment and management of risk. § Conduct toxicity testing in a publicly accessible and transparent manner by a credible, independent authoritative body according to generally accepted laboratory practices. § Balance the communication of benefits and risks. § Label consumer products incorporating nanotechnology.
Governance approaches	***Recommendations to international expert bodies:*** § Collate and disseminate research into toxicology and eco-toxicology and make this publicly available. § Provide a clearing house for safer alternatives and new methodologies and make this publicly available. § Develop an inventory for all engineered nanomaterials and make this publicly accessible to the international community. § Develop an export notification and tracking system and make the results publicly available. § Provide educational training to organisations on potential benefits for sustainable development. § Explore new models of intellectual property specific for nanotechnology. § Create an International Convention on the Evaluation of New Technologies. § Create a new United Nations body to track, evaluate and accept or reject new technologies and their products. ***Recommendations for self-regulation by industry*** § Comprehensively identify risk and management systems prior to and following commercialisation. § Develop a risk management system to provide a clear explanation of company's actions to interested parties; present environmental and health information related to nanomaterials production, use and disposal; facilitate tracking and comparison over time and across organisations; and credibly address issues of concern to stakeholders. § Adopt feedback mechanisms to monitor assumptions concerning risks and the effectiveness of risk management practices. § Adopt lifecycle-based 'standards of care' for responsible nanotechnology development, taking into account worker safety, manufacturing releases and wastes, product use and product disposal. § Adopt worker safety guidelines that assume toxicity unless otherwise shown, provide for worker training, industrial hygiene and worker health monitoring, and treat wastes as hazardous materials.

Type of governance strategy	Recommendations, suggestions and ideas (to industry and government unless otherwise stated)
	§ Adopt environmental safety guidelines which restrict dispersive uses until hazard/fate data is available to demonstrate safety, and provides for environmental monitoring after release. ***Recommendations to government*** § Guide 'beneficial outcomes' through appropriate public sector R&D, market guidance and regulatory behaviour (with the respondent adding that beneficial should not be interpreted as meaning good for corporate shareholders of existing companies). § Create environments for societal discussion of new and emerging technologies at an early enough stage to influence the direction of R&D. § Advise political leaders on how innovation can be driven to socially and environmentally beneficial goals. § Develop the 'Science Commons' to provide easier global access to new R&D materials, methods and processes and to prevent misuse of intellectual property rights. § Introduce open access publishing of intellectual property. § Prohibit production of free manufactured nanoparticles in environmental applications until research demonstrates that the potential benefits outweigh the potential risks. § Support substantial R&D in the evaluation of hazards associated with research, the expected outcomes and training. § Assess objectively the capacities of regulatory authorities and clarify roles and responsibilities. § Require toxicity testing for engineered nanomaterials intended to be commercially viable. § Require publication by manufacturers of available safety data sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment. § Require disclosure of full hazard characterisation and control during the development process, including: a full lifecycle analysis, including fate and effects information; solubility; bioavailability; basic physical/chemical properties such as electrical conductivity; particle size; configuration; mass/surface area ratio. § Require analysis of unintended outcomes and products and appropriate means of reducing these. Disclose this information to workers, potentially impacted communities and funding entities. § Develop an information source geared to the investor communities regarding liabilities and risks. § Require students, educators, laboratory managers and administrators to take appropriate training. § Develop financial and career incentives for those who use safer alternatives, employ safe practices, provide training and produce new products which pose minimal hazards to health or environment. § Introduce strong financial and career penalties for the violation of safe practices. § Subsidise the use of safer chemicals and compensate institutions for time and costs § Classify engineered nanomaterials as 'new'. § Develop a protocol for the tracking of released nanomaterials. § Place a moratorium on the release of manufactured nanoparticles until lab protocols are established to protect workers and regulations in place to protect consumers and the environment.

4. RESEARCH AND DEVELOPMENT STRATEGY

Question 1 of the survey addressed research programmes into particular issues, including a description of the organisations focus. Also included in this section of the report is an analysis of questions 5 and 6 which considered the potential risks and benefits of nanotechnology. The following provides a summary of key points identified.

AREAS OF RESEARCH AND DEVELOPMENT STRATEGY

All of the respondents considered that the benefits of nanotechnology could be extensive and should be pursued, with the majority highlighting potential benefits in the areas of energy, water treatment and health. For example, Forum for the Future saw the biggest benefits as emerging in relation to energy conversion and storage, access to water, and the improvement of medical diagnosis and treatment. Greenpeace focused on those benefits relating to energy generation, efficient insulators and energy storage, clean production processes and reduced costs of clean water production. Sciencecorps considered a wider range of benefits and, in particular, new materials and tools to improve health, food security, housing and economic development.

Nevertheless, the respondents all recognised that a consequence of these developments might be potentially new risks - incorporating ethical, legal and social issues (ELSI) as well as environmental, health and safety (EHS). Many felt that governments and industry were beginning to take these risks seriously, but were reactively focusing on the EHS issues caused by the development of new products and applications, and taking insufficient notice of ELSI issues. In particular, many of the respondents saw a need for decision makers to proactively consider what society might want to be developed and avoided, and to define policies which reach (or prevent) these goals. For illustration, Greenpeace emphasised that nanotechnology should not be framed purely in terms of risks and benefits which shuts down wider questions, inter alia, the values, purposes and ends to which innovation is being directed.

In contrast to the views expressed in IRGC's survey on the role of industry (Volume B of this series), the NGOs surveyed were focused on issues associated with both near-term passive applications and longer term actively evolving nanomaterials and systems. Given the broad range of nanotechnology implications, it is perhaps not surprising that these NGOs focused on specific aspects of nanotechnology core to the focus of their organisation rather than covering a broader spectrum. However, there are two particular elements of R&D strategy which stand out as being significant in the majority of responses:

- NGOs have become quite extensively involved in many different areas very early in the development of nanotechnology, and,
- All of those surveyed were positive about the environmental and health benefits which **could** be achieved.

Unlike the situation with Genetically Modified Organisms (GMOs) no NGOs have as yet come out against nanotechnology as a whole, although specific elements of the risks have been highlighted. Many of the respondents suggested that one of the highest risks could be the potential to miss out on opportunities due to insufficient assessment and management of the potential risks and the wider questions related to innovation and emerging technologies.

The following are examples of specific areas where the respondents were focusing their research:

- **Ethical, Legal and Social Issues (ELSI)**

  - Accountable public policy. For example, Demos is focusing on broad questions such as: Can processes of innovation in nanotechnology be made more open and accountable through public engagement and greater social reflection by scientists and policymakers? and, How can public policy be more effective in addressing the challenges and opportunities created by nanotechnology and other emerging technologies?
  - Equitable development. For example, ETC Group is researching the impacts of enhancement technologies on the rights of the disabled and the potential impacts of nanoscale technologies on democracy and dissent; and, Greenpeace is focusing on how to make the transformative applications yet to be developed more responsive to the needs of society.
  - Intellectual property rights. For example, the Foresight Nanotech Institute is beginning an informal process to explore the problems of the current Intellectual Property (IP) regime and to identify potential solutions, such as 'open-source' style ownership models for publicly-funded research;

and, ETC Group is researching the societal impacts of patenting the fundamental building blocks of nature.

- International trade. For example, ETC Group is looking at the potential impacts of new nanomaterials on commodity markets and their implications on developing countries; and, Foresight Nanotech Institute is investigating whether competitive advantage issues would lead firms to relocate to nations with less strict export controls so that approvals could be processed quicker and potentially in a more irresponsible manner.
- Impacts of molecular manufacturing. For example, CRN is engaging individuals and groups in dialogue to better understand the implications of molecular engineering, and in particular, they are focused on the development of new weapons, new products for surveillance and control and new environmental pollutants being released on a large scale.
- Non-proliferation. For example, Foresight Nanotech Institute has sponsored lectures for early exploration of new nanotech-based weapons.
- Public engagement. For example, Environmental Defense is urging government to engage a broader range of stakeholders in dialogue, such as labour organisations, health organisations, consumer advocates and environmental NGOs; and, Demos is focusing on promotion of nanotechnology 'upstream engagement', involving a variety of stakeholders in collaboration with scientists at the earliest stages of R&D to determine the direction of innovation.
- Sustainable Development. For example, Forum for the Future is promoting the development of nanotechnology in a sustainable manner focused on solving some of the world's problems**.**

Ø **Environment, Health and Safety Issues (EHS)**

- Research into implications of EHS. For example, Environmental Defense is advocating the investment of more public money in EHS to ensure that research identifies potential risks.
- Strategies for safety within the R&D community. For example, Sciencecorps is looking at methods to introduce safety into laboratories thereby increasing safety within the production process and allowing faster commercial distribution.
- Safety of engineered nanoparticles. For example, NDRC is addressing issues such as the environmental impacts of nanomaterials, the testing and regulation of nanomaterials as 'new' chemical substances, required 'reasonable' safety evaluations by manufacturers, an inventory for engineered nanomaterials, the development of an export notification and tracking system, and the development of adequate information for hazard and exposure.
- Regulations and corporate standards. For example, Environmental Defense is asking for the roles and responsibilities of regulatory authorities to be objectively assessed and clarified and for any governance gaps in nanotechnology to be identified. In the interim, they are promoting the adoption by industry of 'standards of care'.

RESEARCH FOCUS – NANOTECHNOLOGY RISKS

The following section investigates those aspects of risk which the respondents considered to be the most significant. Some participants felt that this type of categorisation of risk was not necessarily beneficial for informing decision makers; for example, Demos remarked that precise risks and benefits could not be predicted and of more importance was to design robust, resilient and accountable frameworks for governance that could cope with any issues which may arise; and, Greenpeace saw risk as being a value based judgement about tolerability rather than a definitive fact so that decision makers should not rely solely placed on scientific evidence to calculate risk and define risk governance strategies, but rather incorporate the impact of different values.

Of those who did define specific risks, some also indicated areas which they felt to be of higher risk than others and these areas of highest concern are listed below:

Ø Foresight Nanotech Institute considered abuse of surveillance to be a higher risk in the mid-term and military applications in the longer term.

Ø CRN considered the creation of the first general-purpose nanofactory with the potential for exponential distribution to be of higher risk.

- Environmental Defense was most concerned about applications intended to be dispersed into the environment, or have the potential to do so unintentionally.
- Demos were most concerned about the products which could be directly or indirectly ingested by humans, for example, beauty products and food (Demos also emphasised that risk could be real or perceived).
- Greenpeace considered the highest risks to be an inadequate risk profile for nanoparticles in the short-term, and the potential for a 'new technological arms race' in the longer term.

The following risks were also mentioned by the respondents as giving a cause for concern:

- **ELSI Risks**

  - Economic issues. For example, CRN considered potential risks to include economic oppression from artificially inflated prices, economic disruption from an abundance of cheap products, the development of a black market in nanotechnology (which increases other risks), and high competition in nanotechnology programmes (which also increases other risks); Forum for the Future felt that a reliance on market conditions to dictate R&D would not deliver optimal solutions; and, ETC Group saw a key economic risk as being potential changes in manufacturing processes and new products leading to a displacement of jobs and changes in trade balances between countries.
  - Ethical issues. For example, Greenpeace was concerned that nanotechnology might be used to exaggerate existing problems, such as making air pollution 'cheaper' to clean up. They were also concerned that many opportunities for potential benefits would be missed, such as creating western playthings rather then water treatments; and for ETC Group, one of the key ethical risks was the creation of a societal inequality between the enhanced and the unenhanced and between the rich and poor (the technology 'haves' and 'have not's').
  - Social issues. For example, CRN mentioned personal risks with respect to criminal or terrorist uses, rapid changes in lifestyle and an unstable arms race; and, Environmental Defense considered the possibility of a backlash which could delay, reduce, or even prevent the realisation of many of the potential benefits.

