

INTERNATIONAL RISK GOVERNANCE COUNCIL

# **SURVEY ON NANOTECHNOLOGY GOVERNANCE**



## **Volume A. The Role of Government**

**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 government’ 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.

## CONTENTS OVERVIEW

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1.	BACKGROUND.....	5
2.	LIST OF SURVEY PARTICIPANTS.....	6
3.	WHAT ARE THE MAIN FINDINGS?.....	7
	Summary of current governance strategies.....	7
	Recommended governance strategies.....	8
4.	RESEARCH AND DEVELOPMENT STRATEGY .....	9
	Overall research and development strategy.....	9
	Research focus – fundamentals and applications .....	11
	Research focus - risks .....	12
5.	REGULATIONS FOR NANOTECHNOLOGY.....	13
6.	CURRENT GOVERNANCE STRUCTURES IN PLACE.....	13
7.	COOPERATION .....	14
	International cooperation .....	14
	Coooperation amongst policymakers.....	15
	Cooperation with NGOs.....	16
	Co-operation with research organisations.....	16
	Cooperation with industry .....	17
	Cooperation with the public.....	17
8.	RECOMMENDATIONS FOR RISK GOVERNANCE.....	17
	Risk Research recommendations .....	18
	Stakeholder Engagement recommendations .....	18
	Risk communication recommendations.....	19
	Governance approaches.....	19
9.	REFERENCES .....	22
10.	ANNEXES .....	23
	Annex A – About the IRGC .....	23
	Annex B – A definition of ‘risk governance’ .....	24
	Annex C – Acknowledgements .....	24
	Annex D – Tables with detailed survey results.....	25
	Annex E – Questionnaires .....	33
	Questionnaire answers from Canada.....	33
	Questionnaire answers from Chinese Taipei.....	40

Questionnaire answers from France .....	44
Questionnaire answers from Germany.....	55
Questionnaire answers from Ireland.....	66
Questionnaire answers from Italy.....	75
Questionnaire answers from Japan (Dr M. Ata and Dr. K. Tanaka).....	77
Questionnaire answers from Japan (Dr T. Marimoto).....	77
Questionnaire answers from PR China .....	77
Questionnaire answers from South Korea.....	77
Questionnaire answers from United Kingdom (UK).....	77
Questionnaire answers from United States of America (US).....	77
Annex F – Summaries on nanotechnology activities from other countries (from Meridian Institute study sponsored by NSF, 2004).....	127
Nanotechnology in Argentina.....	127
Nanotechnology in Australia.....	128
Nanotechnology in Austria.....	130
Nanotechnology in Belgium.....	131
Nanotechnology in Brazil.....	132
Nanotechnology in Czech Republic.....	132
Nanotechnology in European Union.....	135
Nanotechnology in India.....	135
Nanotechnology in Israel.....	136
Nanotechnology in Mexico.....	137
Nanotechnology in The Netherlands.....	137
Nanotechnology in New Zealand.....	138
Nanotechnology in Romania.....	140
Nanotechnology in Russia.....	142
Nanotechnology in South Africa.....	144
Nanotechnology in Switzerland.....	146

**TABLES**

Table 1:	Survey participants .....	6
Table 2:	Risk governance recommendations .....	8
Table 3:	Overview of research and development strategy .....	25
Table 4:	Overview of current governance practices .....	30

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## 1. BACKGROUND

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This survey on the role of governments, which took place during the period July to November 2005, is the first in a series which 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 NGOs, industry, international organisations, research organisations, and others. 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 main 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 an expert workshop held in May 2005 and the IRGC White Paper 'Nanotechnology and the Need for Risk Governance', will be used as source materials for a further expert workshop on 30<sup>th</sup> and 31<sup>st</sup> January 2006 – at which the proposals for risk governance recommendations will be developed. The project will conclude with a final conference on the 6<sup>th</sup> and 7<sup>th</sup> of July 2006 at which IRGC will endeavour to reach a consensus of opinion amongst key stakeholders regarding appropriate risk governance approaches for nanotechnology. IRGC's final recommendations will be published shortly after the conference.

The surveys were originally sent to potential participants from 16 different economies (Australia, Brazil, Canada, Chinese Taipei, Egypt, France, Germany, India, Ireland, Italy, Japan, PR China, South Korea, South Africa, the UK and the US), as well as the European Commission, and during the relevant time period the following 12 responses were received: Canada, Chinese Taipei, France, Germany, Ireland, Italy, Japan (two separate responses), PR China, South Korea, the UK and the US. These responses are summarised in the following sections, whilst each full survey reply is annexed (Annex E).

The respondents' countries represent a significant portion of those actively engaged in advanced nanotechnology development. Nevertheless it must be recognised that the responses received, and as a consequence this summary report, can only be representative of the activities and views of those countries, agencies, or individuals surveyed. In particular it should be noted that this survey has not been completed by countries with relatively smaller and relatively recent R&D programmes. The reason for this is twofold: either the particular respondent selected by IRGC has not yet responded to the survey, or we were unable to detect any significant governance approaches and policy specific for nanotechnology. Those countries (such as Brazil, India and South Africa) responded to a previous survey focused only on the status of nanotechnology (study completed by the Meridian Institute and sponsored by NSF in June 2004; see website: <http://www.nsf.gov/crssprgm/nano/activities/dialog.jsp>). Summaries of those statements in the 2004 study are given in Annex F for the following economies: Argentina, Australia, Austria, Belgium, Brazil, Czech Republic, European Commission, India, Israel, Mexico, the Netherlands, New Zealand, Romania, Russia, South Africa, and Switzerland.

The following interpretations of the responses by the individuals are based on their personal recommendations and suggestions for risk governance and are not directly attributable to the countries which these respondents represent. The responses are listed in this survey without any relative ranking. The full text of the responses is provided in the Annex.

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## 2. LIST OF SURVEY PARTICIPANTS

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

**Table 1: Survey participants**

Country	Participants	Title and/or organisation
Canada	Paul Dafour	Senior Advisor, International Affairs, Office of the National Science Advisor
Chinese Taipei	Dr. Gwo-Dong Roam	Director General, Environmental Protection Agency
France	Dr. Françoise Roure	Vice President Legal and Economic Section, Council General for Information Technologies, Ministry of Economy, Trade and Industry
Germany	Dr. Dr. Bernd Hunger Dr. Gerd Bachman	German Federal Ministry of Education and Research VDI Technologiezentrum GmbH
Ireland	Dr. Helena Acheson	Science, Technology and Innovation Policy And Awareness Division Advisory Council for Science and Technology
Italy	Dr. Elvio Mantovani	Airi/Nanotech-IT General Manager, Italian Centre for Nanotechnology
Japan	Dr. Masafumi Ata  Dr. Kazunobu Tanaka	Senior Researcher, Ministry of Economy, Trade and Industry, National Institute of Advanced Industrial Science and Technology Senior Fellow, Center for R&D Strategy (CRDS), Japan Science and Technology Agency (JST)
Japan	Dr. Tatsuo Marimoto	Director for Nanotechnology, Materials and Manufacturing Technology, Cabinet Office of Prime Minister, Bureau for Science and Technology Policy
PR China	Prof. Chunli Bai	Director of the National Center for Nanoscience and Technology, Chinese Academy of Sciences
South Korea	Dr. Jo-Won Lee	Director, The National Program for Terra-level Nanodevices
UK	Dr. Randal Richards	The Engineering and Physical Sciences Research Council
US	Dr. Mihail Roco	Senior Advisor, National Science Foundation, and Chairman, NSTC Subcommittee on Nanoscale Science, Engineering and Technology

## 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. All budgets which have been provided within the surveys and are included in this report have been expressed in US Dollars for comparison purposes – the main exchange rates used are 1.18 USD/EUR and 0.85 USD/CAD.

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### 3. WHAT ARE THE MAIN FINDINGS?

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#### SUMMARY OF CURRENT GOVERNANCE STRATEGIES

The rapidly increasing amount of research and development taking place in nanotechnology suggests that this area is an important part of national science and technology agendas particularly within the fields of materials, biotechnology, medicine, electronics, engineering, sensors, aerospace, food quality, environmental monitoring and metrology. To date, less emphasis has been placed on risk governance, although projects which address health, safety and the environment, toxicology and ecotoxicology, standards and nomenclature, patenting and worker safety have been initiated in the last few years. Information on this work is being compiled through international expert bodies, research institutes, industry representative groups, and public bodies. In several countries, central research coordination bodies have been established, and many existing research institutions and national ministries are prioritising nanotechnology. The national ministries involved in R&D are science and technology, education, defence, health, energy, environment and economic development. In order to facilitate collaboration, and provide access to tools and materials, nanotechnology centres are being constructed in nearly all of the countries surveyed.

In order to promote transfer of knowledge to the market sector, governments are encouraging collaboration between industry and academia. Strategies include financial support for small business and start-ups, tax incentives, the establishment of nanotechnology networks and funding of collaborative projects. Internationally, cooperation is taking place within the fields of fundamental research and education, science and technology innovation, responsible development, development of standards and environment, health and safety. Methods of cooperation include, inter alia, networks, workshops, committees, dedicated internet sites, exchanges of personnel, and collaborative projects.

At the national level some countries have established nanotechnology-specific inter-ministerial bodies to provide guidance for policy development, with members drawn from within government and external experts. The majority of these bodies are established within the national ministry for science and technology, and this ministry is the focal point for policy development. Other ministries involved in governance policy include those for the economy and the environment. In several countries (the US, Japan, PR China, Chinese Taipei, South Korea), there are interagency coordinating offices under the offices either of the prime minister or of the president. Strategic policy for risk governance is still underdeveloped although there is a clear acknowledgement that this needs to become a focal point. Some examples of current activity include, inter alia, a requirement for nanotechnology centres to address issues of risk, establishment of best practices and standards, and the funding of research programmes for both physical and social risks. Currently the main priority is to increase the knowledge base and monitor development so that efficient strategies can be put in place in the future.

## RECOMMENDED GOVERNANCE STRATEGIES

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

Type of governance strategy	Recommendations, suggestions and ideas
Risk research recommendations	<ul style="list-style-type: none"> <li>§ Advance studies of hazard, exposure and risk of nanoproducts</li> <li>§ Categorisation and standardisation of materials</li> <li>§ Education and training for researchers and manufacturers</li> <li>§ Application of risk evaluation procedures tailored to nanotechnology applications</li> <li>§ Environmental, health and safety impacts required input to R&amp;D projects</li> <li>§ Specific plans for environmental impact, chemical toxicity and pollution control</li> <li>§ Green design and green manufacturing</li> <li>§ Nanoproducts lifecycle approach</li> <li>§ Address questions of ownership, control and social ends</li> <li>§ Identification of stakeholder needs through engagement</li> <li>§ Investment in key areas for sustainable development</li> </ul>
Stakeholder engagement recommendations	<ul style="list-style-type: none"> <li>§ Regular workshops with stakeholders</li> <li>§ Dedicated public groups</li> <li>§ Social scientist participation at R&amp;D stage</li> <li>§ Lowering of organisational barriers</li> <li>§ International dialogue between ethical advisory committees</li> </ul>
Risk communication recommendations	<ul style="list-style-type: none"> <li>§ Balanced disclosure of positive and negative evidence</li> <li>§ Information provided tailored to the knowledge levels of different stakeholders</li> <li>§ Channels for dissemination of information appropriate for accessibility by different stakeholder groups</li> <li>§ Encourage independent sources of information</li> <li>§ Communication of secondary unanticipated consequences</li> <li>§ Periodical re-evaluation of risk to be disseminated to the public</li> <li>§ Maintaining a minimum level of interaction with the public for a continuum message</li> </ul>
Governance approaches	<p>International expert bodies:</p> <ul style="list-style-type: none"> <li>§ Joint projects of industry and scientific organisations</li> <li>§ International networks of excellence on risk governance of nanotechnology</li> <li>§ A supranational body to supervise international rules</li> <li>§ An issue specific expert advisory committee</li> <li>§ UN to coordinate conflicting national policies</li> <li>§ Focus on topics of global interest</li> <li>§ Sharing of materials and instrumentation</li> <li>§ Collaboration of national nanotechnology coordination bodies</li> <li>§ Coordinated planning for transporting nanomaterials across boundaries</li> <li>§ Technology-by-technology approach to ethical considerations</li> <li>§ Technical advice based on unified criteria</li> </ul> <p>Self-regulation</p> <ul style="list-style-type: none"> <li>§ International standards on classification, terminology and nomenclature</li> <li>§ Guidelines for research and development</li> <li>§ Peer review of publications</li> <li>§ Voluntary peer reviews of decision processes</li> <li>§ Open-source software development model</li> </ul> <p>Government</p> <ul style="list-style-type: none"> <li>§ Labelling of consumer-sensible nano-related products</li> <li>§ Structured international agreement</li> <li>§ R&amp;D channelled through national coordinating bodies</li> <li>§ Strengthened capacity of legislative institutions to respond to emerging technologies</li> <li>§ Development of compensation mechanisms</li> <li>§ Development of nomenclature and standards of risk for different categories or products</li> <li>§ National, international and supranational cohesiveness on regulatory schemes, definitions and nomenclature, best practices, common assessment policies and testing protocols</li> </ul> <p>Industry</p> <ul style="list-style-type: none"> <li>§ Voluntary disclosure and product labelling</li> <li>§ Collaborate with governments, NGOs, researchers and public organisations</li> </ul>

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#### 4. RESEARCH AND DEVELOPMENT STRATEGY

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Questions 1 and 2 of the survey addressed research and development strategies, including the scope and type of research being conducted, any specific investment funding for nanotechnology, and information regarding the institutions involved. The following provides a summary of key points identified. For further information and for comparison purposes Table 3 provides a breakdown of the strategies of each country based on the responses received.