- **EHS risks**

  - Health issues. For example, Environmental Defense referred to the potential for nanomaterials to cross the blood-brain barrier and damage brain, lung and skin tissue, and to cause lung inflammation, fibrosis and damage to skin cells; and, NDRC was concerned about the potential for nanoparticles to enter the blood stream, be transported throughout the body and possibly enter the heart, bone marrow, ovaries, muscles, brain, liver, spleen and lymph nodes, and to disrupt the immune system, cause allergic reactions, interfere with essential signals sent between neighbouring cells, or disrupt exchanges between enzymes.
  - Environmental issues. For example, CRN considered the possibility of collective environmental damage from unregulated products; Environmental Defense mentioned the potential for nanomaterials to be persistent and mobile in the environment and in living organisms; and NRDC was concerned that nanoparticles may remain for very long periods in the air as they do not settle readily on surfaces, would spread rapidly in water and pass through most currently available filters, and enter the roots of plants through soil and thereby the food chains of humans and animals.

5. REGULATIONS FOR NANOTECHNOLOGY

Respondents did not identify any national or international regulations in place for nanotechnology; however, decision making processes in place for EHS risks of bulk-sized materials were recognised as also being applicable for nanomaterials. That being said, no regulatory instruments were identified by the respondents as being able to adequately address the size-specific nature of nanotechnology. According

to Sciencecorps, there were no special requirements for the health protection of workers or for the prevention of nanomaterials entering the environment; for example, there were no regulations regarding the use of filters to prevent the release of nano-sized materials - either through air vents or wastewater streams. No systems were identified which were able to govern ELSI risks.

6. CURRENT GOVERNANCE STRUCTURES IN PLACE

No respondent was able to identify any national or international standards or best practices for nanotechnology although one voluntary practice was commented on: the US Environmental Protection Agency (EPA 2006) proposal for a voluntary pilot programme whereby companies producing nanoscale materials would be asked to voluntarily provide risk related information to the EPA. ETC Group did not consider this to be an effective measure and indicated in their response that 17 environmental, health and civil society groups had also found this programme to be inadequate and inappropriate. No other respondents commented on the adequacy of this measure.

Ø Governance gaps

Many of the respondents identified governance gaps in current decision making practices, including within national regulatory programmes, cross-border regulatory programmes, self-regulation, and within laboratory practices. The majority of the survey participants thought the ineffectiveness of current regulatory systems to be a key element of risk; according to Greenpeace, the likelihood of risk occurring is greatly increased where supervision and control structures are inadequate. The following nanotechnology-specific governance gaps were identified by the respondents:

- National regulatory programmes. For example, Environmental Defense identified deficiencies and gaps in US regulatory programmes addressing environmental and health risks from chemical substances. These include: uncertainty as to whether some nanomaterials are considered new substances or are to be treated as their bulk counterparts; products and substances that fall through regulatory ‘cracks’ and can go under-regulated or even unregulated (for example, the triggering of action by mass-based thresholds or standards); the weak enforcement capabilities or limited resources of certain regulatory agencies; lack of any regulations governing the end-product (for example, in the case of clothing); regulatory programmes which allow for assessment of a chemical or product only after it has been shown to cause a problem (for example, cosmetics and medical devices); and the separation in agency jurisdiction that allows some risks to go unidentified (for example, the US Food and Drug Administration (FDA 2006) reviews sunscreens for health effects but does not analyse downstream effects, such as when it is washed off into aquatic ecosystems, whilst the Environmental Protection Agency (EPA 2006) reviews environmental impacts, but does not have any jurisdiction over cosmetics).
- Cross-border regulatory programmes. For example, Foresight Nanotech Institute identified a two-fold gap caused by different regulations in different countries: firstly, countries with less strict regulatory controls may allow products to be manufactured which would not be accepted in other jurisdictions; and, secondly products developed in these countries may then be sold worldwide with potential consequences related to the product lifecycle.
- Self-regulation. For example, according to Sciencecorps, current regulatory practices provide minimal incentives for researchers and companies to either devise safe production methods or produce non-toxic products. Possible incentives could be related to financial or career rewards; and furthermore, Environmental Defense considered that the lack of regulatory clarity meant companies have little guidance on how to identify and manage risks. One consequence of this is the drive for short-term competitive advantage leading to irresponsible behaviour.
- Research and development. For example, NDRC felt the lack of experience which scientists have with nanoparticles, both in terms of health risk and as a new form of pollutant, has created a governance gap that needs to be guided by government direction; and Sciencecorps agreed with this considering there to be a gap in programmes to provide education, protective strategies, and monitoring.

7. COOPERATION

Question 3 considered issues of national and international cooperation in nanotechnology, including with networks, NGOs, international organisations, countries and regulators. The following provides a summary of key areas in which cooperation is taking place.

CCOPERATION WITH OTHER ENTITIES

The survey responses show that NGOs are involved in dialogue with a wide range of stakeholders and in particular with government, international organisations and nanotechnology networks incorporating NGOs, industry, government and academia. According to Greenpeace, informal networking with other NGOs also takes place but tends to be haphazard and project-based. The nanotechnology-specific areas being addressed primarily concern public engagement, the development of standards, societal impacts and policy implications. In addition, many of the NGOs had wider networks with which they cooperate and are therefore able to exert influence within regarding the development of nanotechnology. For example, ETC Group collaborates with organisations such as the UN Conference on Trade and Development (UNCTAD 2006) and the World Social Forum (WSF 2006). The types of cooperation taking place are through: seats on advisory bodies (for example, Foresight Nanotech Institute sits on the American National Standards Institute (ANSI 2006) Nanotechnology Standards Panel); briefing of government policymakers (for example, CRN prepared and presented information for the US Congressionally mandated National Academy of Sciences (NAS 2006) / National Research Council (NRC 2006) study on 'Molecular Self-Assembly' in Washington DC February 2005); working with the press and media (for example, Demos publish widely on issues in the UK press); and producing publications on policy issues. The following examples of cooperation were provided by the survey respondents:

- Cooperation with government. For example, Demos is collaborating on the NanoDialogues project (2006) funded by the UK Office of Science and Technology (OST 2006). NanoDialogues is a process of upstream engagement between scientists, government, NGOs and the public concerning the societal implications of nanotechnologies. Four working groups are investigating nanoparticles, risk and regulation; bio-nanotechnology and the implications of convergence; public engagement in the corporate innovation cycle; and, globalisation and nano diffusion. Foresight Nanotech Institute is collaborating on California's Blue Ribbon Task Force on Nanotechnology (2006), the primary objective of which is to help develop a regional nanotechnology economic development initiative and to position California as the national and worldwide centre for nanotechnology research, development and commercialisation.
- Cooperation with international organisations. For example, Foresight Nanotech Institute is collaborating with the International Organization for Standardization (ISO 2006) Technical Committee 229 on Nanotechnologies through the ANSI Technical Advisory Group for Nanotechnology (2006). This advisory group has more than 45 representatives from academia, government, industry, non-government and standards' developing organisations and has the objective of informing US collaboration with ISO. In Trieste in 2005, CRN participated in an expert Group Meeting of the International Centre for Science and High Technology, part of the United Nations Industrial Development Organization (2006): the workshop 'North-South Dialogue on Nanotechnology: Challenges and Opportunities' was designed to indicate areas in developing countries where nanoscience and nanotechnology should be promoted; to identify specific needs and opportunities of a given developing country to endorse nanotechnology; and to discuss the role of education in developing countries in supporting nanotechnology. Environmental Defense is participating with the OECD Chemicals Programme (2006) which held two workshops on nanotechnology in 2005. The first workshop 'Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety' was held in June 2005 with 80 participants from 22 delegations of OECD member countries as well as other organisations and invited experts. The second workshop, 'First OECD Workshop on the Safety of Manufactured Nanomaterials' was held in December 2005.

- Cooperation with nanotechnology specific networks. For example, Demos is part of the International Nanotechnology and Society Network (2006) which is coordinated by Arizona State University. This is a forum for social scientists and policymakers from the US, Europe, Brazil, Japan, China and elsewhere. Forum for the Future is part of Nanologue (2006) which brings together businesses, local and regional government, NGOs and educational bodies to promote a Europe-wide dialogue on benefits, risks and social, ethical and legal implications of nanotechnologies.
- Cooperation with other NGOs. For example, Environmental Defense is collaborating with the International Council on Nanotechnology (ICON 2006) which is focused on the environmental and health risks of nanotechnology. In particular, Environment Defense is working with ICON on reviewing best practices for nanomaterial safety. CRN has provided a consultant for the Millennium Project of the American Council for the United Nations University (2006), the purpose of which is to work internationally to organise and improve futures' research.
- Cooperation with industry. For example, Environmental Defense is working with companies such as DuPont and Rohm and Haas, and with the American Chemistry Council's Chemstar Nanotechnology Panel.

PUBLIC ENGAGEMENT

The survey respondents communicated with the public in a variety of ways. For example, Foresight Nanotech Institute has a public membership, CRN issues a public newsletter and maintains a weblog, and Forum for the Future is a charity open to public engagement. Nevertheless, it appears from the responses that none of the NGOs surveyed have formal procedures through which the public can directly influence their policies. This was expressed directly by Greenpeace, although they also commented that when taking action they are mindful of what the public would hope for in terms of environmental and health protection. The following specific examples of direct public engagement were mentioned by the participants:

- Foresight Nanotech Institute is working with ICON to coordinate the preparation of best practices in citizen participation events for nanotechnologies.
- Greenpeace participated in the organisation of a NanoJury (2006) in the UK between April and September 2005, which sought to address the role that nanotechnology might play in a range of possible futures.

8. RECOMMENDATIONS FOR RISK GOVERNANCE

Questions 5-14 addressed aspects of risk governance and the recommendations of the participants in addressing this issue. The following sections provide thoughts and suggestions made by the survey respondents: no weighting has been attributed to the answers. Where there is commonality of thought this has been directly stated.

RISK RESEARCH RECOMMENDATIONS

Increased investment in critical research to identify and assess the health and environmental implications of nanotechnology was an important element of some of the responses. Environmental Defense in particular considered this issue to be very important and noted that without a more detailed assessment of the fundamental properties and characteristics of nanomaterials insufficient data would be available to adequately evaluate hazards and exposure. In terms of who should play the most critical role, Environmental Defense focused on both government and industry: government to develop the necessary infrastructure; and industry to fund the majority of research and testing on their marketed products. The strategies highlighted by the respondents focused predominantly on EHS and issues associated with current near-future applications, although some mention was also made of ELSI. The following specific risk research recommendations were mentioned in the responses:

- Develop the methods, protocols and tools needed to characterise nanomaterials or to monitor and measure their presence.
- Identify and understand the critical characteristics of nanotechnology, including toxicity and eco-toxicity, and biological and environmental fate and transport.
- Determine whether existing testing and assessment methods and protocols need to be modified to allow for the particular characteristics if nanotechnology.
- Ensure coordination between different agencies involved in risk research to ensure that all needs are being addressed and that sufficient resources are available.
- Consider the social and ethical aspects of scientific training and how this influences the culture and practice of research.
- Study the potential (positive and negative) issues of molecular manufacturing.

STAKEHOLDER ENGAGEMENT RECOMMENDATIONS

Dialogue and debate were seen to be crucial to the safe development of nanotechnology, with a broad community of participants needed to be involved in determining how nanotechnology might affect society's future. In particular, the majority of the respondents felt that members of civil society should be included in the risk governance process from the very beginning. One of the reasons for this was given by ETC Group who considered that society should understand the direction of science and technology innovation and the potential impacts which it may have on them as individuals, their political systems and on society as a whole. Environmental Defense saw it as essential that potential beneficiaries of new technologies, and those most likely to bear any risks, are actively engaged so that their expectations and concerns can be identified: the beneficiaries should include labour, consumers and NGOs that represent those interests. For NDRC, the public and workers should have the possibility of participating in the evaluation and regulation of nanomaterials. For Demos, those included in stakeholder engagement should reflect wider decision making governance and policy frameworks and be directly related to the balance of decision making between scientists, policymakers and other stakeholders. The following specific stakeholder engagement strategies were suggested by the respondents:

- Identify R&D priorities and agendas through upstream public engagement, with wider dialogue between scientists, policymakers and publics.
- Government to initiate and adequately fund public dialogue.
- Include civil society in discussion of risk assessment and management strategies.

RISK COMMUNICATION RECOMMENDATIONS

The majority of the respondents were primarily concerned with the transparency of the information being provided, rather than the mode or type of communication itself. For example, Environmental Defense considered transparency to be central to the risk governance process as affected parties and stakeholders should be able to independently evaluate the adequacy of risk reduction and management measures. Forum for the Future saw the need for companies to become more transparent, as the example of Genetically Modified Organisms shows that making risk governance decisions behind closed doors does not work. A few respondents did consider the mode of risk communication, for example, NDRC mentioned the importance of information being provided through an independent authoritative body. In addition, the type of communication was mentioned by some respondents: for example, Foresight Nanotech Institute stated that communication should include analysis of both the benefits and the risks; Forum for the Future considered that hype should not obscure the real potential of applications; and, NRDC and Environmental Defense recommended that consumer products should be labelled. The following risk communication recommendations were provided by the respondents:

- Develop standards of care in a transparent and accountable manner.
- Make research and development funding transparent, including assessment and management of risk.
- Conduct toxicity testing in a publicly accessible and transparent manner by a credible, independent authoritative body according to generally accepted laboratory practices.
- Balance the communication of benefits and risks.

- Label consumer products incorporating nanotechnology.

GOVERNANCE APPROACHES

The vast majority of recommendations given by the respondents were related to actions that government must take to ensure that any risk governance gaps are closed as soon as possible. A commonality of opinion appeared to be that self-regulation will not be sufficient and that governments need to act now both to ensure the risks are adequately assessed and managed and to ensure that potential benefits are not missed. The following sections highlight possible roles for international expert bodies, self regulation and for government.

A role for international expert bodies

Several key roles were identified for international bodies by the respondents. The first role was that of an independent and authoritative clearing house for risk related information: for example, NRDC would like an inventory for engineered nanoparticles to be made publicly available; and, Foresight Nanotech Institute would like different models for intellectual property to be investigated. The second role was a body which promotes sustainable and responsible development internationally, for example, Forum for the Future would like such a body to address questions about what society does with existing and new technology. The third role was an international regulatory body which can decide on whether society will accept the development of certain technologies taking account of issues related to both EHS and ELSI: for example, ETC Group advocated the creation of a United Nations body for new technologies. The following recommendations for roles for international expert bodies were made by the respondents:

- Collate and disseminate research into toxicology and eco-toxicology and make this publicly available.
- Provide a clearing house for safer alternatives and new methodologies and make this publicly available.
- Develop an inventory for all engineered nanomaterials and make this publicly accessible to the international community.
- Develop an export notification and tracking system and make the results publicly available.
- Provide educational training to organisations on potential benefits for sustainable development.
- Explore new models of intellectual property specific for nanotechnology.
- Create an International Convention on the Evaluation of New Technologies.
- Create a new United Nations body to track, evaluate and accept or reject new technologies and their products.

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

The role of self-regulation was only really highlighted by one respondent the remainder did not make any recommendations. Environmental Defense noted that, given the time that it may take to develop sufficient information for regulatory approaches, it was necessary to adopt proactive corporate standards in the interim. Environmental Defense also made several recommendations with respect to the adoption of 'Standards of Care', effective risk assessment and risk management systems, worker safety and environmental safety. The following examples highlight their perspective:

- Comprehensively identify risk and management systems prior to and following commercialisation.
- Develop a risk management system to provide a clear explanation of company's actions to interested parties; present environmental and health information related to nanomaterials production, use and disposal; facilitate tracking and comparison over time and across organisations; and credibly address issues of concern to stakeholders.
- Adopt feedback mechanisms to monitor assumptions concerning risks and the effectiveness of risk management practices.
- Adopt lifecycle-based 'standards of care' for responsible nanotechnology development, taking into account worker safety, manufacturing releases and wastes, product use and product disposal.

- Adopt worker safety guidelines that assume toxicity unless otherwise shown, provide for worker training, industrial hygiene and worker health monitoring, and treat wastes as hazardous materials.
- Adopt environmental safety guidelines which restrict dispersive uses until hazard/fate data available and provide for environmental monitoring after release.

A role for government in governance approaches

The vast majority of recommendations made by the respondents were with respect to actions that policymakers should take in order to prevent, reduce or mitigate potential risks. The general opinion seemed to be that a precautionary approach should be taken with respect to the development of nanotechnology. This was emphasised by Greenpeace, who felt that risk governance mechanisms need to be found which do not rely on corporate largesse, and by NRDC, who advocated that nanomaterials should be assumed to be hazardous until demonstrated to be safe, based on a reasonable set of criteria. Sciencecorps felt that the focus of policy needed to be changed so that precautionary approaches are used during R&D, rather than solely at the point when the product reaches the market. CRN was also concerned to see government addressing the potential risks of molecular manufacturing now, in order to prepare for the new solutions, systems and structures which may be necessary to deal with them.

Despite the fact that the majority of work being carried out by the respondent NGOs is focused on ELSI, the majority of recommendations were with respect to EHS risks. Of those recommendations which addressed ELSI risks, the majority advocated new mechanisms whereby government can provide guidance for the focus of R&D. For example, Greenpeace endorsed a better understanding among policy makers and those responsible for decisions of science funding about the values that inform priorities and funding decisions. More specifically, Demos recommended the creation of a Commission for Emerging Technologies and Society in the UK, and remarked on the crucial role that the EU can play in setting standards and experimenting with more open, deliberative methods.

Many suggestions were made with respect to EHS risks, with the majority of respondents providing recommendations for the prevention of the release of free manufactured nanoparticles into the environment, for how risk research should be funded and for how toxicity testing, hazard characterisation and exposure assessment should be structured. Other recommendations that were raised by one or two of the respondents focused on the declaration of nanomaterials as ‘new’, the mandatory tracking of released nanomaterials, a moratorium over R&D until better controls are in place, the establishment of an international regulatory authority, and recommendations for worker safety. The following recommendations on the role of government were suggested by the survey respondents:

Recommendations for ethical, legal and social issues (ELSI)

- Guide ‘beneficial outcomes’ through appropriate public sector R&D, market guidance and regulatory behaviour (with the respondent adding that beneficial should not be interpreted as meaning good for corporate shareholders of existing companies).
- Create environments for societal discussion of new and emerging technologies at an early enough stage to influence the direction of R&D.
- Advise political leaders on how innovation can be driven to socially and environmentally beneficial goals.
- Develop the ‘Science Commons’ to prevent misuse of intellectual property rights.
- Introduce open access publishing of intellectual property.

Recommendations for environment, health and safety (EHS)

- Prohibit production of free manufactured nanoparticles in environmental applications until research demonstrates that the potential benefits outweigh the potential risks.
- Support substantial R&D in the evaluation of hazards associated with research, the expected outcomes and training.
- Assess objectively the capacities of regulatory authorities and clarify roles and responsibilities.
- Require toxicity testing for engineered nanomaterials intended to be commercially viable.

- Require publication by manufacturers of available safety data sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment.
- Require disclosure of full hazard characterisation and control during the development process, including: a full lifecycle analysis, including fate and effects information; solubility; bioavailability; basic physical/chemical properties such as electrical conductivity; particle size; configuration; mass/surface area ratio.
- Require analysis of unintended outcomes and products and appropriate means of reducing these. Disclose this information to workers, potentially impacted communities and funding entities.
- Develop an information source geared to the investor communities regarding liabilities and risks.
- Require students, educators, laboratory managers and administrators to take appropriate training.
- Develop financial and career incentives for those who use safer alternatives, employ safe practices, provide training and produce new products which pose minimal hazards to health or environment.
- Introduce strong financial and career penalties for the violation of safe practices.
- Subsidise the use of safer chemicals and compensate institutions for time and costs.
- Classify engineered nanomaterials as ‘new’.
- Develop a protocol for the tracking of released nanomaterials.
- Place a moratorium on the release of manufactured nanoparticles until lab protocols are established to protect workers and regulations in place to protect consumers and the environment.

9. REFERENCES

All descriptions are taken from the websites of the organisations. All references are to internet sites last accessed in April 2006.

American National Standards Institute (ANSI) - the US cross-sector coordinating body for the purposes of developing standards in the area of nanotechnology
http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3

Blue Ribbon Task Force on Nanotechnology – their charter is to promote all of California as the national and worldwide centre for nanotechnology research, development and commercialisation
http://www.blueribbonnano.org

Center for Responsible Nanotechnology (CRN) – a non-profit organisation whose mission is to raise awareness of the issues presented by nanotechnology: the benefits and dangers, and the possibilities for responsible use
http://www.crnano.org/

Demos – a democracy think-tank which aims to work with organisations in ways that make them more effective and legitimate http://www.demos.co.uk/

Environmental Defense – a non-profit organisation, representing more than 400,000 members, that links science, economics and law to create innovative, equitable and cost-effective solutions to society's most urgent environmental problems http://www.environmentaldefense.org/go/nano.

Environmental Protection Agency (US) – a federal agency responsible for researching and setting national standards for a variety of environmental programmes http://www.epa.gov/

ETC Group – a non-profit organisation which supports socially responsible developments of technologies useful to the poor and marginalized and addresses international governance issues and corporate power
http://www.etcgroup.org/

Food and Drug Administration (US) - 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/

Foresight Nanotech Institute – a non-profit organisation focused on guiding nanotechnology research, public policy and education to address the critical challenges facing humanity http://www.foresight.org/

Forum for the Future – a charity whose objective is to promote sustainable development and to educate different groups in sustainable development, in order to accelerate the building of a sustainable way of life, taking a positive solutions-oriented approach http://www.forumforthefuture.org.uk/

Greenpeace UK - an independent non-profit global campaigning organisation that exposes global environmental problems and their causes and researches the solutions and alternatives
http://www.greenpeace.org.uk/

International Centre for Science and Technology (ICS) - an international technology centre of the United Nations International Development Organization (UNIDO), created to assist countries in their industrial development through technology transfer programmes
http://www.ics.trieste.it/ActivityDetails.aspx?activity_id=387

International Council on Nanotechnology (ICON) – an international non-profit 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 Nanotechnology and Society Network – a network of researchers representing 37 institutions from 11 countries that explores the connections between society and the possible upcoming changes provided by nanotechnology research http://www.nanoandsociety.com/index.htm

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

Nanodialogues - A UK government 'Sciencewise' project to investigate the most appropriate methods of 'upstream' engagement, designed to inform decision-making in two research councils, a regulator, a company and an NGO https://www.sciencewise.org.uk/site/projects/nanodialogues/nanodialogues%20one%20page%20summary%20Aug05.pdf

Nanojury UK - randomly-chosen people from different backgrounds in the UK heard evidence about a wide range of possible futures, and the role that nanotechnologies might play in them. They then debated how this emerging and potentially revolutionary technology should develop http://www.nanojury.org/aims.htm

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

National Academy of Sciences (US) - an honorific society of scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare http://www.nasonline.org/site/PageServer

Nanotechnology Engagement Group – A UK government 'Sciencewise' project to help bring about a change in government thinking and acting on public engagement in the lifecycle of nanotechnologies. https://www.sciencewise.org.uk/site/projects/neg/NEG%20one%20page%20summary%20Aug05.pdf

National Research Council (US) - the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public and the scientific and engineering communities http://www.nationalacademies.org/nrc/

National Resources Defense Council (NRDC) – a non-profit US environmental action organisation which uses law, science and more than 1 million members and activists to protect the environment http://www.nrdc.org/

Office of Science and Technology (UK) - leads for Government in supporting excellent science, engineering and technology and their uses to benefit society and the economy http://www.ost.gov.uk/index_v4.htm

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

Sciencecorps – a small international alliance of scientists, technical experts, educators and others http://sciencecorps.org/org/

The Millennium Project - initiated by the The Futures Group International, and the United Nations University (UNU). This project provides an international capacity for early warning and analysis of global long-range issues, opportunities, and strategies http://www.acunu.org/index.html

UN Conference on Trade and Development - promotes the development-friendly integration of developing countries into the world economy
http://www.unctad.org/Templates/Startpage.asp?intItemID=2068&lang=1

World Social Forum – a forum for those opposed to neo-liberalism and a world dominated by capital or by any form of imperialism come together to pursue their thinking, to debate ideas democratically, for formulate proposals, share their experiences freely and network for effective action
http://www.forumsocialmundial.org.br/index.php?cd_language=2

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

This IRGC project is supported by the Swiss Federal Agency for Development and Cooperation, Swiss Re, the US Department of State and the US Environmental Protection Agency.