##### OVERALL RESEARCH AND DEVELOPMENT STRATEGY

###### Ø Coordination of research and development (R&D)

The respondents provided information regarding the coordination of research and development at national level. All 11 countries have a nationally coordinated R&D activity, but use different mechanisms. Three types of R&D strategies can be identified: four countries (France, Chinese Taipei, the UK and the US) have in place a central coordinating body approved by the legislative branch with funding mechanisms specific for nanotechnology; five countries provide funding through existing research mechanisms (Canada, PR China, Ireland, Italy and Japan) while having a consultative body in the government at national level; and the remaining two countries provide funding through individual national ministries and agencies (Germany and South Korea) under a national framework approved by the legislative body. Specific examples of each strategy are listed below:

- A central coordinating body. For example Chinese Taipei has in place a National Science and Technology Program for Nanosciences and Nanotechnology (2003-2008) which coordinates four sub-programmes: the Industrial Program receives 61% of funding; the Academic Excellence Program 21%; the establishment of Core Facilities 16%; and the Education Program 2%.
- Funding through existing national funding and research mechanisms under a consultative body in government. For example, Italy is allocating funds through its National Research Programme with about 50% of overall funding being used for nanoscience and nanotechnology at universities and public research organisations.
- Investment in nanotechnology through individual national ministries and agencies under a national framework. For example, Germany funds 43% of its public expenditure on nanotechnology through the Federal Ministry of Education and Research (BMBF), 8% through the Ministry of Economics and Employment (BMWA), and 49% via institutional support of the BMBF-funding agencies of the German Research Society (DFG), the Leibniz Science Association (WGL), the Helmholtz Association of National Centres (HGF), the Max Planck Society (MPG), and the Fraunhofer Society (FhG).

###### Ø Avenues for research and development funding

The major avenues for research and development funding were identified as national and local public agencies, at times under specific nanotechnology programmes, universities and research institutes, nanotechnology centres, and the private sector. The majority of responses were focused on R&D carried out by publicly funded agencies (this was a government survey), although some information was also provided regarding academic and private avenues.

- Public agencies - a large amount of research funding for nanotechnology comes from national science institutions, education, defence, health, energy and economic agencies. For example:

- § Italy has a technological district called Veneto Nanotech which promotes and supports R&D and has built a nanofabrication facility funded by both the local region and the Ministry for Education, University and Research;
  - § Estimated research funding in the US for 2005 was attributable to the National Science Foundation (31%), Department of Defence (24%), Department of Energy (19%), National Institutes of Health (13%), National Institute for Occupational Safety and Health (0.3%), and the Environmental Protection Agency (0.5%);
  - § In Japan, in 2004, 76.3% of the nanotech and materials budget was held by the Ministry of Education, Culture and 19.5% by the Ministry of Economy, Trade and Industry.
- Universities and research institutes – support for funding through these entities is featured in the survey. Three examples are in Canada, the UK and the US: in Canada university research is funded through already existing grant making platforms - the Natural Sciences and Engineering Research Council (NSERC), the Canada Foundation for Innovation (CFI), and the Canadian Institutes for Health Research (CIHR); in the UK, the Micro and Nanotechnology Initiative in the Department of Trade and Industry (DTI) directly funds pre-competitive research at universities, research institutes and in industry, and the Research Councils (RCs) fund basic and applied nanotechnology research at universities and research institutes; in the US – 65% of funding is dedicated to academic research, and 25% to research institutes and laboratories.
  - Specific nanotechnology programmes – there are many programmes being initiated at national level, with the majority being geared towards the development of fundamental and applied science and engineering over a wide range of research areas. In the large number mentioned, the following three examples provide an illustrative selection:
    - § In 1991, the US National Science Foundation began a programme on nanoparticle synthesis and processing at high rates.
    - § In 1999, PR China began an ongoing Nanomaterial and Nanostructure project which provides support for basic research in nanomaterials;
    - § Japan, through its Coordination Program of Science and Technology Projects has selected 8 themes for Nanotechnology – hydrogen and fuel cells, nanobiotechnology, ubiquitous network, next generation robots, biomass utilisation, post genome, infectious diseases, and regional clusters;
    - § South Korea's Frontier Program promotes research into nanodevices, nanomaterials and nanomechatronics.
    - § In the UK, the Interdisciplinary Research Collaboration in Bio-Nanotechnology aims to investigate bio-molecular systems, from the level of single molecules to complex molecular machines, to establish their function; and apply this knowledge to produce artificial electronic and optical devices
  - Nanotechnology centres – nearly all of the countries surveyed used dedicated centres for both developing infrastructure for widespread use and advancing knowledge. For example, Ireland's Centre for Research on Adaptive Nanostructures and NanoDevices (CRANN) has received US\$11.8m from the National Science Foundation Ireland for research into inter alia, nanoscale organisation and self-assembly. In the US the 16 Nanoscale Science and Engineering Centers (NSEC) have been funded by the National Science Foundation since 2000; the National Nanotechnology User Network was created in 1994. In South Korea, the National NanoFab Center provides facilities for nanotechnology research.
  - Private sector – several respondents provided information on public funding of the private sector. For example, France is funding small-to-medium sized enterprises (SMEs) through the French Agency for Innovation, Ireland has a major strategy during the next 3 years to create 8 new start-up companies, and Canada is promoting private sector

development through tax incentives. In addition, information was provided regarding the development of nanotechnology in the German industrial sector (e.g. 400-500 companies are involved primarily in the automotive and machine construction industries, in chemicals and pharmaceuticals, in the optical industry, medicine and biotechnology, as well as in power generation and construction). In March 2005, about 1400 companies dealing with nanotechnology were reported in the US.

## RESEARCH FOCUS – FUNDAMENTALS AND APPLICATIONS

The focus of nanotechnology research is broad and development is taking place across a wide range of sectors. A consolidation of those developments mentioned in the survey shows that the majority of R&D activity is taking place in the areas of materials, biotechnology, medicine, electronics, sensors, aerospace, engineering, food quality, environmental monitoring and metrology. The funding of several institutions outside of the academic arena illustrates areas of interest: for example, the Atomic Energy Commission and the National Aerospace Establishment in France, the National Metrology Institute in Germany, and the National Cancer Institute in the US (which has established a 5 year initiative - NCI Alliance for Nanotechnology in Cancer - with funding of US\$145m).

There are also differences between countries, some of which are mentioned below, however in order to provide appropriate comparisons further questions need to be asked. For instance, are certain areas of research excluded for research funding, such as the integration of biotechnology and nanotechnology? Is any funding being provided for research into applications which would benefit developing countries or promote sustainable development?

- PR China has a focus on nanomaterials, nanodevices, nanobiology and medicine, detection and characterisation.
- France allocates a large proportion of its public nanotechnology research funding to electronics (25%), with 20% going to optoelectronics, 10% to micro systems and another 10% to assembly, hybrids and connections.
- Canada has active nanotechnology research programmes in molecular sciences, microelectronics, materials sciences and engineering, aerospace, metrology, and biotechnology.
- Ireland is investing significantly in several research areas. One example is US\$14.2m nanotechnology-specific funding to the National Centre for Sensor Research (NCSR) to focus on chemical sensors and biosensors for uses including medical diagnostics, food quality and environmental monitoring.
- The major research strategy for Italy is in the integrated development of nanotechnology, microtechnology and advanced materials.
- In the UK there are currently three Interdisciplinary Research Collaborations (IRCs) in nanotechnology and examples of research include the fabrication of complex three dimensional structures with molecular precision, bio-nanotechnology in the area of bi-molecular systems to inter alia, produce artificial electronic and optical devices, and bio-nanotechnology in the area of tissue engineering.
- The US, Japan and Germany have broad programmes across most disciplinary areas

## RESEARCH FOCUS - RISKS

The responses indicate that risk studies seem to be focused on research into physico-chemical aspects related to nanomaterials. Participants identified progress being made in the following areas: issues associated with environmental, health, and safety (EHS); standards and nomenclature; patenting; and worker safety. The following examples demonstrate how research into risk is now beginning to accelerate:

- ∅ Environment, health, safety and environment (EHS) – several developments in this area include:
  - Ministry and agency coordination into the potential health risks of nanomaterials. For example the Nanotechnology Environmental and Health Implications Working Group in the US has membership from all Agencies which support or regulate nanotechnology research and products. In another example the Environmental Protection Agency of Chinese Taipei has introduced an Environmental Protection Programme in collaboration with the Council of Labour Affairs and Department of Health to examine issues such as environmental applications and implications of nanotechnology (databank development), pollution prevention and remediation, monitoring and measuring nanoparticles in the atmosphere (from automobile and industrial emissions), exposure to nanoparticles, and the proposal of regulations.
  - Measures at ministry level. For example the Ministry of Ecology and Environment (MEDD) in France has asked the Committee of Prevention and Precaution (CPP) to address the subject of relationships between health and environment, and between health and labour in general;
  - Focused investments in toxicology studies. For example, in the US the Department of Health and Human Services, National Institute of Occupational Safety and Health (NIOSH), and the Environmental Protection Agency (EPA) are funding the National Toxicology Program which studies the potential risks of exposure to nanomaterials and, in particular, titanium dioxide, quantum dots and fullerenes.
  - Establishment of a database for EHS. In Chinese Taipei a database has been set up for research materials concerning environmental applications and implications of nanotechnology.
  
- ∅ Standards. For example the French Standards Agency (ANFOR) has created a working group on nanotechnology which will address the needs for standards and regulations and is participating with the European Conformity scheme (CE marking) as part of Working Group 166 as well as with the International Standards Organization Technical Committee 229 on 'Nanotechnologies' to help ensure conformity of standards worldwide. In Germany the Federal Ministry of Education and Research (BMBF) is funding a collaborative project to compile recommendations for standards and nomenclature of processes capable of being calibrated; and in PR China the National Technical Committee 279 within the Nanotechnology Standardization Administration of China has already established 7 national standards on testing of surface area, pore size distribution of powdered or solid materials via gas adsorption, and the granularity of nano-sized powders. In the United States, the American National Standards Institute (ANSI) coordinates the national efforts and represents the US within the International Organization for Standardization (ISO) in Geneva.
  
- ∅ Patents. There is collaboration between the E.U., Japan and US patent offices on patents related to nanotechnology. Also, there are national efforts for improving the patent activities and education of examiners.
  
- ∅ Worker safety. For example the US National Institute of Occupational Safety and Health (NIOSH) is leading an effort within the federal government to develop a set of recommended safe handling practices for nanomaterials for both research and commercial production facilities, and they have published recommendations on the NIOSH website.

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## 5. REGULATIONS FOR NANOTECHNOLOGY

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There is no specific legislation nor regulations for nanotechnology with the exception of the US which in 2003 signed into law the '21<sup>st</sup> Century Nanotechnology Research and Development Act' (Public Law 108-153) [15] and which contains a section dedicated to the need to address societal implications. In addition, the US Department of Defence participation within the National Nanotechnology Initiative has been established by Public Law 107-314, and the National Institutes of Health also operate within special legislation regarding nanotechnology derived from Congress.

However, many respondents did recognise that nanotechnology may need new regulatory approaches due to the implications of size, persistence in the environment, disposal and self-assembling nanosystems. For several of the countries a first step towards researching the need for adapting existing legislation is a focus on developing appropriate monitoring and warning systems when current legislation proves insufficient.

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## 6. CURRENT GOVERNANCE STRUCTURES IN PLACE

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Question 4 of the survey addressed governance approaches to nanotechnology including how risks are assessed, monitored and managed. A summary of key points follows and for further information and comparison Table 4 provides a breakdown of the governance strategies of each country based on the responses received.

### Ø Policy coordination for nanotechnology

Two different structures for policy coordination for nanotechnology can be identified from the survey responses, although it is not clear how much influence the agencies involved can exert. In the majority of cases it appears that the agencies are a means of enhancing dialogue and exchanging information among policymakers with the potential to provide policy recommendations rather than bodies with specific authority.

The first structural type involves a single body which provides a cross-departmental forum for policy makers. For example PR China has a National Steering Committee for Nanoscience and Nanotechnology which provides planning, coordination and consultation for projects at national level and has members from all of the ministries as well as 21 leading scientists. In Canada the Federal Network on Nanotechnology provides an information-sharing forum for policy makers.

The second type of policy coordination takes place within an autonomous group as part of the national science and technology agency. For example, Ireland's NanoIreland project is developing a policy strategy which is managed within the Office of Science, Technology and Innovation (Forfás), whilst in Japan one member of the Council for Science and Technology Policy is directly responsible for the coordination of nanotechnology policy.

### Ø Public agencies involved in the governance of nanotechnology

The major public agencies reported as being involved in the governance of nanotechnology are within economic development, science and technology and environment for example:

- In Canada the Minister of Industry provides oversight to science and technology policy whilst the Prime Minister's Advisory Council on Science and Technology, co-chaired by

the Minister of Industry, and the National Science Advisor provide advice to Government on S&T issues and priorities. In the UK the Nanotechnology Issues Dialogue Group (NIDG) determines strategic actions which are then coordinated by the Department for Environment, Food and Rural Affairs. In addition to this the Research Councils are administered within the Office of Science and Technology Policy which is part of the Department of Trade and Industry.

- In the US policy is coordinated by the Nanoscale Science, Engineering and Technology Subcommittee of the National Science and Technology Council (NSET), the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB). These agencies all have oversight over the National Nanotechnology Initiative (NNI) which implements the policy recommendations of these Agencies.

#### ∅ Methods of risk governance

Very few policies were mentioned by respondents as having been established at national level to enhance risk governance in relation to nanotechnology. It seems from the survey responses that methods of risk governance are only at the very early stages of development, although the following examples provide evidence that countries are increasingly taking risk into account:

- ∅ In Canada existing risk governance practices in research ethics ensure compliance with guidelines maintained and developed through an Interagency Panel on Research Ethics.
- ∅ In the US recent developments include the 2005 National Institute for Occupational Health and Safety (NIOHS) best practices statements, and a public hearing held by the Environmental Protection Agency (EPA) to inform discussion as to how the Toxic Substances Control Act (TSCA) should be applied to nanomaterials, in particular as part of a voluntary pilot programme.

## 7. COOPERATION

Questions 5 and 6 considered issues of national and international cooperation in nanotechnology, including both formal and informal arrangements, such as “horizontal” connections within government, and with other organisations such as private industry and NGO’s.

### INTERNATIONAL COOPERATION

There are no specific international agreements pertaining to nanotechnology. However there is a great deal of activity taking place, mainly in the fields of innovation, responsible development, and environment, health and safety issues. The following two lists provide examples of those formal and informal international arrangements which have a direct impact on nanotechnology development and which were mentioned by the survey respondents.

#### **Formal arrangements**

- ∅ General Science and Technology (S&T) agreements between different nations. For example, Canada-Japan and South Korea-US within which nanotechnology forms a part of the activities.
- ∅ Standardisation - ISO TC229 is an international technical committee which is overseeing standardisation in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterisation (including calibration and certification), risk and environmental issues. The UK British Standards Organisation is providing the Secretariat for the committee, 23 other countries are participating in the committee (Australia, Belgium, Brazil, Canada, PR China, Denmark, Finland, France, Germany, India, Iran, Israel, Japan, South Korea, Malaysia, Netherlands, Poland, Russian

Federation, Spain, Sweden, Thailand and the US) and 10 countries are observing (Czech Republic, Egypt, Estonia, Hong Kong China, Italy, Morocco, Singapore, Slovakia, Switzerland and Venezuela)

- Ø The European Commissions 6<sup>th</sup> Framework Programme Nanosciences and Nanotechnology Initiative within which different nations (both European and international) cooperate through a National Delegate who is deemed to be their National Contact Point for nanotechnology.

### ***Informal arrangements***

- Ø Global Dialogue on Nanotechnology and the Poor – this Meridian Institute project is seeking to: raise awareness about the implications of nanotechnology for the poor; close the gaps within and between sectors of society to develop an action plan that addresses opportunities and risks; and identify ways that science and technology can play an appropriate role in the development process. This project is financially supported by the Rockefeller Foundation (US) and the International Development Research Centre (Canada).
- Ø International Dialogue on Responsible Research and Development in Nanotechnology – this is another Meridian Institute project which aims to bring together governmental representatives from countries with significant nanotechnology R&D programmes to discuss how to best ensure such programmes are carried out in a responsible manner. The first meeting, which took place in Alexandria in June 2004, brought together 25 governments and the EU to discuss nanotechnology development. This has become an annual dialogue and the third meeting will take place in Japan in 2006.
- Ø OECD workshop on 'Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety' conducted by the Working Group on Nanotechnology established under the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnologies of the Environment Directorate of the OECD.
- Ø Joint research projects, groups and bilateral symposiums. For example, PR China has held bilateral seminars on nanotechnology with several countries including the US, France, Germany and South Korea, whilst Japan has held a workshop with the UK on Health, Environment and Societal Issues of Nanotechnology.
- Ø Agency to agency cooperation. For example, the National Institute for Occupational Health and Safety in the US with the Health and Safety Executive in the UK.
- Ø Networks and forums. For example, EUREKA (a Europe wide network for market-orientated industrial R&D), European Parliamentary Technology Assessment (EPTA) Network; National Science Foundation (NSF) Nanotechnology Network; Networks of Excellence (NoE) in Europe; Global Nanotechnology Network; the European Commission funded Nanoforum network; and the Asia Nanotech Forum

### **COOPERATION AMONGST POLICYMAKERS**

The survey responses indicated that co-operation in the general realm of science and technology and amongst policymakers are taking place at a high government level through two types of collaborative bodies, in the form of interagency committees and through an interdepartmental advisory body. In addition to this, some countries have begun to develop nanotechnology-specific collaboration at policy level through the use of interagency projects, national networks and via nanotechnology research and policy coordination agencies. Examples of these different types of cooperation include:

#### ***General Science and Technology cooperation***

- Ø Interagency committees. For example, in Canada the Committee of Research Agencies, Councils and Foundations (Chaired by the National Science Advisor) addresses issues of science policy development in Canada.
- Ø National interdepartmental advisory body. For example, the Council for Science and Technology Policy in Japan contains members of all of the ministries and seeks to address

specific issues concerning Science and Technology R&D. The aim of this body is to eliminate vertical divisions amongst departments and provide influence directly to the Prime Minister.

### ***Nanotechnology specific cooperation***

- ∅ Interagency projects. For example, the Taiwan Environmental Protection Agency (TEPA) has collaborated with the Industrial Research Institute (ITRI) to study possible applications of nanotechnology for environmental protection.
- ∅ National networks specifically for nanotechnology. For example, the Canadian Federal Network on Nanotechnology, co-ordinated by Industry Canada, brings together policy analysts and programme managers
- ∅ A coordinating agency which orchestrates efforts for nanotechnology at national level. For example, in the US the National Nanotechnology Initiative develops partnerships with states, industry and local organisations.

### **COOPERATION WITH NGOS**

The survey answers did not introduce any evidence of official governmental collaboration with NGOs, and there was also little discussion on the influence that NGOs have been able to exert over the governance of nanotechnology. However a few respondents provided information regarding which NGOs are active in the field of nanotechnology. For example, in Canada the ETC Group and the National Farmers Union have both protested concerning the introduction of new technologies into the agricultural sector; and possible ways through which NGOs are able to provide support to decision making processes. In the US, Environmental Defence has engaged with the Federal Government on nanotechnology related environmental, health and safety issues on nanotechnology.

### **CO-OPERATION WITH RESEARCH ORGANISATIONS**

Two different aspects of this question were addressed in the survey with participants providing information regarding both the ability for researchers and research organisations to cooperate with government in terms of general science and technology policy; and methods through which researchers are able to cooperate amongst themselves with particular regard for R&D in nanotechnology. The following paragraphs provide particular examples of these two types of co-operation:

#### ***Cooperation between government and researchers***

- ∅ Meetings and workshops between policymakers and researchers. For example, in Chinese Taipei government agencies hold regular meetings to which researchers and scholars are invited to present research results and provide recommendations. In the US, the National Science Foundation has organized a series of workshops on the societal implications of nanotechnology, and the NNI a series of workshops on various topics involving the research and education community.
- ∅ Professional societies which provide independent counsel to government on appropriate policy matters. For example, in the UK the main societies concerned with nanotechnology are: The Royal Society, The Royal Academy of Engineering, The Royal Society of Chemistry, The Institute of Physics, and The Institute of Materials, Minerals and Mining.

#### ***Co-operation amongst researchers***

- ∅ Establishment of facilities through which researchers can access tools and collaborate with other researchers'. For example, the Nanotechnology Infrastructure User Network in the US which is supported by the National Science Foundation.

- ∅ Creation of a network to promote cooperation amongst scientists of different backgrounds. For example the Observatory for micro and nanotechnologies in France provides a network for strategic outlooks, whilst in Japan the establishment of a network among researchers and research institutes is a R&D priority.

## **COOPERATION WITH INDUSTRY**

Cooperation between government and industry appears to hold an important focus for many of the participants due to the need to transfer growing innovation in nanotechnology research to positive industrial development. In Japan, for example, industrialisation of nanotechnology is being promoted by a project which aims to introduce methods that: enhance technology transfer from academia to industry; introduces incentives for industry, academia and government collaboration such as prioritising research funds; and increases the number of researchers who migrate from industry to academia. As well as the need for cooperation between industry, academia and government the surveys also identified activities which are taking place to ensure government nanotechnology policy development is supported by the need for an industrial focus.

### ***Cooperation amongst industry, academia and government***

- ∅ Funding of collaborative projects. For example, the 'Verbundprojekte' of the German Federal Ministry of Education and Research (BMBF) aims to bring together industry and research institutions in order to promote those applications in which a dominant market position and high profits appear attainable.
- ∅ Establishment of a specific body responsible for collaboration. For example, in the US, the Nanoscale Science, Engineering and Technology (NSET) working group on Nanotechnology Innovation and Liaison with Industry (NILI) has established Consultative Boards for Advancing Nanotechnology (CBAN).

### ***Cooperation between government and industry***

- ∅ Financial support of small business. For example, in France an investment fund has been created called Emertec 2 which is dedicated to financing SMEs focusing on micro and nanotechnology. The financing potential of this fund reached US\$23.60 million in 2005.
- ∅ Business Associations. For example, the Canadian NanoBusiness Alliance has the dual mission of establishing a Canadian National Nanotechnology Initiative and creating commercially orientated nanotechnology hubs.

## **COOPERATION WITH THE PUBLIC**

Activities concerning cooperation with the public are mentioned by very few of the respondents, although it should be acknowledged that the survey did not pose a specific question in this regard. Nevertheless some examples were identified, including: a 2004 census on nanotechnology held in Italy as input for the creation of a national database; the initiation of a debate concerning nanoparticle risk for the environment and health in France in 2005; and the creation of the networks 'Nanotechnology in Society' and 'Nanoscale Informal Science Education' by the US National Science Foundation in order to address the best mechanisms for communicating with the public.

## **8. RECOMMENDATIONS FOR RISK GOVERNANCE**

Questions 8-15 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 and in general there was very little commonality of thought, except where directly stated.

## **RISK RESEARCH RECOMMENDATIONS**

Risk research recommendations mentioned in the surveys included the need for risk assessment to be both rational and transparent, with research and development projects to include assessment of both physical risks - such as toxicology and ecotoxicology - and social, cognitive and ethical risks. Several participants considered that the physico-chemical and social risks should be identified at the beginning of research and development projects in order to identify suitable avenues for innovations and to better inform decisions on development.

Examples of recommendations for governance of physical risks included:

- Ø Rigorous advance studies of hazard identification, hazard characterisation, exposure assessment and risk calculation
- Ø Categorisation of materials according to certain characterisations such as gaseous/liquid/solid phase; single-particles/agglomerates; and untreated/surface modified nanostructures.
- Ø Education and training for the safe and effective use of nanotechnologies during research, development and manufacturing.
- Ø Risk evaluation procedures to be individually tailored towards the specific final application.
- Ø Development of plans for environmental impact, chemical toxicity and pollution control.
- Ø Green design and green manufacturing policies.
- Ø The use of a lifecycle approach.

The following recommendations were made for governance of social, cognitive and ethical risks:

- Ø Inclusion of environmental, health and safety impacts as a required input to research and development.
- Ø The need for fundamental questions to be addressed concerning ownership, control and the social ends to which the technologies are being directed.
- Ø The identification of stakeholders' needs through public dialogue and active engagement
- Ø A focus on investment into key areas for sustainable development.

## **STAKEHOLDER ENGAGEMENT RECOMMENDATIONS**

It was felt by the majority of survey participants that debate regarding nanotechnology policies and research initiatives should be collective and democratic with consultation taking place among an extensive array of stakeholders, including different levels of government, different nations, industry and academia. Some participants also saw the need for the public to play an active role at an early stage of the research and development process - it was suggested by one respondent that many decisions are not technical but are in fact value judgments and, as such, need the input of civil society. Another participant added that two-way interactions between the public and policymakers can provide a useful tool in identifying possible areas of risk in framing public concerns - early citizen and stakeholder collaboration was seen as an essential step in preventing risk in the longer term. In terms of practical recommendations for stakeholder engagement, the following strategies were suggested:

- Ø Regular workshops where stakeholders can communicate and exchange information.
- Ø Dedicated public groups which meet regularly to debate issues associated with nanotechnology.
- Ø The involvement of social scientists in research and development projects, so that input is received at the laboratory stage.

- Ø The lowering of organisational barriers to facilitate smooth cooperation amongst different stakeholders.
- Ø International dialogue between ethical advisory committees.

## **RISK COMMUNICATION RECOMMENDATIONS**

One of the main issues raised with regard to risk communication was the need to identify a common, accurate language whereby different stakeholders with different interests and concerns can properly communicate with each other. Several participants noted that nanotechnology risk must be more adequately defined before appropriate risk communication can take place – an emphasis on the need for rational assessment rather than hype and speculation. A particular gap in communication between stakeholders was identified as being between the scientific sector and the general public - the importance of a public dialogue with citizens and consumers was promoted by one respondent as being a necessary basis for an objective judgement on nanotechnology, and as a means to avoid baseless fears. The following risk communication strategies were suggested in the responses:

- Ø A balanced disclosure of both positive and negative results.
- Ø Communication provided through channels which are appropriate to the level of knowledge of the recipient, and which is accessible to different stakeholders.
- Ø Sources of information should be independent and based on sound, documented proof, not provided by those with vested interests.
- Ø The communication of unanticipated consequences including secondary health and environmental impacts, for example sunscreen which is only evaluated for risk to humans and is then washed off into the environment.
- Ø Periodical evaluation of higher risk applications and dissemination of the results to the public.

Specific practical examples:

- Ø 'Nanotruck' a vehicle which is being used to travel around Germany and explain the new functionalities of nanostructures to the general public
- Ø Internet based "nano journeys" for children, where future scientists can explore the nanoworld in comparison to everyday objects.