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

ANNEX D – THE IRGC QUESTIONNAIRE TO NGOS

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.*

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)
- Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
- Patents owned
- Any other information you would like to provide

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*

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, international trade, consumer protection etc.) and how it applies to nanotechnology.
- A description of any practices which you would recommend e.g. full body protection for workers, fair trading, development of particular technologies etc.

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 '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.
- Brief description of their focus and scope, how the 'horizontal' connections work and your participation in it
- The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).

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

- Ø Description of how the public are able to participate in and influence your organisation.
- 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 organizational 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 E – QUESTIONNAIRE RESPONSES

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

E1. QUESTIONNAIRE RESPONSES FROM THE CENTER FOR RESPONSIBLE NANOTECHNOLOGY, US

Questions 1-4

1. *Briefly describe your organisation's* ***interest in nanotechnology research and*** *any particular issues / areas which you are investigating.*

Ø A brief description of the organisation's focus i.e. scope, type of investigation and any results (if available, links to published results)
- The Center for Responsible Nanotechnology (CRN) is a non-profit research and advocacy organization concerned with the major societal and environmental implications of advanced nanotechnology. CRN promotes public awareness and education, and the crafting of effective policy to maximize benefits and reduce dangers.
- We engage individuals and groups to better understand the implications of molecular manufacturing and to focus on the real risks and benefits of the technology. Our goal is the creation and implementation of wise, comprehensive, and balanced plans for global management of this transformative technology.
- Published papers: http://www.crnano.org/papers.htm

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*

Ø Knowledge of any developments with implications for the regulation of nanotechnology practices
- With regard to our area of focus (exponential, general-purpose, molecular manufacturing), no regulatory instruments, standards or best practices have yet been positively identified that will be effective. Because molecular manufacturing introduces new classes of risks, and unprecedented levels of risk (as well as benefits!), new solutions, systems, and structures may be necessary.

Ø Any other information you would like to provide.
- Because of the largely unexpected transformational power of molecular manufacturing, it is urgent to understand the issues raised. To date, there has not been anything approaching an adequate study of these issues. CRN has recommended a series of thirty essential studies that should be performed as early as possible. http://www.crnano.org/studies.htm

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

Please provide the following details:

Ø The name(s) of the organisation(s) involved.
- CRN executive director Mike Treder is a consultant to the Millennium Project of the American Council for the United Nations University.

Ø The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).
- Participated in an Expert Group Meeting organized in February 2005 by the International Centre for Science and High Technology, Trieste, Italy
- Prepared and presented information for the U.S. Congressionally mandated NAS/NRC study on "Molecular Self-Assembly," Washington DC, February 2005
  - Prepared and presented information to the U.S. Environmental Protection Agency's Science Advisory Board, Washington DC, 2003

The following optional details may also be provided if available:

- Description of how the public are able to participate in and influence your organisation.
  - The public can participate by reading and commenting on our daily "Responsible Nanotechnology" weblog (http://crnano.typepad.com/crnblog/), can receive our monthly newsletter, and can join our C-R-Network.

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).*
   - There are too many to list here. Please see http://www.crnano.org/papers.htm

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)*
   - The development of the first general-purpose nanofactory with potential for exponential distribution will represent a potential for tremendous change, including grave risks. (http://www.crnano.org/bootstrap.htm)
   - Risks (http://www.crnano.org/dangers.htm):
     - Economic disruption from an abundance of cheap products
     - Economic oppression from artificially inflated prices
     - Personal risk from criminal or terrorist use
     - Personal or social risk from abusive restrictions
     - Social disruption from new products/lifestyles
     - Unstable arms race
     - Collective environmental damage from unregulated products
     - Black market in nanotech (increases other risks)
     - Competing nanotech programs (increases other risks)
     - Attempted relinquishment (increases other 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.*
   - Please see this page on Benefits (http://www.crnano.org/benefits.htm), and this paper on "Bridges to Safety, and Bridges to Progress" (http://www.crnano.org/Bridges.htm).

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 organizational capability to address nanotechnology risk?*
   - We have begun to study that question, and others, with the formation of a Global Task Force on Implications and Policy. See http://www.crnano.org/CTF.htm

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - See answer to #8.

10. *In your opinion what are the potential risk prevention approaches?*
    - Not enough is yet known; see answer to #8.

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - Not enough is yet known; see answer to #8.

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?*
    - Not enough is yet known; see answer to #8.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Not enough is yet known; see answer to #8.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - Not enough is yet known; see answer to #8.

E2. QUESTIONNAIRE RESPONSE FROM DEMOS, UK
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..*
   - Demos is an independent think tank which works on public policy issues in the UK and internationally. We work across a variety of policy areas, including science and innovation, and it in this context that we have become involved with debates over nanotechnologies over the past 2-3 years.
   - Our main focus in this work is:
     - How processes of innovation in nanotechnology can be made more open and accountable, through public engagement and greater social reflection by scientists and policymakers;
     - How public policy can more effectively address the challenges and opportunities created by nano and other emerging technologies.

Please provide the following details:

Ø A brief description of the organisation's focus i.e. scope, type of investigation and any results (if available, links to published results)
   - Demos has 25 staff, and 4 of these work on science and technology policy.
   - We are currently involved in two major projects on nanotechnology. These web pages contain full details of both projects:
     - Nanotechnologies, risk and sustainability http://www.demos.co.uk/projects/currentprojects/ESRCnanotech/
     - The NanoDialogues http://www.demos.co.uk/projects/currentprojects/nanodialogues/

Ø Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
   - We work closely with social scientists at Lancaster University – both of our nanotech projects are collaborations with Lancaster
   - The NanoDialogues project is also a partnership with the UK government (through the Office of Science and Technology), the UK Environment Agency, the Biology and Biological Sciences Research Council, the Engineering and Physical Sciences Research Council; and Practical Action (a development NGO)

Ø Patents owned
   - None

Ø Any other information you would like to provide
   - We have contributed in the past couple of years to the wider climate of policy debate about public engagement in nano and other technologies - in particular through two publications:
     - See-through Science: why public engagement needs to move upstream http://www.demos.co.uk/catalogue/paddlingupstream/
     - The Public Value of Science http://www.demos.co.uk/catalogue/publicvalueofscience/

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*
   - This is not our area of expertise.

The following optional details may also be provided if available:

- If, in your opinion, there are any governance gaps which need to be filled.
  - Our work tends to focus less on the specifics of particular regulations and standards and more on the wider frameworks of governance and policy that surround emerging technologies e.g. what is the balance in decision-making between scientists, policymakers, other stakeholders and the wider public
  - In our view, there is still a lot to be done to make processes of innovation more transparent and accountable
  - See, for example, this recent article which summarises our position: http://www.opendemocracy.net/globalization-accountability/science_2871.jsp

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.
  - We are founder members of the International Nanotechnology & Society Network, which is coordinated by Arizona State University and includes social scientists and policymakers from the US, Europe, Brazil, Japan, China and elsewhere
  - See this site for more details: http://www.nanoandsociety.com/

- The name(s) of any advisory body(s) that your organisation participates in (both formal and informal).
  - We are also members of the UK government's Nanotechnology Engagement Group, which is designed to coordinate and facilitate public input on nanotechnology policy
  - This is funded by the UK government and coordinated by Involve, an NGO. See here for more information: http://www.involving.org/index.cfm?fuseaction=main.viewSection&intSectionID=213&intParentID=2

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 closely involved in debates about nano within the UK government and amongst wider communities of scientists and stakeholders
  - We also publish widely on these issues in the UK press

- Description of how the public are able to participate in and influence your organisation.
  - Our two nano projects both involve extensive public engagement – see weblinks for more details
  - In particular, the 'NanoDialogues' project is the largest public engagement exercise on nano in the UK, funded by the government

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).*

   As mentioned above:
   - See-through Science: why public engagement needs to move upstream http://www.demos.co.uk/catalogue/paddlingupstream/
   - The Public Value of Science http://www.demos.co.uk/catalogue/publicvalueofscience/
   - Plus there are a number of working papers, journal articles and other press articles listed on our website

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)*
   - Beauty products, foods – anything that humans ingest or apply direct to their bodies – this is likely to give rise to the greatest risk concerns – whether 'real' or 'perceived'

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 clearly both risks and benefits that will flow – and it is impossible to predict with any certainty how these will play out over time. Our focus in on how we can put in place robust, resilient and accountable frameworks of governance that can cope with specific issues as they arise
   - We are also critical of the framing of these debates purely in terms of risks and benefits – as we argue in 'See-through Science' (pp.25-36), purely adopting a risk discourse in relation to these debated can close off or shut down some of the wider questions that need to be discussed and deliberated – around the values, purposes and ends to which innovation is being directed. Policymakers and scientists find a risk discourse more manageable and comfortable – but there is a danger that it actually avoids or bypasses some of the most important issues at stake in these discussions about new technologies.

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.*
   - Wider dialogue between scientists, policymakers and publics is key if these benefits are to be realised.

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

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - See our two reports for a detailed discussion of this issue – we describe a framework for 'upstream' public dialogue on these issues

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
   - Our recent report – The Public Value of Science – focuses on the role that scientists and engineers can themselves play in these debates, by building more social and ethical reflection into scientific training and the culture and practice of research.

E3. QUESTIONNAIRE RESPONSE FROM ENVIRONMENTAL DEFENSE, US
Questions 1-4

Please provide answers electronically beneath the questions.

See www.environmentaldefense.org/go/nano for a description of our organization's position and activities on nanotechnology safety and health issues. See also Environmental Defense's perspective on responsible nanotechnology development: Presentation to the Special Session on Nanotechnology 38th OECD Joint Meeting, Paris, France 7 June 2005 www.environmentaldefense.org/pdf.cfm?ContentID=4533&FileName=EDnanopersp.pdf and our *Issues in Science and Technology* paper, "Getting Nanotechnology Right the First Time" http://www.environmentaldefense.org/documents/4816_nanotechstatementNAS.pdf

More specific information is given in response to questions below.

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..*
   - We believe that nanotechnology has the potential for major societal and environmental benefits, but may also pose threats to human health and the environment.
   - For a brief summary of our position, please see attached "ED nano position paper-may05". For a more detailed description, please see our article on "Getting Nanotechnology Right the First Time" in the National Academy of Sciences' Issues in Science and Technology magazine (also attached).s

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 pursuing four key goals to ensure that this technology is developed in a responsible way: increased government research to identify risks, improved regulation to manage risks, proactive corporate standards in advance of regulations, and broad stakeholder engagement to inform government and corporate actions.

- Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
  - We are reaching out to a broad range of stakeholders: leading companies including DuPont, Rohm & Haas, Procter & Gamble, Intel and Swiss Re; government agencies including the U.S. EPA, FDA, OSHA, and the environmental agencies for the European Union, the OECD Chemicals Programme, the UK and Japan; academic institutions such as UC Berkeley, Harvard, Rice, and Johns Hopkins; and public interest groups including NRDC, Consumers Union, Greenpeace UK, and WWF Japan.

- 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 U.S. has many regulatory programs in place to address environmental and health risks from chemical substances, whether used industrially or in agriculture; present in consumer products, drugs or foods; or released to or disposed of in the environment. Each year thousands of new substances and products are subject to varying degrees of regulatory review intended to assess

and manage consumer and worker safety as well as environmental risks. But there are deficiencies and gaps in these regulatory programs – with the result that some products and substances can fall through regulatory "cracks" and go unregulated or under-regulated, posing risks that are not discovered until after widespread introduction. Unfortunately, much of current nanotechnology appears to fall between those cracks.

- In the United States, four agencies currently carry the bulk of chemical and product development regulatory authority. The Environmental Protection Agency (EPA) assesses risks from chemical substances, the Food & Drug Administration (FDA) reviews drug, food additive and cosmetic safety, the Occupational Safety and Health Administration (OSHA) oversees worker protection and the Consumer Product Safety Commission (CPSC) manages risks from the use of consumer products. The relevant regulatory programs administered by each agency are listed in Appendix 1 along with an annotated list of issues relevant to how the programs might address nanotechnology. In general, several recurring themes emerge:
  - It is unclear whether some nanomaterials are considered new substances under several regulatory programs, or whether they are to be treated in the same manner as their larger scale counterparts. Since nano-versions of conventional substances are created explicitly to exhibit novel physical and chemical properties, a regulatory scheme that does not acknowledge and account for those differences would be inadequate.
  - Action under most existing regulations is triggered by mass-based thresholds or standards, where the decision as to whether regulations apply or the level of scrutiny or protection required for a substance are based on the mass of the substance produced. In many cases, this approach is not appropriate for nanomaterials, which by their very definition are reduced in size and mass, and exhibit increased potency or other activity, attributes that are often based on surface area or other properties not reflected in mass-based measures.
  - Several of the regulatory programs establish no processes to review and approve chemicals or products before they are released into the market, but only allow for regulation of a chemical or product after it has been shown to cause some problem. Even those that do include pre-market assessment often require little or no data with which to evaluate whether a chemical or product presents any risk.
  - Many of these regulatory programs have weak enforcement provisions, or the agencies charged with enforcing them have limited resources to do so.
  - Some potential nanotechnology applications touch upon or fall through the cracks between the jurisdictions of multiple regulatory programs. For example, sunscreens using nanoparticles of titanium dioxide have been reviewed by the FDA for potential immediate health effects on consumers. However, there has apparently been no review by FDA or EPA of how titanium dioxide nanoparticles may affect aquatic ecosystems when these sunscreens wash off. FDA reviews typically do not address such "downstream" effects, while EPA generally lacks authority over cosmetics.
  - There are many potential nanotechnology applications that are simply not regulated at all. For example, there are few U.S. regulations regarding the safety of clothing. However, there are already a number of clothing products that incorporate nanomaterials to resist stains and wrinkles. There are no requirements for companies to test these clothes to ensure that the nanomaterials in them do not pose any risks to consumers when they wear the clothes, or to the environment when the clothes are laundered or discarded.
- There are similar questions about whether and how other countries will apply regulatory oversight to ensure the safe development, use and disposal of nanotechnology products. For multinational companies, there are also questions about how different countries' regulations apply to products that are manufactured in one country and sold in another.
- Beyond the potential for these regulatory gaps to allow for unintended or unmanaged impacts on human health and the environment, the lack of regulatory clarity leaves companies with little guidance on what they should do to identify and manage the risks of the nanomaterials they are developing or using in their products. Thus it creates an uneven playing field: more responsible companies may place themselves at a short-term competitive disadvantage by incurring costs to identify and manage potential risks from their products, while their competitors are not obligated to do the same. More broadly, even if the majority of companies act responsibly, just one

company acting less cautiously could cause a problem that results in a backlash against the entire industry.

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*
   - See answer to collaboration question under #1 above.

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).*

From www.environmentaldefense.org/go/nano:

- Getting Nanotechnology Right the First Time National Academy of Sciences article on nanotech summarizing Environmental Defense's perspective on this evolving science. [PDF]
- Environmental Defense presentation to the National Academy of Sciences' Committee to Review the National Nanotechnology Initiative (written statement; PowerPoint slides). (3/05) Provides our views on the federal government's role in addressing nanotechnology risks. [PDF]
- Environmental Defense proposal to increase federal funding of nanotechnology risk research to at least $100 million annually. (4/05) Analysis providing support for spending at this level to identify the potential risks of nanomaterials. [PDF]
- Environmental Defense's Perspective on Responsible Nanotechnology Development - (6/05) Presentation to the Special Session on Nanotechnology at the 38th OECD Joint Meeting, Paris, France. [PDF]
- Environmental Defense's presentations at the Environmental Law Institute/Woodrow Wilson Center Forum on Nanotechnology (5/05) Technical and legal aspects of identification and management of nanotechnology risks. [PDF]
- Letter from Environmental Defense to USEPA addressing the Toxic Substances Control Act and nanotechnology issues (9/04) [PDF]
- Bibliography of references and abstracts of risk-related research studies on nanomaterials compiled by Environmental Defense. (4/05) [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)*
   - Dispersive applications. See the UK's Royal Society & Royal Academy of Engineering report "Nanoscience and nanotechnologies: opportunities and uncertainties" (http://www.nanotec.org.uk/finalReport.htm). We agree with their recommendation "that the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks. (Section 5.4: paragraph 44)

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.)*
   - The limited data now available demonstrate the potential for some nanomaterials to be both persistent and mobile in the environment and in living organisms; to cross the blood-brain barrier;

and to be capable of damaging brain, lung and skin tissue. Published studies have documented the following types of adverse effects exhibited by various nanomaterials:

- Carbon nanotubes can cause lung inflammation, fibrosis.
- Carbon nanotubes can damage skin cells.
- Nano-sized carbon can be translocated into the brain after inhalation in mammals.
- Buckyballs (fullerenes) can kill soil bacteria and aquatic invertebrates.
- Buckyballs can be transported across gills into the brains of fish and damage brain tissue.
- Quantum dots injected into skin can be transported to lymph nodes, with possible immunotoxicity.

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.*
   - We are pursuing four key goals to ensure that this technology is developed in a responsible way: increased government research to identify risks, improved regulation to manage risks, proactive corporate standards in advance of regulations, and broad stakeholder engagement to inform government and corporate actions.

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?*
    - Establishment and implementation of lifecycle-based "standards of care" for nanomaterials: These standards should include a framework and a process by which to identify and manage nanomaterials' risks across a product's full life-cycle, taking into account worker safety, manufacturing releases and wastes, product use, and product disposal. Standards of care should also include and be responsive to feedback mechanisms, including environmental and health monitoring programs to check the accuracy of the assumptions about a material's risks and the effectiveness of risk management practices. Such standards should be developed and implemented in a transparent and accountable manner, including by publicly disclosing the assumptions, processes, and results of the risk identification and risk management systems.
    - More specifically,
      - Proactive Risk Identification & ManagementAcknowledge that nanomaterials are different
        - *Hazards cannot be inferred from bulk materials*
      - Commit to up-front research and testing
        - *Sufficient testing to identify risks prior to commercialization*
      - Take a responsible approach to managing risks
        - *Risks addressed across the lifecycle*
        - *Protective interim risk management <u>in advance</u> of testing*
        - *Appropriate risk management <u>in response</u> to testing, monitoring*
      - Embrace transparency
        - *Public disclosure of all risk-related information*
        - *Labeling, accurate MSDS disclosures*
    - Responsible Interim Risk Management Approaches
      - Interim worker safety steps
        - *Assume toxicity until shown otherwise*
        - *Worker training, industrial hygiene, appropriate use of engineering controls and personal protective equipment to prevent release and exposures*
        - *Workplace, worker health monitoring*
        - *Wastes treated as hazardous materials*
      - Interim environmental safety steps
        - *Restrict dispersive uses until hazard and exposure/fate data available*
        - *Manufacturers assess and disclose lifecycle risks in advance of commercialization*
        - *Release/environmental monitoring*

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - Comprehensive risk identification and management process both prior to and following commercialization of nanomaterial-containing products. See details above.

Nanotechnology at the international level

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - Transparency is central to any type of reporting or disclosure. For example, generally accepted accounting principles seek to ensure that investors are given a clear picture (with supporting documentation) of an organization's financial condition. Other common transparency systems include Material Safety Data Sheets, nutrition labels for food, and material and care labeling for clothing.
    - Nanotechnology risk identification and management processes should include systems for recording, compiling, analyzing and disclosing information about nanomaterials or nano-enabled products at appropriate stages of use, as necessary. Access to information is a powerful tool for educating workers and consumers and for insuring against negligence and corruption; hence the extent of and access to such information should be sufficient to allow affected parties and stakeholders to independently evaluate the adequacy of risk reduction and management measures. Any risk management system should be designed to:
        - Provide a clear and open explanation of the company's actions to interested parties, such as employees, regulators, shareholders, insurers and consumers;
        - Present environmental and health information relating to nanomaterials production, use and disposal;
        - Facilitate tracking and comparison over time and across organizations; and
        - Credibly address issues of concern to stakeholders.

Appendix 1 – Regulatory programs relevant to nanotechnology and associated issues

- Toxic Substances Control Act (TSCA)
    - Definition of new
    - Exemptions
    - Mass based standards
    - No required tests
    - Incorporation into articles
- Occupational Safety and Health Act (OSHA)
    - Mass based standards
    - No dermal exposure standards
    - Personal protective equipment questions
    - Lack of enforcement requires public transparency
- Resource Conservation and Recovery Act (RCRA)
    - Mass based standards
    - Definitional question – are nanomaterials hazardous waste?
    - Listing process
    - No tests for fate
- Federal Food, Drug, and Cosmetic Act (FFDCA)
    - No premarket approval for cosmetics, medical devices
    - European standards much tougher
    - No consideration of subsequent entry into environment
- Consumer Product Safety Act (CPSA)
- Federal Hazardous Substances Act (FHSA)
    - No premarket approval
    - Whole range of products not covered (clothes, tennis balls, etc.)

E4. QUESTIONNAIRE RESPONSE FROM ETC GROUP, CANADA

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..*

Please provide the following details:

- Ø Any other information you would like to provide
  - o ETC Group is a civil society organization dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights. To this end, ETC Group supports responsible developments of technologies useful to the poor and marginalized and it addresses international governance issues and corporate power. In the context of nanotechnology, ETC Group focuses primarily on the socio-economic implications (though we paid a considerable amount of early attention to the environmental and health impacts, particularly the impacts of engineered nanoparticles and of nanobiotechnology and/or synthetic biology). Some of the socio-economic implications we consider include the impacts of patenting the fundamental building blocks of nature, the impacts of new nanomaterials on conventional commodity markets, the impacts of "enhancement" technologies on the rights of the disabled and the potential impacts of nanoscale technologies on democracy and dissent

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*

- Ø Any other information you would like to provide.
  - o While others have explored the possibility that existing regulations (such as TSCA in the US or Europe's new chemicals policy, REACH) could be applied to the products of nanotechnology, the fact remains that no government regulation in the world currently addresses the size-specific nature of these products. In May 2005 the U.S. Environmental Protection Agency announced that it was "considering a potential voluntary pilot program for nanoscale materials that are existing chemical substances." Seventeen environmental, health and civil society groups, including ETC Group, found the proposed voluntary initiative to be "inadequate and inappropriate." (The groups' submission, "Re: EPA Proposal to Regulate Nanomaterials through a Voluntary Pilot Program," is available on the Internet at www.environmentalobservatory.org/library.cfm?refid=73094 .) In addition to advocating for legally-binding regulations, ETC Group, in 2002, called for a moratorium on the release of manufactured nanoparticles until lab protocols are established to protect workers and until regulations are in place to protect consumers and the environment.
  - o At a time when nanoscale technologies and their convergence are developing faster than public policies can evolve to address them, it is critical to broaden the community of participants who play a role in determining how these technologies should affect our future. Society must gain a fuller understanding of the direction and impacts of science and technology innovation in a broader sociopolitical context. To keep pace with technological change, we need innovative approaches to monitor and assess the introduction of new technologies. The international community should create a new United Nations body with the mandate to track, evaluate and accept or reject new technologies and their products. To this end, ETC Group has put forward a proposal for an International Convention on the Evaluation of New Technologies—an intergovernmental facility capable of earning the confidence of governments and society as well as of the scientific community.