## **GOVERNANCE APPROACHES**

### ***A role for international expert bodies***

The majority of survey participants agreed that the main role for international expert bodies should be to create an independent foundational pool of knowledge which could be accessed globally by all stakeholders and through which the development of nanotechnologies could be monitored. It was agreed that this body should be a conduit through which dialogue could be enhanced and, also, a means of challenging the claims of powerful actors. One respondent commented that a transparent and independent organisation could provide a source through which the legitimacy of policy choices that impact on the globe could be promoted. The following are examples of the type of provision suggested:

- Ø Technical advice based on unified criteria.
- Ø Dissemination of information through workshops, dedicated documents and articles in the media.
- Ø Engagement with government bodies.
- Ø Internet forum for experts to collaborate with questions and issues being posted on specific websites.

There were many different suggestions for the form which an international body should take, with some respondents considering that a formal regulatory organisation should be put in place, whilst others preferred more informal committees and networks. One participant did not see the need for an additional international body suggesting that critical issues can already be raised through bodies such as the United Nations and the OECD. The following are examples of international bodies suggested by the participants:

- Ø Joint projects of industry and scientific organisations.
- Ø International networks of excellence.
- Ø A supranational body to supervise clear rules of worldwide validity with strict requirements for access to funding and markets.
- Ø An issue specific expert advisory committee, perhaps established by a treaty, which produces reports detailing state-of-the-art knowledge and answering specific technical questions. This committee could also provide models for solutions, examples of best practices and recommendations for international standards.
- Ø An international committee of working scientists, with participation on a voluntary basis.

Several respondents also agreed that an international body could be the only means through which responsible development of nanotechnology could be ensured – by providing for example:

- Ø A focus on topics of global interest such as energy conversion, water filtration and reduction of pollution.
- Ø Sharing of materials and instrumentation.
- Ø High level collaboration of nanotechnology coordinating organs from all countries.
- Ø Coordinated planning for transporting nanomaterials across boundaries.
- Ø A technology-by-technology approach to ethical considerations.
- Ø A role for the United Nations in coordinating conflicting national policies, although with the power of enforcement in only extreme cases.

### ***A role for self regulation***

Respondents saw a need for researchers to exercise personal responsibility towards issues of human health and environmental safety. One respondent thought that self-regulation was an effective tool, forcing researchers to be accountable when their work was exposed to the international arena; another went further than this suggesting that self-regulation is sufficient for the governance of research practices and that research should only be regulated in exceptional cases, such as human cloning using nanotechnology. In order to prevent inaccurate information reaching the public it was recommended that there should, instead, be an increased emphasis on public education, and not regulation.

The following methods for informal approaches to governance and self-regulation were suggested by the participants:

- Ø The International Organization for Standardization (ISO) to promote non-mandatory regulation and agreement on definitions and nomenclature.
- Ø Professional organisations to develop guidelines for research and development, the review of publications and encouragement of dialogue.
- Ø Voluntary peer reviews to create an evaluation methodology at local, national and global level.
- Ø An 'open-source software development model' combines collaboration with structured processes for filtering and validating innovations, to ensure maximum public benefit, efficacy, and reliability of innovations.

### ***A role for government in governance approaches***

Many of the survey respondents considered self-regulation to be insufficient for the governance of nanotechnology - alternative policy processes are seen as being essential for obtaining public and stakeholder trust and support. One participant also raised the issue of the decreased accountability of scientists and engineers who are able to profit from their innovations through public-private partnerships. Examples of the government policies recommended are listed below:

- Ø Accurate labelling of consumer-sensible nano-related products.
- Ø A structured international agreement.
- Ø A requirement for research and development to be channelled through national coordinating bodies.
- Ø National, international and supranational cohesion on regulatory schemes, definitions and nomenclature, best practices, common assessment policies and testing protocols.
- Ø Strengthened capacity of legislative institutions to respond to new and emerging technologies so that the courts are not the first responders in building regulation.
- Ø Development of mechanisms to compensate parties who suffer harm or bear risk.
- Ø Allowance of different standards of risks to apply to different nanotechnology products or categories.

Several participants also commented that many of the benefits promised by nanotechnology for developing countries would only materialise if policies are put in place to guide technologies towards sustainable development. It was argued that a concerted effort needed to be made by governments to achieve these goals, as for-profit corporations will only have a limited ability to address these needs. The following government actions were recommended:

- Ø Cooperative projects providing access for developing countries to research facilities and equipment.
- Ø Referable guidelines for research organisations, allowing them to distribute benefits from nanotechnology research and development in an equitable manner, potentially resulting in standardisation under ISO.
- Ø International engagement under a coordinating committee with representation by the United Nations, OECD, G8 and other concerned international bodies.
- Ø Funding through an international body to research appropriate technologies with the outcome being given free to developing countries.
- Ø Research and development programmes which are accountable to those whose lives they are intended to impact.
- Ø A dedicated patent regulation system for emerging countries.
- Ø Access to private royalties opened in order to assess what belongs to public missions and to the common good.

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**9. REFERENCES**

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## 10. ANNEXES

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### 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 organizations and, with them, foster public confidence in risk governance and other related decision taking by:

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

- Ø Dr. Lutz Cleemann, Director of the Allianz Technology Center, Germany
- Ø Dr. Thomas K. Epprecht, Chief Underwriting Office, Risk Engineering Services, Swiss Reinsurance Company
- Ø Dr. Jeff McNeely, Chief Scientist, World Conservation Union, seated in Switzerland
- Ø Prof. Nick Pidgeon, Director of the Centre for Environmental Risk, School of Environmental Sciences, University of East Anglia
- Ø Prof. Dr. Ortwin Renn, Professor of Environmental Sociology, University of Stuttgart, and Director of the non-profit Research Institute "DIALOGIK", Germany

- Ø 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
- Ø Dr. Joyce Tait, Professor and Director of Innogen, the ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh, UK
- Ø 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 US Environmental Protection Agency (EPA), Swiss Re, and the Swiss Federal Agency for Development and Cooperation,

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

## ANNEX D – TABLES WITH DETAILED SURVEY RESULTS

Table 3: Overview of research and development strategy

Country	Coordination of research	Overview of research activities	Research funding
Canada	No central programme or coordinating committee. Programmes and activities are funded through existing funding mechanisms.	<ul style="list-style-type: none"> <li>o University research – funded through 3 main granting bodies Natural Sciences and Engineering Research Council (NSERC), Canada Foundation for Innovation (CFI), Canadian Institutes for Health Research (CIHR)</li> <li>o National Research Council Canada (NRC) performs collaborative R&amp;D and allocates funds on basis of economic and social value. Co-founded National Institute for Nanotechnology (NINT), with University of Alberta in 2001</li> <li>o Federal laboratories - Natural Resources Canada, Environment Canada, Health Canada and National Defence allocate funds to research and laboratory work</li> <li>o Private sector - funded through the taxation system through accelerated depreciation for equipment used in R&amp;D and tax credits for eligible expenses. No specific grant system. Small and Medium sized enterprises (SMEs) are funded through the NRC Industrial Research Assistance Programme</li> <li>o The following research areas have active nanotechnology research programmes: molecular sciences, microelectronics, materials science and engineering, aerospace, metrology, and biotechnology that have active</li> </ul>	<ul style="list-style-type: none"> <li>o Targeted research and open competitions 2004 – NSERC CAD15m (US\$12.75m), CIHR CAD7m (US\$5.95m)</li> <li>o Major capital equipment grants 2004 – CFI (and partners) CAD115m (US\$97.75m)</li> <li>o NRC operating expenses 2004 CAD20m (US\$17m)</li> <li>o NRC capital investments 2004 CAD10m (US\$8.5m)</li> </ul>
Chinese Taipei	National Science and Technology Program for Nanoscience and Nanotechnology 2003-2008	<ul style="list-style-type: none"> <li>o 4 sub-programmes: Industrial programme (61% of funding), Academic Excellence programme (21%), Core facilities programme (16%), and Education programme (1.3%)</li> <li>o Taiwan Environmental Protection Program (TEPA) plans a 3 year road map to work in collaboration with the Council of Labor Affairs and Department of Health in order to examine issues that deal with Environment, Health and Safety. The goal is to examine issues such as environmental applications and implications of nanotechnology (databank development), pollution prevention and remediation, monitor and measure nanoparticles in the atmosphere (from automobile and industrial emissions), exposure to nanoparticles, and proposing regulations, in four focal areas: Environment, Health and Environment, Exposure and Control, Risk Assessment and Management</li> </ul>	<ul style="list-style-type: none"> <li>o US\$700m under central programme</li> <li>o In 2005 TEPA commissioned projects granted US\$0.34m</li> </ul>
France	The RMNT (national network for micro and nanotechnologies, which was transformed into R3N in 2005), allocates public funding.	<ul style="list-style-type: none"> <li>o Main areas of spending - 25% of public funding is allocated to electronics, 20% to optoelectronics, 10% to Microsystems, and another 10% to assembly, hybrids and connections.</li> <li>o Public actors - ministries in charge of research, economy, finance and industry and defence</li> <li>o Other public entities – National Centre for Scientific Research (CNRS), Atomic Energy Commission (CEA), National Aerospace Establishment (ONERA) and the French Agency for Innovation (OSEO/ANVAR) for small businesses involved in applied research and innovation, the National Laboratory of Metrology and testing (LNE)</li> <li>o Office for evaluation of the risks of products and chemical agents (BERPC) created in 2005 to provide scientific expertise about impacts of chemical agents on men and the environment</li> <li>o The French standards agency (ANFOR) has created a working group on nanotechnology which will address</li> </ul>	<ul style="list-style-type: none"> <li>o Capital investment in fundamental research 2005 – €184m (US\$217.1m)</li> <li>o Annual expenditure is of €150m (US\$177m)</li> <li>o Infrastructures and networks will receive €100m (US\$ 118m) over 4 years.</li> </ul>

**Table 3: Overview of research and development strategy**

Country	Coordination of research	Overview of research activities	Research funding
France (cont.)		<p>the need for standards and regulations, and participate in CEN/ WG 166 and ISO TC 229.</p> <ul style="list-style-type: none"> <li>o The ministry in charge of ecology and environment (MEDD) has asked the Committee of Prevention and Precaution (CPP) to address the subject of relationships between health and environment, and between health and labour in general.</li> </ul>	
Germany	No central coordinating agency – funding is carried out by different ministries.	<ul style="list-style-type: none"> <li>o Project related investments are financed by the Federal Ministry of Education and Research (BMBF), the Ministry of Economics and Employment (BMWA), and by institutional funding (German Research Society (DFG), the Leibniz Science Association (WGL), the Helmholtz Association of National Centres (HGF), the Max Planck Society (MPG), and the Fraunhofer Society (FhG)).</li> <li>o BMBF main funding in 2005 – 36% in Nanoelectronics (including lithography, e-biochips and magneto electronics), 29% in Nanomaterials (including nanobiotechnology, nanostructured materials, recruiting new talent and creating opportunities), and 20% in Optical technologies (including ultraprecision processing, photonic crystals, molecular electronics and diode lasers)</li> <li>o Private sector - 400-500 companies are involved with nanotechnology primarily in the automotive and machine construction industries, in chemicals and pharmaceuticals, in the optical industry, medicine and biotechnology, as well as in power generation and construction</li> <li>o Research programmes in cooperation with mainly SMEs and with large corporations such as Infineon, DaimlerChrysler, Schott, Carl Zeiss, Siemens, Osram, BASF, Bayer, Metallgesellschaft and Henkel. Either in cooperation with universities, as wholly-owned subsidiaries, as spin-offs or through internal research.</li> <li>o Research into standardisation, in particular analysis and metrology. BMBF are compiling processes capable of being calibrated as part of an international collaboration.</li> <li>o Research is also taking place into whether a strategic initiative is necessary in areas that have high market potential or a pivotal character.</li> </ul>	<ul style="list-style-type: none"> <li>o BMBF funded projects 2005 - €129.5m (US\$152.8m)</li> <li>o BMWA funded projects 2005 - €23.7m (US\$28m)</li> <li>o Institutional Funding – €145m annually (US\$342m)</li> <li>o Total public expenditure 2004 - €293.1 (US\$345.8m)</li> <li>o Total public expenditure 2005 - €298.3 (US\$352m)</li> </ul> <p>This does not include the Federal States' expenditures on the universities' basic budgets, nor industry's own funding of nanotechnology research apart from public funding.</p>
Ireland	No central coordination – majority of funding is carried out by different agencies.	<ul style="list-style-type: none"> <li>o Main aims of strategy - 1) the development and application of nanotechnology by existing clients i.e. up to 40 companies to apply the technology to yield products which offer a significant competitive advantage 2) a doubling in the number of researchers from 130 to 260 with Science Foundation Ireland supporting new basic research centres of excellence 3) the creation of 8 new start-up companies over the next 3 years</li> <li>o Main research institutions - The Tyndall National Institute (Microelectronics, Photonics and related technologies); Centre for Research on Adaptive Nanostructures and NanoDevices (CRANN) (Membrane-Fluidic Interface, Nanoscale Organisation and Self-Assembly, Nanoscale Contacts and Spin-Transport, and Nanomagnetic Applications); National Centre for Sensor Research (NCSR) (focused on chemical sensors and biosensors including medical diagnostics, food quality and environmental monitoring); Sami Nasr Institute for Advanced Materials Science (semiconductor science, magnetic and spin electronic domain and self-assembling and organic nanostructures); Materials and Surface</li> </ul>	<ul style="list-style-type: none"> <li>o CRANN - €10m (US\$11.8m) from Science Foundation Ireland</li> <li>o NCSR - €12 m (US\$14.2m) from Higher Education Authority's Programme for Research in Third Level Institutions.</li> <li>o Sami Nasr - €14.6 million (US\$17.2m) from Higher Education Authority's Programme for Research in Third Level Institutions.</li> <li>o Materials and Surface Science Institute - €16m (US\$18.9m) from Higher Education</li> </ul>

**Table 3: Overview of research and development strategy**

Country	Coordination of research	Overview of research activities	Research funding
Ireland (cont.)		Science Institute - University of Limerick (surface science and materials)	Authority's Programme for Research in Third Level Institutions.
Italy	No specific programme but allocated funds through National Research Programme (NRP)	<ul style="list-style-type: none"> <li>o Main focus - -- integrated development of nanotechnology, microtechnology and advanced materials</li> <li>o About 50% of overall research funding used for nanoscience and nanotechnology at universities and public research organisations.</li> <li>o Nanotec is a nanotechnology centre which monitors research and development at national and international level and communicates this via a website, newsletter, reports, scientific events, conferences and workshops. Main areas of research are atomic and molecular physics, nanooptics and photonic devices, nanostructured surfaces and powders, nanocomposites, biomaterials, biosystems (medical applications), IRC, transportation, and energy.</li> <li>o Veneto Nanotech – technological district which promotes and support R&amp;D and has built a nanofabrication facility (NFF). Financed by local region and Ministry for Education, University and Research (MIUR)</li> </ul>	<ul style="list-style-type: none"> <li>o National Research Programme 2001-2003 – in 2004 funding for R&amp;D in nanotechnology was €40million (US\$47.2m)</li> </ul>
Japan	No specific programme but funds and strategy coordinated through the Coordination Program of Science and Technology Projects – aim is to enhance inter-ministerial cooperation and coordination between projects.	<ul style="list-style-type: none"> <li>o Nanotechnology and Materials is one of the 4 prioritised areas under the Science and Technology Basic Plan (2001-2005)</li> <li>o CSTP has selected 8 themes for nanotechnology programme - hydrogen and fuel cells, nanobiotechnology, Ubiquitous Network, next generation robots, biomass utilisation, post genome, infectious diseases, and regional clusters.</li> <li>o 5 prioritised sub-areas (3 in application, 2 in basic research): nanodevices and materials for next generation information and telecommunications; materials for environmental conservation and efficient energy consumption; Microsystems and materials for medical applications and nano-biology based on bio mechanisms; fundamental research such as instrument, evaluation, processing and computational simulation; and Innovative Material Technology for realising advances in physical properties and functions.</li> <li>o Several research institutes including the National Institute of Advanced Industrial Science (NIAIS), and the National Institute of Material Science (NIMS) are conducting research on the EHS impacts of nano-materials</li> </ul>	<ul style="list-style-type: none"> <li>o In 2005 the Nanotechnology and Materials R&amp;D budget was US\$99 m which was 4.9% of the total S&amp;T budget (the largest are energy 31.9% and life sciences 22.7%)</li> <li>o In 2004 76.3% of nanotech and materials budget was held by MEXT (Ministry of Education, Culture, Sports, Science and Technology) – who on focus on basic research, 19.5% held by METI (Ministry of Economy, Trade and Industry) – who tend to focus on application for manufacturing.</li> </ul>
PR China	No central programme – research is funded through national projects.	<ul style="list-style-type: none"> <li>o 1999 Nanomaterial and Nanostructure project continually supports basic research on nanomaterials.</li> <li>o The National High Technology Plan established projects such as: nanomaterials, nanodevices, nanobiology and medicine, detection and characterization</li> </ul>	
South Korea	Funding is carried out by the government	<ul style="list-style-type: none"> <li>o There are no indicative goals for nanotechnology. The government is responsible for fundraising, establishing a national master plan, monitoring activities, reporting national activity to national science and technology committee, education and facilities.</li> <li>o Current research: Frontier Program (nanodevices,</li> </ul>	<ul style="list-style-type: none"> <li>o Frontier Program: US\$10m annually for 10 years</li> <li>o Nano Challenge Program: US\$8m per annum</li> </ul>

**Table 3: Overview of research and development strategy**

Country	Coordination of research	Overview of research activities	Research funding
South Korea (cont.)		<p>nanomaterials, nanomechatronics); Nano Challenge Program; Nanofusion Program.</p> <ul style="list-style-type: none"> <li>Facilities: National NanoFab Center and National Nanotechnology Cluster Centers.</li> </ul>	<ul style="list-style-type: none"> <li>Nanofusion Program: US\$6.4m per annum</li> <li>National NanoFab Center -US\$100m, application specific US\$50m</li> <li>National NT Cluster Centers - US\$75m</li> </ul>
UK	<ul style="list-style-type: none"> <li>Research is coordinated through the Nanotechnology Research Coordination Group (NRCG) and is administered through the UK Research Councils</li> </ul>	<ul style="list-style-type: none"> <li>The Research Councils (RCs) fund basic and applied research at Universities and Research Institutes in Nanotechnology in the UK. The RCs that are primarily involved are: Biotechnology and Biological Sciences Research Council (BBSRC); Engineering and Physical Sciences Research Council (EPSRC); Medical Research Council (MRC); Economic and Social Research Council (ESRC); Natural Environment Research Council (NERC)</li> <li>There are currently two Interdisciplinary Research Collaborations (IRCs) in nanotechnology), which are intended to be virtual centres of excellence. The main objectives of the IRC in nanotechnology are to fabricate complex 3-dimensional structures with molecular precision, to control growth and assembly of soft layers by directed self assembly on patterned substrates and to produce architectures for new devices in biomedicine and information technology. The IRC in Bio-Nanotechnology aims to investigate bio-molecular systems, from the level of single molecules to complex molecular machines, to establish their function; and apply this knowledge to produce artificial electronic and optical devices. A third joint Research Council IRC carries out research relevant to Bio-nanotechnology in the area of Tissue Engineering.</li> <li>A joint Research Councils programme in Basic Technologies has also been established which aims at building up the UK's means to acquire capability in fundamental technology with over half of the projects being relevant to nanotechnology.</li> <li>The Department of Trade and Industry (DTI) also directly funds pre-competitive research at Universities, Institutes and Industrial concerns principally via the Micro and Nano Technology initiative but also by means of their Technology Programme. It is the intention of the DTI's programmes to lever additional funding from local government (Regional Development Authorities) who may also directly fund Nanotechnology research</li> </ul>	<ul style="list-style-type: none"> <li>Joint Research Councils Programme in Basic Technologies - US\$13m investment in nanotechnology.</li> </ul>
US	<ul style="list-style-type: none"> <li>Nanotechnology research is coordinated by the US Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC)</li> <li>Research is organised by the National</li> </ul>	<ul style="list-style-type: none"> <li>The current five year strategic plan (2001-2006) has five prioritised areas: fundamental research; nine Grand Challenges; centers of excellence and networks; infrastructure; and societal and educational implications of nanotechnology.</li> <li>16 Nanoscale Science and Engineering Centers (NSEC) are funded by the NSF specifically to carry out R&amp;D into nanotechnology.</li> <li>The National Nanotechnology Infrastructure Network (NNIN) coordinates the different nanotechnology infrastructures. In addition, state, local, and private organisations have regional nanotechnology investments in infrastructure, education, and support for business.</li> <li>The NNI is supported by several federal agencies. In FY2005 the major estimated contribution by each agency is: National Science Foundation (NSF) 31%,</li> </ul>	<ul style="list-style-type: none"> <li>Federal government FY2004 - about US\$1billion</li> <li>State and local government, industry and private organisations FY2004 – about US\$1.7 billion</li> <li>National Cancer Institute Initiative – total award US\$145m.</li> </ul>

**Table 3: Overview of research and development strategy**

Country	Coordination of research	Overview of research activities	Research funding
US (cont.)	Nanotechnology Initiative (NNI)	<p>Department of Defence (DOD) 24%, Department of Energy (DOE) 19%, National Institute of Health (13%), National Institute for Occupational Safety and Health (NIOSH) 0.3%, and the Environmental Protection Agency (EPA) 0.5%.</p> <ul style="list-style-type: none"> <li>o Since FY2001 about 10% of the NNI budget has addressed issues, related to environment, health and safety, including basic research, applications, and implication. These efforts are funded by several agencies incl. NSF, EPA, National Institutes for Health (NIH), DOE, NIOSH, United States Department of Agriculture (USDA), and DOD.</li> <li>o Activities into the potential health risks of nanomaterials are coordinated by an NSET subgroup, the Nanotechnology Environmental and Health Implications Working Group (NEHI WG) with membership from all agencies which support or regulate nanotechnology research and products.</li> <li>o The Department of Health and Human Services, NIOSH, and EPA fund the National Toxicology Program (NTP) which studies the potential risks of exposure to nanomaterials, beginning with titanium dioxide, quantum dots and fullerenes.</li> <li>o NIOSH is also leading an effort within the government to develop a set of recommended safe handling practices for nanomaterials, for both research and commercial production facilities.</li> <li>o All 16 NSF's Nanoscale Science and Engineering Centers (NSEC), the National Nanotechnology Infrastructure Network (NNIN) and Network for Computational Nanotechnology (NCN) are required to have research and education components addressing environmental and societal implications.</li> <li>o The National Cancer Institute has established a five year initiative (NCI Alliance for Nanotechnology in Cancer) with a total award of about \$145 with the mission of "eliminating suffering and death from cancer". It will include four major programmes: Centers of Cancer Nanotechnology Excellence, Multidisciplinary Research teams, Nanotechnology Platforms for Cancer Research, and the Nanotechnology Characterization Laboratory.</li> </ul>	

**Table 4: Overview of current governance practices**

Country	Coordinating Committees for national policy	Main government bodies involved
Canada	The Federal Network on Nanotechnology, co-ordinated through Industry Canada, is the main coordinating body providing a cross-government information-sharing forum for policy makers. This includes research funding organisations, regulatory and policy based departments and agencies and science based organisations	<p>Federal bodies:</p> <ul style="list-style-type: none"> <li>o The Minister of Industry provides oversight on Science, Technology and Innovation Policy to Cabinet</li> <li>o Prime Minister's Advisory Council on Science and Technology (PMACST) conducts assessments of Canadian Nanotechnology and provides advice</li> <li>o Office of the National Science Advisor looks at strategic options for nanotechnology</li> </ul> <p>Provincial level – Quebec:</p> <ul style="list-style-type: none"> <li>o Ministère de développement économique, innovation et de l'exportation (Minister of economic development, innovation and trade) provides policy oversight on science and technology policy and funds R&amp;D through different agencies</li> <li>o Conseil de la science et de la technologie Québec (Science and Technology Council) provides the Minister with advice on science and technology issues as they pertain to economic, social, environmental and health issues and explores issues related to public acceptance of nanotechnology</li> <li>o NanoQuébec (a not-for-profit organisation) develops collaborations between industry, academia and government for the development of nanotechnology, through networking and joint actions, partnering support and marketing, awareness building and outreach, and strategic positioning</li> </ul> <p>Provincial level – Alberta:</p> <ul style="list-style-type: none"> <li>o Ministry of Innovation and Science provides policy direction for science and technology support</li> <li>o Alberta Science and Research Authority (iCore) iCore helps to promote scientific excellence and technological development in the information and communications technologies and has a dedicated programme in nanoscale and quantum informatics</li> </ul> <p>Ethics in research is maintained through compliance with research ethic guidelines developed and monitored by the Interagency Panel on Research Ethics. Regulatory oversight is provided by the existing rules and regulations of responsible Ministries and Agencies.</p>
Chinese Taipei	No information provided	
France		<ul style="list-style-type: none"> <li>o There is no centralised approach to nanotechnology, however at regional level there are technical platforms for networks of excellence and competitive centres at the convergence of biotechnologies, information technologies, and nanotechnologies</li> </ul>
Germany	No information provided	
Ireland	Nanolreland project is developing a strategic policy intelligence capability, including Technology Assessment (TA). This is managed by Office of Science, Technology and Innovation (Forfàs) and advised by a high level taskforce	<ul style="list-style-type: none"> <li>o NanoIreland has 3 scenario building panels: NanoBiotechnology, NanoMaterials, and NanoElectronics, both the high level task force and these panels are currently investigating issues such as risk in detail.</li> <li>o Ireland is also actively participating in the development of the European Strategy for Nanotechnology.</li> <li>o The senior decision making body for science and technology in Ireland is the Cabinet Committee on Science, Technology &amp; Innovation, under which sits the Office of Science, Technology and Innovation (fForfàs), the Inter-Departmental Committee of Senior Officials, and the Advisory Council on Science, Technology and Innovation (which has an independent chair).</li> </ul> <p>Members of government departments are able to influence policy and collaborate through the Inter-Departmental Committee.</p>
Italy		The Office of the Presidency of Ministry has set up a Bionanotechnology Working Group to address safety and ethical issues
Japan	There is no coordinating committee for nanotechnology. Science policy is organised by the Council for Science and Technology Policy, one of whose members is responsible for	<ul style="list-style-type: none"> <li>o The cabinet makes the Science and Technology basic plan every 5 years, with the last starting in 2001, the plan must prioritise key areas and design an R&amp;D strategy for them. The current 4 prioritised areas are. Life science, Information and Telecommunication Technology, Environmental Science and Nanotechnology and Materials.</li> </ul>