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

The following optional details may also be provided if available:

- Any other information you would like to provide.
  - ETC Group works with civil society partners, particularly in the global South, and has consultative status with the United Nations Economic and Social Council (ECOSOC), Food and Agriculture Organization (FAO), UN Conference on Trade and Development (UNCTAD), and UN Biodiversity Convention (CBD). ETC Group participates in international fora such as the World Social Forum.

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).*

   - Since 2002, ETC Group has produced reports on a wide variety of aspects of nanoscale technologies, including engineered nanoparticles, nanotech in food and agriculture, intellectual property and the political landscape. All of our reports are available on our web site (www.etcgroup.org). Below is a partial list of our major nanotech reports:
     - The Big Down: Technologies Converging at the Nanoscale
     - No Small Matter II: Size Matters! The Case for a Global Moratorium
     - Down on the Farm: The Impact of Nanoscale Technologies on Food and Agriculture
     - Nanotech's "Second Nature" Patents: Implications for the Global South
     - NanoGeoPolitics: ETC Group Surveys the Political Landscape

E5. QUESTIONNAIRE RESPONSE FROM FORESIGHT NANOTECH INSTITUTE, US

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..*
   - Foresight is primarily an educational public interest organization, so our involvement here is primarily through other organizations, such as ICON for which I serve as an Advisor. We are beginning an effort to coordinate the preparation of best practices in citizen participation events for nanotechnologies (e.g. "citizen juries", etc.), but this is in the very early stages. We welcome new participants in this effort. While Foresight participates in policy issues arising in various timeframes, we have a special interest and expertise in productive nanosystems, i.e. atomically-precise manufacturing, a development expected in the longer term.

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*
   - **Intellectual property**
     There is growing concern that the current intellectual property regime may be creating a nanotechnology "patent thicket" in which overly-broad, poorly reviewed patents will conflict and hinder progress. Foresight is beginning an informal process to explore this possible problem and potential solutions. Also to be discussed is the question of whether the current regime hinders R&D by smaller firms and in developing nations, and possible "open source" style IP ownership models for fundamental publicly-funded research results.
   - **Nonproliferation**
     While new nanotech-based weapons may still be in the future, Foresight has sponsored lectures for early exploration of this challenging issue. Prof Gary Marchant of Arizona State University has done the most advanced analysis to date, presented in a Foresight-sponsored talk at a U.S. National Science Foundation-funded Nanoethics conference. We plan to expand these policy activities as nanotech weapons draw closer.
   - **Export controls**
     Current export controls in the more advanced nations (e.g., "International Traffic in Arms Regulations" in the U.S.) may be overly strict or slow to process approvals, leading cutting-edge firms to consider relocating to less responsible nations. Foresight will be examining this possible problem and exploring potential recommendations.
   - **Citizens participation** -- see #1

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*
   - Foresight participates in the International Council on Nanotechnology (ICON) through Christine Peterson, the organization's VP Policy & Research, who serves as an Advisor. She is also a member of ASTM International's nanotechnology subcommittee and California's Blue Ribbon Task Force on Nanotechnology.
   - In response to a proposal by the British Standards Institute, a new International Standards Organization (ISO) technical committee, TC229, is being established to develop an ISO standard on Nanotechnologies. ISO is convening a meeting in London, England, 2005 Nov. 9-11 to vote on and initiate efforts toward this standard development.
   - The American National Standards Institute (ANSI) is the United States' representative body on the ISO council, and has solicited representation by experts in the nanotechnology technical community to participate in a Technical Advisory Group (TAG) that will guide ANSI's participation

in TC229. Dr. David Forrest, a Foresight Senior Fellow, is representing the Foresight Nanotech Institute on this TAG, bringing special expertise in molecular machine systems and productive nanosystems.
- Three areas of initial focus in the ISO effort will be: terminology, metrology, and Environment, Safety and Health (ESH). These may be structured either as Subcommittees or as Working Groups within ISO (each with subtle political ramifications depending on who chairs the group and how members are selected--e.g., geographically: x number of members per continent).
- The ANSI TAG forms equivalent Working Groups, one matched to each of the ISO working groups.
- Foresight participation in ANSI in 2005 included: attending two meetings at NIST in Gaithersburg MD, learning about the standardization process, selecting and voting on delegates to represent ANSI at the ISO London meeting, participating in discussions related to terminology, participating in a Working Group to develop a National Body Statement to be read at the London meeting, participating in a continuing working group on Metrology.

Ø Description of how you, and/or they, are able to influence national and international policies, decisions and agreements
- In addition to the activities above, Foresight representatives testify for governmental bodies, brief government policymakers, work with the press and media, and produce publications on policy issues.

Ø Description of how the public are able to participate in and influence your organisation.
- Foresight is a non-profit public interest group having membership categories at various levels, including a free electronic membership.
- Members of the public worldwide give their views directly to Foresight leadership to influence the organization's positions and policies.

5. *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).*
   - The primary Foresight publication of relevance to risk governance is the document "Foresight Guidelines Version 4.0: Self Assessment Scorecards for Safer Development of Nanotechnology", published at http://www.foresight.org/guidelines/current.html. Version 5.0 will be published shortly.

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)*
   - Military applications.

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.)*
   - Primary benefits are in medical and environmental applications. While these will be substantial in the mid-term, the most dramatic benefits should arrive with atomically-precise manufacturing (productive systems).
   - Primary risk in the mid-term is abuse of surveillance. Primary risk in the long term is abuse of new nanotech-based weapons.

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.*
   - Sustainable development: Need to educate foundations on nanotech benefits.
   - Balanced distribution: Need to explore new models of intellectual property making fundamental advances more widely available.

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 organizational capability to address nanotechnology risk?*
   - On the topic of weapons, see work of Gary Marchant.

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - Depends on audience. Communications should be balanced between benefits and risks. Public, at least in U.S., is willing to accept some risk if personal benefits are clear. Foresight has presented these issues for 20 years and can provide sample communications.

10. *In your opinion what are the potential risk prevention approaches?*
    - Regarding the Precautionary Principle, see the work of Gary Marchant.

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 near term, existing regulatory agencies need to expand their procedures to adequately address the new nanostructures being produced. Nations with inadequate or non-existent regulatory structures need to establish or strengthen them. In the mid-term, public policy will need to address the challenge of nanotech-based surveillance, which can both increase security and be abused to control populations. Longer-term, atomically precise manufacturing (productive nanosystems) will raise substantial new challenges in terms of security and defense which will ultimately need to be addressed at an international level.

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?*
    - Due to the complexity and highly technical nature of the challenge, policymakers at the international level will need expert bodies to present their recommendations in two forms: (1) a simplified overview understandable by less-technical members of the policy community, and (2) highly detailed and technically supported specific wording to be used in policy documents produced at the international level. This puts a large burden on the expert bodies; they must do all the research, analysis, and policy crafting on an extremely complex area. This work will be extraordinarily time-consuming and therefore, compared to other areas of policy, expensive. Substantial amounts of funding will be needed to do this well.

13. *In your opinion how can formal and informal approaches for research and development be combined and implemented for nanotechnology?*
    - Foresight is exploring open access publishing and the Science Commons as approaches to this question.

14. *In your opinion how can the responsible development of nanotechnology be assured at the international level?*
    - See work of Gary Marchant for long-term weapons issues.

E6. QUESTIONNAIRE RESPONSE FROM FORUM FOR THE FUTURE, UK

Questions 1-4

Please provide answers electronically beneath the questions.
Please note that I am replying to this on a personal basis and not representing the views of the Nanologue project or Forum for the Future.

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)
  - UK's leading sustainable development charity. Our object as a charity is to promote sustainable development and to educate different groups in sustainable development, in order to accelerate the building of a sustainable way of life, taking a positive solutions-oriented approach.
  - Forum for the Future is one of the partners in the Nanologue project (see www.nanologue.net for details)

- Collaboration with other entities i.e. universities, regulators, trade associations, international organisations
  - Nanologue only: Wuppertal Institute, Germany; Triple Innova, Germany; EMPA, Switzerland

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*

Please provide the following details:

- The name of the regulatory instrument, standard or best practice.
  - REACH. No real knowledge of others.

- Brief description of what it regulates (e.g. environmental impacts, human health, worker safety, international trade, consumer protection etc.) and how it applies to nanotechnology.
  - Introduction of new chemicals

- A description of any practices which you would recommend e.g. full body protection for workers, fair trading, development of particular technologies etc.
  - Classification of nanomaterials as "new". Additional testing needed asap before introduction to environment.

The following optional details may also be provided if available:

- Knowledge of any developments with implications for the regulation of nanotechnology practices
  - Changes to REACH?

- If, in your opinion, there are any governance gaps which need to be filled.
  - Need international body to collate and disseminate studies into eco-toxicology and other info on nanomaterials. E.g. why has L'Oreal not released info on nanoparticles and skin barrier?

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*
   - See partnerships with other organisations in Nanologue project. Forum has numerous partnerships with businesses, local and regional government and educational bodies. See http://www.forumforthefuture.org.uk/aboutus/Businesspartners2_page1663.aspx for business links

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
  - Producing report for European commission for Nanologue.

- Description of how the public are able to participate in and influence your organisation.
  - As part of Nanologue project have engaged Civil Society. Forum For The Future is a charity so open to public engagement

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).*
   - Some that we have used:
     - Future Technologies, Today's Choices – Greenpeace Environmental Trust
     - Royal Society/Royal Academy of Engineering report
     - See website (www.nanologue.net) for further literature reviews

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)*
   - Major distinction is between free and fixed nanoparticles and questions around life cycle impact especially disposal or recycling.
   - Therefore all free particles need to be thoroughly assessed before release and we need to understand the impacts over whole life cycle.

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 to help solve issues surrounding energy conversion and storage, access to water and help improve medical diagnosis and treatment.
   - However market conditions are unlikely to deliver the best solutions to those areas that need it most.
   - Considering the energy situation that is rapidly arising it is amazing that the world is not making a concerted effort to enhance distributed renewable energy production. The social risk is not being highlighted enough.
   - The eco-toxicology issue needs to be given far more prominence.

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.*
   - Needs international governance to maximise potential but this about a much bigger question of what we as a society do with the technology we have – not just about NT.

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

9. *In your opinion how can the potential benefits and risks of nanotechnology best be communicated?*
   - In an open and transparent way. Companies must learn from GM etc that a closed door does not work. Funding should be transparent.
   - Have to ensure that the hype does not obscure the real applications.

10. *In your opinion what are the potential risk prevention approaches?*
   - Not an expert in risk.

E7. QUESTIONNAIRE RESPONSE FROM GREENPEACE, UK

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..*
   - Greenpeace is a civil society organisation which campaigns for environmental protection. We are taking an interest in nanotechnology because of the potential for good and bad impacts.
   - However, we believe at the moment that means that the transformative applications yet to be developed need to be more responsive to the needs of society.
   - Thus we are looking at nanotechnology as a whole rather than attempting to focus on certain applications. The issues raised for nanotech actually apply to many areas of developing science and technology.

Please provide the following details:

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*
   - We are not aware o0f international laws or regs. Best practice would apply to containment of nanoparticles in the lab or in application. However this has not, to our knowledge, been codified anywhere in the world.