**Table 4: Overview of current governance practices**

Country	Coordinating Committees for national policy	Main government bodies involved
Japan (cont.)	nanotechnology	<ul style="list-style-type: none"> <li>○ The Council for Science and Technology Policy (CSTP) assists the Prime Minister and Cabinet on generalizing S&amp;T matters; conducts investigations on S&amp;T basic policies and programmes; evaluates nationally important R&amp;D for Science and Technology; and conveys its opinion to the Prime Minister. The value of the CSTP is providing influence directly to PM and eliminating vertical divisions among departments</li> <li>○ There are 6 Ministers on the CSTP, the President of the Science Council of Japan, and 7 Executive members from Academia and Industries. One of these executive members is responsible for nanotechnology promotion.</li> <li>○ The Ministers who sit permanently on the CSTP are the Minister of Finance, the Minister of Education, Culture, Sports and Science and Technology, the Minister of Economy, Trade and Industry, the Minister of Internal Affairs and Communications and the Chief Cabinet Secretary. Occasionally those from Environment; Health, Labor and Welfare; Agriculture, Forestry and Fisheries; and Land, Infrastructure and Transport also attend.</li> </ul>
PR China	<p>National Steering Committee for Nanoscience and Nanotechnology</p> <ul style="list-style-type: none"> <li>○ provides planning, coordinating and consulting for projects at national level.</li> <li>○ all ministries are members as are 21 leading scientists from institutes and universities</li> </ul>	<ul style="list-style-type: none"> <li>○ State Commission for development and Reform</li> <li>○ Ministry of Science and Technology</li> <li>○ Ministry of Education</li> <li>○ Chinese Academy of Sciences</li> <li>○ National Natural Science Foundation of China</li> </ul>
South Korea	No information provided	<ul style="list-style-type: none"> <li>○ The government is responsible for fundraising, establishing a national master plan, monitoring activities, reporting national activity to national science and technology committee, education and facilities.</li> </ul>
UK	The Nanotechnology Issues Dialogue Group (NIDG), within the Office of Science and Technology coordinates national policy in the UK.	<ul style="list-style-type: none"> <li>○ The NIDG is designed to coordinate government activities, provide a platform to monitor progress and delivery of government commitments, and ensure that the work of the Nanotechnology Research Coordination Group (NRCG) is integrated with other parts of the governments' programme of work.</li> <li>○ Actions determined by the NIDG are being led by the Department for Environment, Food and Rural Affairs.</li> <li>○ The role of the NRCG is to: develop and oversee research programme into the potential human health and environmental risks posed by free manufactured nanoparticles and nanotubes in order to inform regulation and underpin regulatory standards; to establish links in Europe and internationally to promote dialogue and to draw upon and facilitate exchange of information relevant to the Group's research objectives; to consider the outputs of dialogue between stakeholders, researchers and the public with a view to enhancing and informing research decisions.</li> <li>○ The Research Councils are administered by the Office of Science and Technology (OST) which is part of the DTI (Department of Trade and Industry). OST is headed by the Chief Scientific Adviser who provides advice to the Government on science, engineering and technology (SET) matters. The Director General of Research Councils advises on the allocation of the UK science budget.</li> </ul>
US	<p>Nanotechnology policy is coordinated on three levels:</p> <ul style="list-style-type: none"> <li>○ National - NSET Subcommittee in the National Science and Technology Council; Office of Science and Technology policy (OSTP) and the Office of Management and Budget (OMB)</li> <li>○ Principals in the participating agencies of the NNI</li> <li>○ R&amp;D programmes within those</li> </ul>	<ul style="list-style-type: none"> <li>○ NNI was proposed by NSF in March 1999</li> <li>○ NSET has been established in July 2000 by NSTC in order to implement NNI</li> <li>○ NSET has established the National Nanotechnology Coordinating Office (NNCO) in 2001 as its secretariat with one of its role to coordinate monitoring of potential unexpected consequences of nanotechnology.</li> <li>○ Three time scales are used: (1) the long-term vision and strategic plan that is revisited about every five years (strategic plan), (2) agency planning each year (annual plan centralized by the US Office of Management and Budget, OMB), and (3) organisational measures for the implementation of the programmes each month</li> </ul>

**Table 4: Overview of current governance practices**

Country	Coordinating Committees for national policy	Main government bodies involved
US (cont.)	agencies.	<p>(NSET monthly meetings and programme decisions).</p> <ul style="list-style-type: none"> <li>○ The National Science Foundation (NSF) has authority to suspend or terminate ongoing research grants if grantees fail to comply with grant regulations or for 'other reasonable cause'.</li> <li>○ NSET member agencies are working with universities, industry and standards development organisations to develop a clear system of nomenclature for classifying new nanomaterials.</li> <li>○ In 2005 the Environmental Protection Agency (EPA) held a public hearing to inform discussion of how the Toxic Substances control Act (TSCA) should be applied to nanomaterials, starting with a voluntary pilot programme.</li> <li>○ The Nanotechnology Environmental and Health Implications Working Group has been set up by NSET in FY2005 to facilitate an exchange of information, identify, prioritise and implement research and coordinate the preparation of best practice statements.</li> <li>○ The activities of the NNI are periodically reviewed by external, peer groups comprised of the main stakeholders: <ul style="list-style-type: none"> <li>∅ National level: by the President's Council of Advisors on Science and Technology (PCAST) as part of its ongoing responsibilities as the National Nanotechnology Advisory Panel (NNAP); triennially by the National Research Council (NRC); Congress (through required annual reports); OMB crosscut, since 2001.</li> <li>∅ Agency level: Each Federal Agency involved in nanotechnology regulation and oversight considers how nanoscale materials fit within the current laws and regulations administered. Recent developments include the 2005 National Institute for occupational Safety and Health (NIOSH) best practices statements and the 2005 Toxic substances Control Act (TSCA) public meeting to consider voluntary programmes for reviewing nanoscale materials which would be considered industrial chemicals.</li> <li>∅ R&amp;D programme level: evaluation using input from the stakeholder communities (e.g. Committees of Visitors, Advisory Boards).</li> </ul> </li> </ul>

## ANNEX E – QUESTIONNAIRES

This annex contains the 12 survey responses (unedited except as requested) which were provided by the participants. The completed questionnaires are placed in country alphabetical order and include two responses from participants in Japan.

### QUESTIONNAIRE ANSWERS FROM CANADA

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the program, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*<sup>1</sup>

There are four main areas of nanotechnology research in Canada: discovery-based research taking place in universities; innovation-based research targeted at commercialization primarily taking place at the National Research Council Canada ([www.nrc.gc.ca](http://www.nrc.gc.ca)); mission oriented research being undertaken by various federal government departments; and research and development being undertaken by for-profit corporations. The following data provides some information on the amount of nanotechnology research being conducted in Canada with the proviso that data was provided informally without precise definitions.

Canadian researchers are active in nanotechnology. However, the Canadian government has not established a central program and activities are generally financed through existing funding mechanisms. There is no central interdepartmental coordinating committee overseeing new investments in nanotechnology.

#### A. University Discovery-Based Research

The Canadian government provides research grants to discovery-based research at universities. Funding is provided for research studentships, post doctoral fellowships operational support, research equipment, and research infrastructure. Funding is through a competitive peer-reviewed process. There are three main granting bodies supporting nanotechnology, the Natural Sciences and Engineering Research Council (NSERC) ([www.nserc.ca](http://www.nserc.ca)), the Canada Foundation for Innovation (CFI) ([www.innovation.ca](http://www.innovation.ca)) and the Canadian Institutes for Health Research (CIHR) ([www.cihr.gc.ca](http://www.cihr.gc.ca)). While the majority of funding from these councils is apportioned through discipline-based divisions, funding mechanisms are in place to build research networks, foster interdisciplinary research, and build critical mass in emerging research areas such as nanotechnology. In 2002 NSERC appointed a leading nanotechnology researcher to enhance collaborations within the research community and sponsor interdisciplinary nanotechnology research (annual budget of \$1 million Cdn.<sup>2</sup>). Similarly CIHR established an interdisciplinary competition in 2003 in regenerative medicine and nanomedicine. In 2004 estimated research funding, including both targeted research and open competitions, from NSERC was \$15 million and from CIHR \$7 million. In 2004, funding for major capital equipment grants totalled \$115 million through the Canada Foundation for Innovation and its matching partners (provincial government, foundations, other). Some 55 Canada Research Chairs ([www.chairs.gc.ca](http://www.chairs.gc.ca)) have been awarded to leading nanotechnology researchers in Canadian Universities since 2000.

Major funding for salaries, buildings, and equipment to universities is provided by provincial governments based on their teaching component. The government of Quebec launched a targeted \$10 million four-year program in 2001 to build interdisciplinary capability specifically in nanotechnology. The Alberta government has recognized that nanotechnology represents a key

<sup>1</sup> Opinions expressed in this questionnaire do not necessarily constitute official government policy of the Government of Canada and are the sole responsibility of the office of the National Science Advisor

<sup>2</sup> All funding references in this document will be expressed in Canadian Currency (\$ Cdn.).

area to invest in its economic development plan and therefore has provided substantial funding to build expertise and research infrastructure in nanotechnology but like other provincial governments this funding is included within larger programs.

#### **B. National Research Council Canada (NRC) ([www.nrc-cnrc.gc.ca](http://www.nrc-cnrc.gc.ca))**

NRC performs, assists and promotes scientific and industrial research in different fields of importance to Canada. NRC is funded through annual appropriations from the Canadian government and from private sector partners for collaborative research. It has in place a formal strategic planning process that is used to allocate funds on the basis of their potential economic and social value to Canadians. In 2001 in collaboration with the Province of Alberta it launched the National Institute for Nanotechnology (NINT) with funding of \$120 million over five years. The institute will focus on leading edge research in integrated circuit technology, energy and biology that has significant commercialization potential. As well, NRC's other research institutes in molecular sciences, microelectronics, materials science and engineering, aerospace, metrology, and biotechnology have active nanotechnology research programs related to their specific focus area. Total NRC spending on nanotechnology including NINT was estimated at \$20 million for operating expenses and \$10 million in capital investments in FY 2004/05.

#### **C. Mission Oriented Research at Other Federal Laboratories**

Natural Resources Canada, Environment Canada, Health Canada, and National Defence<sup>3</sup> identified the potential of nanotechnology to impact regulatory functions, defence and security, and economic and social benefits for Canadians. These departments are funded through annual appropriations from the federal government and allocate resources to various research and laboratory work within a formal annual planning cycle. In 2003 Natural Resources Canada identified \$2 million in expenditures on nanotechnology research. Specific expenditures by other federal departments are small and are not funded through targeted programs.

#### **D. Private Sector Research**

The Canadian government has a number of programs to foster R&D in the private sector. Most support is provided through the taxation system through the use of accelerated depreciation for equipment used in R&D and tax credits for eligible R&D expenses. There is no specific Canadian government grant program to fund private sector R&D in nanotechnology. R&D contributions are provided to small and medium sized firms (SMEs) through the NRC's Industrial Research Assistance Program.

There are varying estimations of Canadian private sector involvement in Canada, ranging from between 50 to over 100 (depending on the source of information and the definition) that are involved in nanotechnology R&D and adoption of technology. There are, however, no verifiable data to estimate the level of private sector R&D performance.

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development.** Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

In Canada, nanotechnology is covered under a number of existing statutes and regulations. However, it has been noted that nanotechnology could require new approaches to some regulations because these materials have properties that are radically different at the nanoscale than at the bulk scale, their size facilitates exposure through an enhanced ability to cross tissue barriers, and free nanoparticles can easily become airborne. Issues such as persistence in the environment, disposal, self-assembling nanosystems that could be considered animate or combinatorial compounds may stretch the capabilities of current regulatory frameworks.

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<sup>3</sup> Health Canada ([www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)) Environment Canada ([www.ec.gc.ca](http://www.ec.gc.ca)), Natural Resources Canada ([www.nrcan-rncan.gc.ca](http://www.nrcan-rncan.gc.ca)), Defence Research and Development Canada ([www.drdc-rddc.gc.ca](http://www.drdc-rddc.gc.ca)).

Amongst others, the following acts and regulations apply to nanotechnology:

Workplace Safety:

- Ø Canada Labour Code Part II
- Ø Canada Occupational Health and Safety Regulations  
(Approximately ten percent of all workers are covered under the Canada Labour Code and the Canada Occupational Health and Safety Regulations. Other workers are covered under Provincial government acts and regulations.)
- Ø Hazardous Products Act
- Ø Transportation of Dangerous Goods Act

Environmental and Human Safety:

- Ø Food and Drugs Act and Regulations, Cosmetics Regulations, Medical Devices Regulations (human health impacts of foods, drugs, cosmetics and medical devices); Controlled Products Regulations;
- Ø Consumer Chemicals and Containers Regulations;
- Ø Pest Control Products Act and Regulations (environmental and health impacts of pest control products);
- Ø Seeds Act, Feeds Act, Fertilizers Act and Health of Animals Act; and
- Ø Canadian Environmental Protection Act, 1999 and the New Substances Notification Regulations (environmental and indirect human health impacts of substances not regulated by any other federal Act or Regulation)

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

The key institutions supporting nanotechnology research and development in Canada are described in the answer to question 1.

Policy development for nanotechnology is being handled by several bodies working in concert within the Federal government. The Prime Minister's Advisory Council on Science and Technology (PMACST) ([www.acst-ccst.gc.ca](http://www.acst-ccst.gc.ca)) has been commissioned to conduct an assessment of Canadian nanotechnology and provide advice on how to position Canada in this emerging field. The PMACST is working closely with the Office of the National Science Advisor (<http://science.pco-bcp.gc.ca>) who is currently looking at strategy options for nanotechnology. Although there is no interdepartmental coordinating committee, the Federal Network on Nanotechnology, co-ordinated through Industry Canada, is a cross-government information-sharing forum for policy makers within the federal government that includes research funding organizations, regulatory and policy-based departments and agencies and science-based organizations involved in nanotechnology research and development.

At the provincial level, Québec, through the Ministère de développement économique, innovation et de l'exportation, provides policy oversight on science and technology policy, and funds R&D through such agencies as the not-for-profit corporation NanoQuébec ([www.nanoquebec.ca](http://www.nanoquebec.ca)) As its mandate, NanoQuébec develops collaborations between industry, academia and government for the development of nanotechnology in Québec through networking and joint actions, partnering support and marketing, awareness building and outreach, and strategic positioning. The Conseil de la science et de la technologie Québec ([www.cst.gouv.gc.ca](http://www.cst.gouv.gc.ca)), has a mandate to provide the Minister with advice on issues pertaining to all aspects of science and technology as they pertain to economic and social, environmental and health issues in Québec. The CSTQ was one of the first bodies in Canada to formally recommend the development of a nanotechnology

strategy and continues to explore issues related to public acceptance and adoption of nanotechnologies.

In Alberta, the Ministry of Innovation and Science provides policy direction for the province's science and technology support. Under the Alberta Science and Research Authority, iCore ([www.icore.ca](http://www.icore.ca)) helps to promote scientific excellence and technological development in the information and communications technologies and has a dedicated program in nanoscale and quantum informatics.

There are a limited number of business based networking organizations and associations associated with nanotechnology and MEMS in Canada. The Canadian NanoBusiness Alliance ([www.nanobusiness.ca](http://www.nanobusiness.ca)) is a nanotechnology association and facilitator with the dual mission of establishing a Canadian National Nanotechnology Initiative including the creation of commercially oriented nanotechnology hubs, and developing major nanotechnology initiatives globally. Other provincially based nano business networks include Nano BC at <http://www.raw.net/nanobc/> and NanoMEMS Edmonton <http://www.nanomems.org/> in Alberta.

In Canada there are also two lobby groups, ETC Group ([www.etcgroup.org](http://www.etcgroup.org)) (Action Group on Erosion, Technology and Concentration), formerly known as the Rural Advancement Foundation International; and the National Farmers Union ([www.nfu.ca](http://www.nfu.ca)), that are actively engaged in movements for the protection of agricultural lands and communities and have protested the introduction of new technologies such as GMO and nanotechnologies into the agricultural sector in Canada and internationally.

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

The Canadian government currently does not have a dedicated governance framework for nanotechnology. The decision making processes with respect to the funding of research and promotion of industrial development are managed through existing funding mechanisms within the various granting agencies and programs and must comply with research ethics guidelines developed and monitored by the Interagency Panel on Research Ethics [www.pre.ethics.gc.ca](http://www.pre.ethics.gc.ca).

Regulatory oversight for nanotechnology applications in Canada is governed by existing rules and regulations using risk management methodologies in accordance with legislation and mandates of the responsible Ministries and Agencies. Several interdepartmental regulatory bodies ensure consistency and transparency of regulatory processes.

Canada has developed considerable expertise and experience in the regulation and governance of biotechnology and related life science research under the coordination of the Canadian Biotechnology Strategy ([www.biotech.gc.ca](http://www.biotech.gc.ca)) and the Canadian Biotechnology Advisory Committee ([www.cbac-cccb.ic.gc.ca](http://www.cbac-cccb.ic.gc.ca)). (This Committee has provided important insights on applications in other emerging technological fields such as nanotechnology.) The framework currently under development for biotechnology is based on the concept of stewardship with the following eight guiding principles: transparency, international citizenry, respect, science, risk management, proactive engagement, accessibility, and innovation. These principles help project Canadian values here and abroad, and support the Government of Canada's priorities that include ensuring health and safety, protecting the environment, and providing a supportive framework for economic growth. This stewardship framework may be considered in the context of nanotechnology.

5. Please describe **“horizontal” connections in government, with private, NGO’s and other organisations**. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.

Science Deputy Ministers Forum – Chaired by the National Science Advisor meets bi-monthly to address emerging issues of science as they apply to public policy priorities.

Committee of Research Agencies, Councils and Foundations – Chaired by the National Science Advisor brings together the Presidents of the Federal Granting and Research Agencies to address issues of science policy development in Canada. Nanotechnology has been identified as a priority issue within this group.

Prime Minister’s Advisory Council on Science and Technology (PMACST) – Co-chaired by the Minister of Industry to “review Canada’s performance in research and innovation, identify emerging issues of national concern, and advise on a forward-looking agenda with a view to positioning Canada in an international context”. The PMACST has been requested to provide the Federal Government with strategic advice regarding the context, issues, and necessary policy actions related to future federal investments in nanotechnology.

Federal Public Service Network on Nanotechnology, co-ordinated through Industry Canada, brings together policy analysts and program managers to monitor and share information on emerging issues and policy implications of developments in nanotechnology.

Numerous interdepartmental and federal-provincial and territorial working groups exist that monitor and develop integrated responses to regulatory and public policy issues that arise in environmental, health, agricultural, natural resource, security, transport and economic development applications that may be impacted by developments in nanotechnology.

A growing number of provincially and regionally based networks focused on nanotechnology research coordination and development are emerging. The most highly developed organization in Canada at this time is NanoQuébec ([www.nanoquebec.ca](http://www.nanoquebec.ca)), which plays an important mobilizing role for development of nanotechnology R&D and innovation between industry, academia and government.

In addition, Canada’s International Development Research Centre ([www.idrc.ca](http://www.idrc.ca)), a global institution devoted to improving conditions for poor countries through research, is working closely with several NGOS to explore the capacity and governance questions around emerging technologies such as nanotechnology.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.

The Canadian Government does not have any stand alone agreements with other bodies or countries targeting nanotechnology. Canada is working closely within the framework of multilateral institutions that provide global stewardship affecting the emergence of new technologies and their health, environmental and ethical dimensions such as UNESCO, FAO, WHO, etc. In addition, under its various S&T arrangements with developed and developing countries, nanotechnology is often listed as a key area of joint collaboration along with other emerging technologies. This is the case, for example, with the Canada-Japan S&T Agreement, the Canada-EU S&T Agreement, and the negotiations with India and China now underway to incorporate stronger b

ilateral research cooperation in nanotechnology with these countries. Canada, through the Office of the National Science Advisor, has been involved in the meetings of the International Dialogue on Responsible Research and Development in Nanotechnology that has taken place over the past two years in Washington and Brussels. Finally, the International Development Research Centres based in Canada ([www.idrc.ca](http://www.idrc.ca)) has been supporting an emerging Global Dialogue on Nanotechnology and the Poor that is organized by the Meridian Institute and co-sponsored with Rockefeller Foundation in the US. Environment Canada is currently working on the survey of "Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety" as part of the Working Group on Nanotechnology under the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnologies of the Environment Directorate of the OECD. Results of the survey are to be completed at the end of September 2005.

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).
- Ø Advisory Council on Science and Technology (August, 2005), *An Overview of Nanotechnology in Canada: Environmental Scan of the Current State of Play*; A Study prepared by Dr. Mark Roseman
  - Ø Advisory Council on Science and Technology (September, 2005), *The Canadian Industrial Capacity to Absorb Nanotechnology*. A study prepared by David J. Roughley, Victor Jones and Aaron Cruikshank
  - Ø Advisory Council on Science and Technology (September, 2005), *A Review and Analysis of Foreign Nanotechnology Strategies; A Study prepared by Dr. Mark Roseman*
  - Ø Carty, Arthur, Thinking Big about Small Science: Nanotechnology in Canada (speech), NanoForum Conference, June 2005.
  - Ø Caufield, Timothy, et al. Special Issue on Nanotechnology, Health and Law Review, Vol. 12, No. 3 2004, Health and Law Institute
  - Ø Clement, Regime, *Technology Transfer Report: Nanotechnology*, Technology Partnership Program, International Trade Canada, June 2005.
  - Ø ETC Group Report: NanoGeopolitics: ETC Group Surveys the Political Landscape, July August 2005, Communiqué No 89
  - Ø Grütter and Roseman, A Study of Canadian Academic Nanoscience Funding: Review and Recommendations, Science and Engineering Canada, June 2004.
  - Ø Meridian Institute, Global Dialogue on Nanotechnology and the Poor: Opportunities and Risks, 2005, [http:// nanoandthepoor.org](http://nanoandthepoor.org)
  - Ø Patricio, Teresa, *The Social Dimensions of Nanotechnology*, Office of the National Science Advisor, August 2005.
  - Ø Office of the National Science Advisor, (November 2005). *An Assessment of Canadian Research Strengths in Nanotechnology: Report of the International Scientific Review Panel*
  - Ø Salamanca-Buentello et al, *Nanotechnology and the Developing World*, PLoS Medicine 2 (2003) e97
  - Ø Science Metrix, Canadian Stewardship Practices for Environmental Nanotechnology, prepared for Environment Canada, March 2005.
  - Ø Senik, Dennis, Nanotechnology: A preliminary assessment of Canada's relative strengths, prepared for Industry Canada, March 2005.
  - Ø Senik, Dennis, *Nanotechnology: Emerging Applications in Manufacturing*, prepared for Industry Canada, October, 2005.
  - Ø Sheremeta, Lori, *Synthesis Paper on Nanotechnology: The NE<sup>3</sup>LS Issues*, prepared for Health Canada, July 2005.

- Ø Schmidt, Ken et al; Environmental Services Association of Alberta, Nanotechnology in the Environment Industry: Opportunities and Trends - Final Report and Bibliography for the Nano-Environmental Cross Sector Initiative March 4, 2005
- Ø Singer, Peter A. et al., *Harnessing Nanotechnology to Improve Global Equity*, Issues in Science and Technology, Summer 2005, pp. 57-64

#### Questions 8-15

**For the following set of questions please provide your opinion for national and international governance approaches, in topics such as those listed below, or in other topics that you would consider relevant:**

The Government of Canada under the direction of the Minister of Industry and the Prime Minister's Advisory Council on Science and Technology ([www.acst-ccst.gc.ca](http://www.acst-ccst.gc.ca)) and in collaboration with the National Science Advisor to the Prime Minister is currently undertaking an assessment of Canada's current and future prospects in nanotechnology with the following objectives:

- Ø To undertake an early assessment of Canada's current areas of expertise within a comparative world context, including past experiences with other enabling technologies
- Ø To better understand both potential national niche capacity and competitive timelines
- Ø To understand the wider social, economic and regulatory context, in which a national strategy, if adopted, would operate.

The report is expect to be completed in the fall of 2005 and will address many of the questions in the following section.

8. In your opinion how it is possible to build organisational capability to address nanotechnology risk?
9. In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?
10. In your opinion what are the potential risk prevention approaches?
11. In your opinion how should the scientific and technological community be self-regulated?
12. In your opinion how can international expert bodies provide advice for critical issues worldwide?
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 ensured at the international level?
15. 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.

## QUESTIONNAIRE ANSWERS FROM CHINESE TAIPEI

1. *Briefly describe your country's nanotechnology **research and development programs and other investment programs on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

Currently, Taiwan has a National Science and Technology Program for Nanoscience and Nanotechnology. This program coordinates the research efforts from various government organizations to achieve objectives that follow the worldwide nanotechnology development trends. The goals of the program include:

1. Through the establishment of common core facilities and education programs to achieve academic excellence, and promote industrial applications.
2. Based on the national competitive technologies to bring up the academic excellence, and then create innovative industrial applications.
3. Establish international competitive nanotechnology platforms.
4. Enhance advanced innovative research to speed up the commercialization of nanotechnology. (National Science Council, 2004)

This program was formally launched in January 2003 and is scheduled to continue until 2008. An amount of NT\$ 23.2 billion (US \$ 700 million) has been committed to nanotechnology development under the program. The program has four subprograms: Industrial Program (61% of funding), Academic Excellence Program (21% of funding), Core Facilities program (16% of funding), and Education Program (1.3% of funding). Taiwan Environmental Protection Administration (TEPA) has its own commissioned projects related to nanotechnology research. In 2003 and 2004, TEPA has collaborated with the Industrial Technology Research Institute (ITRI) to study possible applications of nanotechnology to environmental protections. The projects in 2003 and 2004 are "Applications of Nanotechnology to Environmental Protections, Safety, and Implications (I)" and "Applications of Nanotechnology to Environmental Protections, Safety, and Implications (II)". In 2003's project, TEPA and ITRI worked together to construct an Internet databank on environmental applications. This databank collects information on international environmental nanotechnology from the U.S.A, Canada, U.K, France, Japan, Taiwan and Mainland China. It contains research fields such as air pollution control, waster water treatment, soil and ground water pollution treatment, environmental impacts and health risks of nanotechnology, and sensing technology. In 2004's project, TEPA and ITRI concentrate on topics of environmental and health impacts of nanoparticles and nanomaterials, and emergency preventions and control. There are 6 focal areas and 36 topics. The focal areas include: (1) Environmental Safety; (2) Health Implications; (3) Measurement in the Environment; (4) Sustainable Materials and Resources; (5) Sustainable Processes and; (6) Social Implications. In 2005, TEPA has five commissioned projects that cover a wide range of topics related to nanotechnology development. The names of these five programs are: (1) Nanotechnology and International Environmental Issues Analysis, Reponses and Development; (2) Promotion of Responsible Nanotechnology in Research Laboratories and Industrial Manufacturing processes; (3) Advanced Nanotechnology and Environmental Implications; (4) Biological Nano-Gold Manufacturing and Applications; (5) Nanotechnology applications in O<sub>2</sub> Sensor design. In 2005, five commissioned projects together are granted a funding of approximately NT\$10.1 million (approximately U.S \$0.34 million).

2. *Please provide an overview of your country's **laws and regulations, which apply directly, or could be applied to nanotechnology development.***

Currently, the standard laws and regulations that govern environmental protection and could be applied to nanotechnology development are: worker safety, medical professional ethics, laboratory operations, product development protocols. However, Taiwan EPA and other government agencies have not yet develop policies or regulations specifically targeting the industrial manufacturing processes, laboratory operations, and commercial products that involve nanotechnology or nanomaterials. Taiwan EPA aims to seek coordination and collaborations with other government agencies, especially the Council of Labor Affairs and Department of Health. Nevertheless, after obtained a comprehensive toxicology data, Taiwan EPA could revise Air Pollution Control Act and Toxic Chemical Substance Control Act accordingly.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

National Science Council is the main institution. However, many other universities and government agencies (such as Taiwan EPA, Council of Labor Affairs, Department of Health, National Science Council) and non-profit organizations (such as National Health Research Institute, Industrial Technology Research Institute, and Development Centre for Biotechnology) are all vigorously involving in the research and development of nanotechnology.