3. *Please describe 'horizontal' connections with other key institutions e.g networks, NGOs, international organisations, countries and regulators.*
   - Informal networking with other NGOs occurs but this is haphazard and generally project based when appropriate. Groups would be – DEMOS, ETC group, ITDG, academics e.g. Lancaster, Newcastle, UEA, and NRDC. Meetings with UK groupings tend to be at events discussing either nanotechnology or other science/society for a.
   - We meet with UK Govt (DEFRA) periodically. Impact has yet to be determined. We have no formal influence from the public but are mindful of what the public would hope for in terms of environmental and health protection.

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).*
   - We have produced 2 reports. One is 'Future Technologies Today's Choices" a publication by Greenpeace Env Trust which surveyed new technologies but did have a significant focus on nanotech. http://www.greenpeace.org.uk/contentlookup.cfm?ucidparam=20030721113521&menupoint=A-L&CFID=2971331&CFTOKEN=59164587
   - We have also recently initiated and sponsored a citizens' jury on nanotechnology. The report is not yet available on the web but should be available soon from http://www.greenpeace.org.uk/contentlookup.cfm?CFID=2971331&CFTOKEN=59164587&SitekeyParam=A-L or on www.nanojury.org

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)*
   - At present the toxicology and risk profile of nanoparticles is poorly defined but potentially worrying. In the longer term the use of nanotech to support military developments may well be more threatening to larger numbers of people in creating a 'new technological arms race' in conventional warfare.

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.)*
   - Generally we have most optimism around energy generation (esp. solar/hydrogen) efficient insulators and energy storage, clean production processes. They may also be considerable benefits in reducing the cost of clean water production although the terms of deployment of new technologies (esp. patent protection, public or private arrangements) could be limiting far more than the potential of the technology.
   - The biggest worry would be that nano becomes a) a risk concern because of inadequate supervision and control, or precautionary approach early on. B) major missed opportunity because it is used, through R&D decisions, to creat playthings for Western consumers and to exaggerate existing problems (it could make global and local air pollution 'cheaper')

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 starts with the direction proviudsed by public sector R&D but also the signalling about the forma of market and regulation that would be provided to what are widely seen as a'beneficial' outcomes. Beneficial does not mean good for corporate shareholders of existing companies.

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 organizational capability to address nanotechnology risk?*
   - 'Risk' is one aspect of this (see also paras 2 & 3 to this answer) – it requires decision makers to understand that whatever they do (or don't do) they are placing themselves somewhere along an axis of precaution – a values based judgement which does not flow from 'science' but comes from a judgement about where to give the 'benefit of the doubt'
   - Better understanding amongst policy and decision makers of science funding about the shaping and values that inform priorities and funding decisions.
   - Better understanding amongst political leaders about the nature of innovation being driven to social and environmentally beneficial goals.

10. *In your opinion what are the potential risk prevention approaches?*
    - Precautionary approach NOW. Find mechanisms that do not rely corporate largess to address risk issues

11. *In your opinion, what are the appropriate measures needed to adequately regulate the scientific and technological communities' activities in the field of nanotechnology?*
    - Greater reflection at points of decision about possible application of new findings.

E8. QUESTIONNAIRE RESPONSES FROM NATIONAL RESOURCES DEFENSE COUNCIL, US

These comments are submitted by The Natural Resources Defense Council (NRDC). NRDC is one of the most effective environmental action organizations in the U.S.A.. We use law, science and the support of more than 1 million members and online activists to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for all living things.

Expectation of hazards associated with nanomaterials

One of the new properties of nano-sized particles is their extreme mobility. In contrast to larger particles, they have "almost unrestricted access to the human body," Swiss Re points out, because they can enter the blood stream through the lungs and possibly through the skin, and seem to enter the brain directly via olfactory nerves. Once in the blood stream, nano particles can "move practically unhindered through the entire body," unlike larger particles that are trapped and removed by various protective mechanisms.

If they become airborne, nano particles can float for very long periods because -- unlike larger particles -- they do not readily settle onto surfaces. In water, nano particles spread unhindered and pass through most available filters. So, for example, current drinking water filters will not effectively remove nano particles. Even in soil, nano particles may move in unexpected ways, perhaps penetrating the roots of plants and thus entering the food chains of humans and animals.

As Swiss Re noted, "As size decreases and reactivity increases, harmful effects may be intensified, and normally harmless substances may assume hazardous characteristics." Nano particles may harm living tissue, such as lungs, in at least two ways -- through normal effects of chemical reactivity, or by damaging phagocytes, which are scavenger cells that normally remove foreign substances. Phagocytes can become "overloaded" by nano particles and cease functioning. Worse, overloaded phagocytes retreat into deeper layers and so become unavailable to protect against foreign pathogens and bodily invaders. Successive particles are then able to do their full reactive damage, and other invaders, such as bacteria, may penetrate unhindered. The surface reactivity of nano particles gives rise to "free radicals," which are atoms containing an "unsatisfactory" number of electrons (either too few or too many for stability). Free radicals swap electrons with nearby atoms, creating further instabilities and setting off a cascade of effects. Free radicals give rise to inflammation and tissue damage, and may initiate serious harm, such as growth of tumors. On the other hand, some free radicals are beneficial, destroying invaders. So the role of nano particles in producing free radicals remains to be clarified.

Nano particles would normally tend to clump together, forming larger, less dangerous particles -- but nanotechnologists take pains to prevent clumping by adding special coatings. As a result, nano particles in many commercial products, sprays and powders remain reactive and highly mobile. Whether nano particles can pass through the skin into the blood stream is the subject of intense debate. Despite this knowledge gap, sun screens, skin lotions and baby products containing nano particles are already on the market. Clearly this is a problem for insurance firms providing liability coverage. Swiss Re says, "Considering the wide variety of products already on the market, the need for a solution is urgent."

Swiss Re expresses concern that ingested nano particles can be absorbed through "Peyer's patches," part of the immune system lining the intestines, and from there may enter the blood stream, be transported throughout the body, and behave in ways that may be detrimental to the organism. While in the blood stream, nano particles have been observed entering the blood cells themselves. Once in the body, nano particles may be able to enter the heart, bone marrow, ovaries, muscles, brain, liver, spleen and lymph nodes. During pregnancy, nano particles would likely cross the placenta and enter the fetus. The specific effects in any given organ would depend upon the surface chemistry of particular particles, which in turn would be determined by their size and surface coating. "It is likely that in the course of its entire evolution, humankind has never been exposed to such a wide variety of substances that can penetrate the human body apparently unhindered," Swiss Re says.

The brain is one of the best-protected of all human organs. A guardian "blood-brain barrier" prevents most substances in the blood from entering the brain (alcohol and caffeine being two well-known exceptions). However, nano particles have repeatedly been shown in animal studies to pass into the brain, where their effects are unknown. Will they accumulate and, if so, to what effect?

Nano particles may disrupt the immune system, cause allergic reactions, interfere with essential signals sent between neighboring cells, or disrupt exchanges between enzymes, Swiss Re says. Some of these characteristics may be harnessed for benefit -- for example, in experiments a carbon nano crystal has been able to disrupt one of the processes that allow the AIDS virus to multiply.

Nano particles in disposable products will eventually enter the environment. In the environment, nano particles represent an entirely new class of pollutants with which scientists (and nature) have no experience. Swiss Re speculates that, "Via the water cycle, nano particles could spread rapidly all over the globe, possibly also promoting the transport of pollutants." Swiss Re asks, "What would happen if certain nanoparticles did exert a harmful influence on the environment? Would it be possible to withdraw them from circulation? Would there be any way of removing nanoparticles from the water, earth, or air?"

Turning to workplace hazards, Swiss Re asks whether nano particles will become the next asbestos. To protect workers, effective face masks are "not a very realistic prospect at present, since the requisite design would render normal breathing impossible." New designs may be possible but remain unproven.

The Need for Caution

What would precaution look like in a rapidly developing field like nanotech? The British Royal Society and the Royal Academy of Engineering[1] issued a nanotech report in July 2004 recommending a series of precautionary actions, with the following chain of reasoning:

- "The evidence we have reviewed suggests that some manufactured nanoparticles and nanotubes are likely to be more toxic per unit mass than particles of the same chemicals at larger size and will therefore present a greater hazard."
- "There is virtually no evidence available to allow the potential environmental impacts of nanoparticles and nanotubes to be evaluated."
- Therefore, "the release of nanoparticles to the environment [should be] minimized until these uncertainties are reduced."
- And, "until there is evidence to the contrary, factories and research laboratories should treat manufactured nanoparticles and nanotubes as if they were hazardous and seek to reduce them as far as possible from waste streams."

NRDC supports these recommendations as rational and practical. They reverse the traditional approach to industrial materials, which have historically been assumed benign until shown otherwise. The Royal Society puts the burden of producing information about safety on industry, not on the public: "A wide range of uses for nanotubes and nanoparticles is envisaged that will fix them within products.... We believe that the onus should be on industry to assess ... releases [of nano particles from products] throughout a product's lifetime (including at the end-of-life) and to make that information available to the regulator." From such a recommendation, it is a very short step to the European Union's precautionary proposal for industrial chemicals, called REACH (Registration, Evaluation and Authorization of Chemicals), which is often summarized as, "No data, no market." The Royal Society recommended that the use of zinc oxide nano particles and iron oxide nano particles in cosmetics should "await a safety assessment" -- in other words a moratorium on these products is recommended. Likewise, "the release of free manufactured nanoparticles into the environment for [pollution] remediation (which has been piloted in the USA) should be prohibited until there is sufficient information to allow the potential risks to be evaluated as well as the benefits.

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[1] U.K. Royal Society of Engineers: Nanoscience and Nanotechnologies: Opportunities and Uncertainties. The U.K. Royal Society report on nanotechnologies - 'Nanoscience and nanotechnologies: opportunities and uncertainties' - was published on 29 July 2004. The report illustrates the fact that nanotechnologies offer many benefits both now and in the future but that public debate is needed about their development. It also highlights the immediate need for research to address uncertainties about the health and environmental effects of nanoparticles – one small area of nanotechnologies. It also makes recommendations about regulation to control exposure to nanoparticles. http://www.nanotec.org.uk/finalReport.htm

The U.S. President's Council of Advisors on Science and Technology (PCAST) issued their review of the National Nanotechnology Initiative at Five Years this spring (May, 2005). [2] Although the text of the report is 46 pages long, the section addressing "Environmental, Health and Safety" concerns doesn't appear until page 35 (Chapter 3), and is less than one page long. In that short section the Report states that only 4% of the total FY2006 budget for nanotechnology is, "aimed primarily at understanding and addressing the potential risks posed by nanotechnology to health and environment." The report weakly adds that there is also research in other areas that "would likely" include health and environmental effects. In any case, the roughly $40 million earmarked for health and environmental effects research is paltry and inadequate to keep pace with the $1 billion budget driving nanotechnology R&D. An equally paltry sum is earmarked for "societal concerns", suggesting that readying the market for nanomaterials will require equal efforts at understanding the health impacts and allaying the public's fears. This "fuzzy thinking" neglects to acknowledge that the public's fears would be best allayed if the potential hazardous health and environmental impacts of nanomaterials were thoroughly researched in an independent and transparent manner by credible institutions, and made available to the public.

As currently allocated, the budget for evaluation of potential health and environmental impacts is following a familiar precedent we observed with genetically modified foods and other biotechnology developments. The results of this serious oversight in addressing public safety issues for these products has been a very widespread public concern regarding safety, rejection of many products, and the barring of some products from large international markets. The lack of adequate information has also led to considerable concerns regarding health impacts of the genetically-modified products among scientists and the medical community who still do not have adequate information to evaluate the risks their hazards. The lack of adequate funding and regulatory requirements for testing are responsible for causing these problems. By ignoring public health and environmental concerns, a public response was generated against genetically-modified foods that resulted in the loss of potential benefits to society, as well as justifiable anger, suspicion, and discrediting of the agencies and institutions charged with the protection of public health. The current budget allocation for evaluation of nanotechnology is so woefully insufficient that it is clear that the same path is being followed for this class of materials, likely leading to the same outcomes we have observed in biotechnology. In fact, the emphasis on health and safety testing, having lagged for years behind the product development and applications efforts, needs a disproportionately large emphasis for some time in order to "catch up" with the R&D that has already been carried out as well as ongoing new developments.

While there is no turning back from nanotechnologies-- and, indeed, we are optimistic about their potential benefits if they are developed in a prudent fashion-- in the face of such large unknowns, proceeding with extreme caution is recommended by all who are monitoring wide-scale use of these new advances. The need for caution draws in part on the experience with the discovery of radiation a century ago. Radiation-based technologies, such as diagnostic X-rays, have saved millions of lives and enhanced the quality of medical and dental care dramatically. But these advances came at an unnecessarily high cost. Early researchers did not consider the possible dangers of radiation, and many research workers died young from radiation sickness. Many others were harmed by radiation-based patent medicines that were brought to market before the biophysics of radiation was understood. The potential hazards of widespread nanotechnology could be far greater than those of radiation. Until we can demonstrate the safety of particular nanomaterials, research and application on them must proceed with great caution.

RECOMMENDATIONS:

These recommendations are generally consistent with the Report of the U.K. Royal Society of Engineers[3] (Spring, 2004); a Report by Swiss Re insurance company[4] (Spring 2004); and by participants in a diverse

[2] U.S. President's Council of Advisors on Science and Technology (PCAST). The U.S. National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel. May, 2005. Report available online at http://www.ostp.gov/PCAST/pcast.html

[3] U.K. Royal Society of Engineers: Nanoscience and Nanotechnologies: Opportunities and Uncertainties. The U.K. Royal Society report on nanotechnologies - 'Nanoscience and nanotechnologies: opportunities and uncertainties' - was published on 29 July 2004. http://www.nanotec.org.uk/finalReport.htm

multi-stakeholder meeting co-hosted by the Environmental Law Institute and the Woodrow Wilson Center for International Studies[5], Washington DC (May 25, 26, 2005).

A. Prevent release of engineered nanomaterials

Until more is known about environmental impacts of nanomaterials (nanoparticles and nanotubes), we recommend that the release of manufactured nanomaterials into the environment be prevented. This recommendation is consistent with those of the Swiss Re insurance company, and of the U.K. Royal Society of Engineers report discussed in these comments. We believe that this is both reasonable and feasible.

B. Declare engineered nanomaterials to be "new" chemical substances

Engineered nanomaterials should be tested and regulated as new chemical substances, and not presumed to be similar to their bulk counterparts. Just as diamond is not coal, we know that carbon nanotubes do not have the same toxicity profile as carbon. Engineered nanomaterials are sufficiently different from existing materials that they are being patented, supporting their classification as "new" materials. The May, 2005 report of a U.S. advisory panel reported that US Patent and Trademark Office have issued over 8,600 nanotechnology-related patents in 2003[6]. This represents an increase of about 50% over the number issued in 2000. Not only the U.S. is considering these materials to be sufficiently innovative as to be patentable; according to this report, nanotechnology-related patents in 2003 were also issued in Japan (926), Germany (684), Canada (244), France (183), and other countries to a lesser degree.

C. Require adequate toxicity testing for engineered nanomaterials intended to be commercially available

We recommend that adequate toxicity testing be required of all engineered nanomaterials before they are released into commerce. For an engineered nanochemical or nanomaterial to remain on or be placed on the market manufacturers must be required to provide publicly available safety data sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment, including hazard, use and exposure information, no matter how little volume of nanomaterials they are producing.

It is necessary to approach these materials as fundamentally different from their bulk counterparts with respect to quantification, and develop a health or damage based metric for establishing reporting and control policies. This is analogous to our approach to gamma emitting radioisotopes, or other materials with unique physiochemical properties such as asbestos fibers. The quantification in those cases is tailored to the behavior and risk management needs of the materials. Because the specific characteristics of nanomaterials vary widely and do not share common characteristics (as, for example, all beta emitting radioisotopes do), it is essential to rapidly identify the critical characteristics that require monitoring and control. The need for this information is fundamental and requires immediate and substantial investment in testing and evaluation in order to establish appropriate regulatory strategies.

D. Develop an inventory for all engineered nanomaterials

We recommend that an International authority oversee the development an inventory for all engineered nanomaterials. It is important that all engineered nanomaterials be included on an inventory as distinct nanoscale materials, with distinct properties. The inventory should be made publicly available in a transparent database or repository that is accessible to the International community, with consideration of reasonable claims for protection of confidential business information.

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[4] Swiss Re. Nanotechnology: Small matter, many unknowns. http://www.swissre.com/

[5] U.S. Environmental Law Institute. Securing the promise of nanotechnology: Is US environmental law up to the job? http://www2.eli.org/research/events/nanotech5.25.05.cfm

[6] President's Council of Advisors on Science and Technology (PCAST). The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel. May, 2005. Report available online at http://www.ostp.gov/PCAST/pcast.html

E. Develop an export notification and tracking system

We recommend that an International authority develop an export notification and tracking system for all engineered nanomaterials. Without some type of export notification and tracking system, nanomaterials could be exported for use, distribution, processing, or disposal to anywhere in the world with no way of tracking its/their movement. The tracking results should be made publicly available in a transparent database/repository that is accessible to the International community, with consideration of reasonable claims for protection of confidential business information.

F. Develop Adequate Information regarding hazard and exposure

We recognize that the definition of "adequate" information regarding nanomaterials will develop in the context of both national and international regulatory needs. We do not here propose to pre-define or limit that determination, but rather to propose basic elements that we feel are necessary but not sufficient elements of an adequate information database to regulate the commercial use of nanomaterials.

We recommend that government require comprehensive safety data for all engineered nanomaterials: For an engineered nanochemical or nanomaterial to remain on or be placed on the market we recommend that manufacturers be required to provide publicly available safety information about that chemical. The information must be sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment, including hazard, use and exposure information.

Basic information required of all engineered nanomaterials should include: a full life cycle analysis including fate and effects information; solubility; bioavailability; basic physical/chemical properties such as electrical conductivity, particle size, configuration, mass/surface area ratio. Importantly, the availability of screening and detection methods must be demonstrated so that tracking of nanomaterials in the ecosystem and as a body burden in human populations can be performed.

All toxicity testing should be done in a publicly-accessible and transparent manner by a credible independent authoritative body, conducted according to generally accepted laboratory practices. All results should be made publicly available in a transparent database/repository that is accessible to the International community, with consideration of reasonable claims for protection of confidential business information.

The public and workers must be provided with the opportunity to know and participate in the evaluation and regulation of nanomaterials. Information disclosed to the public and workers must include quantities of nanomaterials produced, used, released, and exported, hazard, use and exposure information.

To date we have no experience with the impacts of aging, degradation, or interaction on most nanomaterials. The potential hazards posed by interaction or breakdown products is essential and must be addressed in the above described toxicity testing. Mechanisms for safe disposal or destruction of nanomaterials must be described so that cradle-to-grave safety can be assured.

As a precautionary measure to address inevitable shortcomings and uncertainty in any testing regimen, there must be a protocol prescribed for initial tracking of materials that do enter the market with respect to impacts on the health of those involved in production, use, and disposal, of products. As we have learned recently from experience with extensively tested pharmaceuticals on the market, there are many impacts on human health which are not fully characterized and predicted by pre-market testing, no matter how extensive. Even with ostensibly "safe" products, post-market monitoring is essential.

G. Long-term regulatory objectives

- We recommend that nanomaterials be regarded as hazardous until demonstrated to be safe, based on an established set of reasonable criteria.
- We recommend that the ingredients lists of consumer products identify when manufactured nanomaterial has been added.
- We recommend that all nanomaterials be considered hazardous until demonstrated otherwise, and we recommend that those lacking demonstrated safety be prevented from entering commerce unless

they can be used in a safe manner so as to prevent human exposures or releases to the environment.

- We recommend that Governments initiate adequately funded public dialogue around the development of nanotechnologies. We recognize that a number of bodies are appropriate in taking this dialogue forward, including labor unions, public interest groups, the health and medical community, nanotechnology manufacturers, nanotechnology users, nanotechnology regulators, and academic nanoscience researchers.
- Inequalities within and between nations may be exacerbated if individuals and corporations gain monopoly control of nanotech by patenting the building blocks of the universe[7] . International co-operation between nations needs to ensure equitable impact of nanotechnologies.

[7]ETC Group. The Little Big Down: A Small Introduction to Nanoscale Technologies. ETC Group is a public interest group whose position is a moratorium on nanomaterials being used in commerce, until we have a better understanding of the toxicity of these materials, and government regulations to adequately protect human health and the environment. http://www.etcgroup.org/search.asp?theme=11

E9. QUESTIONNAIRE RESPONSES FROM SCIENCECORPS, US

I am providing a response to the survey was forwarded to me by Rory O'Neill last week and apologize for the unavoidable delay in conveying this so you. Due to time constraints, my comments are brief. I have no financial interest in nanotechnology development or in the control, regulation, or policies that may evolve to address nano or micro materials. I am submitting comments as the Director of Sciencecorps.org, Lexington, Massachusetts, which is a small international alliance of scientists, technical experts, educators and others. Our activities are summarized at: www.sciencecorps.org

As a research scientist for many decades, I enthusiastically support the efforts across the sciences to develop new materials and tools to improve health, food security, housing, economic development, and other essentials. Nanomaterials offer tremendous potential in all of these areas, and are a logical product of the evolution of the physical sciences and its integration with other sciences. As with radiological sciences, the unique nature of nanomaterials offers opportunities that are not afforded by other means. And as with radiological materials, the benefits and hazards will only be fully appreciated as this field develops over future decades. Thus governments bear an unusually large burden of both fostering responsible development and mitigating hazards that are associated with these materials. We have the benefit of learning from the history of radiological and chemical sciences that very high hazards may be associated with new technologies. It is our responsibility to take a precautionary approach so that we avoid repeating the mistakes of the past. There is no excuse in the 21st century for the scientific establishment to ignore the hazards of nanomaterials that we have become aware of, having learned from early experiments on radioactivity when tragic deaths occurred among of many scientists and hose working in early production facilities. It is essential that the spectrum of potential hazards be explored as a part of responsible R & D so that the safest possible products can be developed.

We have sufficient knowledge of the behavior of some nanomaterials in the body to know that the pharmacokinetics are nanosized particles are unique and may be far more harmful than their traditionally-sized chemical counterparts. Movement of nanomaterials along neurons to the brain, while potentially life saving in some contexts, is not a trait that we want in materials that laboratory workers or the public are exposed to. Governments and international groups responsible for environmental and worker health and safety (e.g., ILO, UNEP) must take agressive action to require full hazard characterization and strict controls during the development process so that R & D can be conducted safely and with full disclosure to participants and local communities. Using the concept of REACH, researchers and those who fund new materials development must take seriously their responsibilities to consider health and safety first and foremost in their efforts to bring the benefits of new technologies to the fore.

A number of forward thinking groups have suggested specific strategies for protection that I will not repeat here. They focus on production, commerce, and end-of-lifecycle product disposal. My focus is on actions and hazards within the R & D community. Through my work with researchers at Harvard University and the Massachusetts Institute of Technology, both in the Boston area where I live, I am very aware that most who work in R & D for chemicals and materials (including nanomaterials) are unaware that any hazards exist and there are not programs to provide education, protective strategies, or monitoring of those working in R & D. This is a very serious and potentially tragic situation. I have attached information I recently provided at the Collegium Ramazzini conference in September of this year in Bologna, Italy (http://www.collegiumramazzini.org/). The text is brief and contains some specific suggested governmental actions address the unique needs within R & D. Thus, I believe this is relevant to your survey.

It is critical to all scientists that we not allow our colleagues to be harmed in the pursuit of benefits to society. It is both unnecessary and unconscionable. If safety can be introduced at the level of R & D, it can be maintained far easier as any successful new materials proceed to production and commercial distribution. Thus, precautionary actions during the R & D phase are both logically and economically rational.