4. *Please describe your country's **governing approach to nanotechnology.** Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

The National Science and Technology Program for Nanoscience and Nanotechnology is entering Phase II (year 2006-2008) of this program. In Phase II, Taiwan EPA plans a 3 year road map to work in collaboration with the Council of Labor Affair and Department of Health in order to examine issues that deal with EHS (Environment, Health and Safety). The short-term goal is to (1) produce the nomenclature of nanotechnology and nanomaterials for the use of decision making; (2) develop methodologies for risk assessment; (3) exchange information on human and ecological toxicology studies and; (4) discover more environmental benefits of nanotechnology. The continuous goal for Taiwan EPA in the next 3 years is to examine issues such as environmental applications and implications of nanotechnology (databank development), pollution prevention and remediation, monitor and measure nanoparticles in the atmosphere (from automobile and industrial emissions), exposure to nanoparticles, and proposing regulations, in four focal areas: Environment, Health and Environment, Exposure and Control, Risk Assessment and Management.

5. *Please describe "**horizontal**" connections in government, with private, NGO's and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

Organizations, such as The Industrial Technology and Research Institute along with many universities, are in close connection with government. The government agencies hold regular meetings, inviting researchers and scholars to present their research results and to provide their valuable suggestions. These researchers and scholars are the experts from various fields, including chemistry, physics, biology, environmental sciences, health sciences, and psychology.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.

Currently, there are no agreements and advice internationally. However, many researches and scholars have been participating in the international conferences such as ACS National Meeting, Nanosafe meeting, etc.

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

The Taiwan EPA and ITRI held two international conferences, the International Symposium on Environmental Nanotechnology in Taipei (2003 and 2004).

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

Close collaboration between organizations (especially on information sharing/exchanging) is needed

9. In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?

Currently, no one can clearly define what the risks are even though there are many speculations about the risk of nanotechnology. As a result, it is hard to communicate (especially between the scientific sector and the general public) with different sectors that have different interests and concerns. Therefore, it is recommended to progress to risk assessment as early as possible and to identify potential hazards that may be caused by nanotechnology (raw nanomaterial, manufacturing processes, products and wastes, etc.) and have the information transparent to everyone who is interested.

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

Most participants do not know or fully understand the underlying risks pose by nanotechnology. In order to reduce the risk of this new technology, we should approach this problem from all sectors together: government agencies, scientific sectors and general public.

First of all, different levels of governments must collaborate to develop more applicable policies and initiatives to construct a responsible nanotechnology research environment (i.e. government agencies such as TEPA, the Council of Labor Affairs and Department of Health, should collaborate together). The policy or regulation should be comprehensive, but flexible enough, not to necessarily limit the progress of nanotechnology. Secondly, in the early stage of the nanotechnology development, relevant information must be transparent and accessible to the public. For the researchers and industry, any research plan or new product should include assessments of environmental impact, chemical toxicity, raw materials, modifications of the formulation process, and pollution control plan. The research and assessment of and health impact should be conducted simultaneously. Lastly, the society must try to apprehend and differentiate the true and beneficial nanotechnologies from the pseudo-nanotechnologies.

There are various nanotechnology products. Cooperation among nations is necessary to accelerate the risk assessment processes.

11. *In your opinion how should the scientific and technological community be self-regulated?*

Any new research plan or new technology should be 'transparent' and include assessments of environmental impact, chemical toxicity, raw materials, modifications of the formulation process, and a pollution control plan. These criteria should determine whether the proposed plan would pass and should proceed further.

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

The best way to provide advice for critical issues worldwide is through open discussions/forum via internet communications. Questions/issues could be posted on a known specific websites, and experts can often visit the website to answer/discuss/ask questions.

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 ensured at the international level?*

Nanotechnology covers issues relating to environment, health and society. It cannot be dealt by any nation alone. International consultative board need to be organized to discuss issues in developing responsible nanotechnology, and international conferences and forum can be organized to regularly gather and exchange information on various studies.

15. *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 should expand 'appropriate' research, and technology. Nanotechnological developments offer new opportunities that could benefit poor people's food security, and natural resource management. Whether it will do so depends on the relevance of R&D. These benefits will materialize only if policies are in place to guide technological developments toward solving problems in those key areas of global importance. For example, nanotechnology should be developed toward and applied to those options provided by the Millennium Ecosystem Assessment Report in managing ecosystems more sustainably to protect our limited water, energy and material resources that ecological system has provided.

## QUESTIONNAIRE ANSWERS FROM FRANCE

### 1. *Research and development programmes and other investment programmes on nanotechnology*

In France, the main public actors for research and development in the field of nanosciences and nanotechnologies are the ministries in charge of research, of economy, finance and industry and of defence.

Other public entities contribute to this domain: Centre national de la recherche scientifique CNRS (programme d'action concertée Nanosciences<sup>4</sup>), Commissariat à l'énergie atomique CEA<sup>5</sup>, ONERA<sup>6</sup> and OSEO/ANVAR for the small business involved in applied research and innovation mainly.

Capital investment in fundamental research is in 2005 of 184 M€  
Annual expenditure is of 150M€ and involves 1200 researchers.  
Infrastructures and networks will receive a 100M€ support in 4 years.

A new agency dedicated to supporting public programmes with a high governmental priority has been created in January 2005, ANR (Agence Nationale de la Recherche<sup>7</sup>) and will support a new network dedicated to nanosciences and nanotechnologies, called R3N (Réseau national nanosciences nanotechnologies). Nanosciences and nanotechnology will receive 70M€ from the newly created ANR in 2005. The first call for tenders of ANR, called **Programme National en Nanosciences et Nanotechnologies (PNANO)**<sup>8</sup>, ending in June 2005, has been a success, but research into the societal and ethical aspects related to the dissemination of nanotechnologies and nanostructured components in trade and commerce, will not be financed, de facto, within this programme in 2005.

An important effort has been made in the field of nanometrology in order to secure observation, simulation and manipulation at the nanoscale, with strong public support by the Laboratoire national de métrologie et d'essai LNE.<sup>9</sup>

A report on public funding of nanosciences and nanotechnologies in France is available online (<http://lesrapports.ladocumentationfrancaise.fr/BRP/044000118/0000.pdf> )

### 2. *Laws and regulations which apply directly, or could be applied to nanotechnology development.*

There are no specific regulations for nanotechnologies. The rules for protection of environment and workers apply, as well as the social responsibility regime for corporations.

Two organisms take care of the scientific breakthroughs and their consequences for toxicology and ecotoxicology : INRS <sup>10</sup>as part of its mission to prevent, assess and struggle against accidents at work, and Institute national de l'environnement industriel et des risques (INERIS<sup>11</sup>), specialised in risk assessment for industrial activities in general. They have created in May 2005 a common

<sup>4</sup> <http://www.cnrs.fr/DEP/prg/nanosciences.html>, <http://www.recherche.gouv.fr/appe/2004/nano.pdf>

<sup>5</sup> <http://www.cea.fr/fr/sciences/nanosciences.htm>

<sup>6</sup> <http://onera.fr>

<sup>7</sup> <http://www.gip-anr.fr/presentation.htm#programme>

<sup>8</sup> <http://www.gip-anr.fr/appels/2005/pnano.htm>

<sup>9</sup> [http://www.lne.fr/en/r\\_and\\_d/nanometrology/nanometrology\\_introduction.shtml](http://www.lne.fr/en/r_and_d/nanometrology/nanometrology_introduction.shtml)

<sup>10</sup> [www.inrs.fr](http://www.inrs.fr)

<sup>11</sup> [www.ineris.fr](http://www.ineris.fr)

structure called Bureau d'évaluation des risques des produits et agents chimiques (BERPC)<sup>12</sup> to provide scientific expertise about impacts of chemical agents for men and the environment.

Wise implementation of the REACH European directive will be of crucial importance in the field of nanostructures elements dissemination.

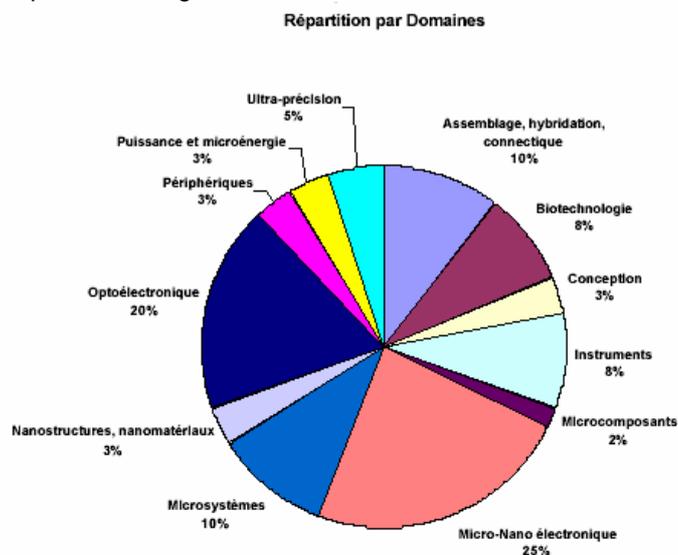
AFNOR<sup>13</sup>, the French standards agency, has created a working group on nanotechnology who will address the need for standards and regulations, and participate to CEN/ WG 166 and ISO TC 229.

The ministry in charge of ecology and environment (MEDD) has asked the Comité de la Prévention et de la Précaution (CPP<sup>14</sup>) to address the subject of relationships between health and environment, and between health and labour in general.

### 3. Key institutions which support nanotechnology

The most important institution which supports nanoscience and nanotechnology is the ministry in charge of research. The description of the program is available online (<http://www.recherche.gouv.fr/discours/2004/dpnanotech.pdf>).

The RMNT (national network for micro and nanotechnologies, who was transformed in R3N in 2005), allocated the public funding as follows:



The results related to the program Pnano implemented by the national network R3N will be available in September 2005.

The French national academy of sciences has made a report<sup>15</sup> on nanosciences and nanotechnologies that gives full support to nanotechnologies and provides recommendations in order to implement a public policy in this field.

<sup>12</sup> [http://www.inrs.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParIntranetID/OM:Document:7AB6DA1BD6120F71C1256FF5002A5B74/\\$FILE/Visu.html](http://www.inrs.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParIntranetID/OM:Document:7AB6DA1BD6120F71C1256FF5002A5B74/$FILE/Visu.html)

<sup>13</sup> [www.afnor.fr](http://www.afnor.fr)

<sup>14</sup> [http://www.sfc.fr/Cpp\\_Min\\_Ecologie.pdf](http://www.sfc.fr/Cpp_Min_Ecologie.pdf)

<sup>15</sup> [http://www.academie-sciences.fr/publications/rapports/rapports\\_html/RST18.htm](http://www.academie-sciences.fr/publications/rapports/rapports_html/RST18.htm)

The ministry of industry, part of the French ministry for economy, science and industry equally support the development of science, technology, innovation and industrial applications in a whole range of sectors, giving special mention to the societal acceptance and ethical aspects of the systemic and dynamic associated risks. (Report Dupuy J-P. –Roure F<sup>16</sup>)

The ministry of industry has realised a communication support on nanotechnologies for all stakeholders, with a special report in its newspaper "Industries" in January 2005, available online (<http://www.industrie.gouv.fr/biblioth/docu/kiosque/cahiers/pdf/c101.pdf> )

A report of the ministry of industry on *nanomaterials* as a key-driver for a sustainable development<sup>17</sup>, prepared within the Conseil National des Ingénieurs et Scientifiques de France, CNISF<sup>18</sup>, makes recommendations in order strengthen and coordinate the vision and guidelines for action of all the stakeholders, including the financial institutions. Ten actions have been defined as follows:

- Ø Energy and environment
- Ø Health, security and comfort improvement
- Ø Flexible interactive items
- Ø Interfacing research and industry by networking
- Ø Information and communication
- Ø Nanomaterials regulation concepts
- Ø Industrial best practices guidelines
- Ø Early financing of nanotechnology businesses
- Ø Nanomaterials research and education
- Ø A specific ERA-NET+ network related to nanomaterials, in addition to Nano-Sci ERA European consortium project.

A Fund called Emertec 2<sup>19</sup> dedicated to seed capital began to finance micro and nanotechnology small businesses with 20M€ in 2005 to be increased to 40M€.

#### 4. *Governing approach to nanotechnology.*

(Please note that this answer does not commit the French government and represents the contributor's opinion only)

The French governing approach to nanotechnology has not been yet expressed at the Prime minister's level but when supporting regional technical platforms for network of excellence and competitive centres at the convergence of biotechnologies, information technologies, and nanotechnologies<sup>20</sup>. Nevertheless, there are converging attitudes from the different ministries and public agencies involved in public policy and increasing cooperation.

We may characterise the French global governance on nanotechnology as a pragmatic one, taking full account of the precautionary principle and aiming at using this emerging technical field; which opens the way to a wide range of products and services to be provided by nano-enabled converging transformational technologies, at the service of such national, European and world challenges as sustainable development, climate change convention implementation, and health improvement.

Risk perception *from institutional stakeholders* has already reached an appropriate level of awareness, and what is more, the risk perception does not seem limited to a linear and causal, risk/benefit approach focused on health and environment unwanted impacts. It involves a

<sup>16</sup> <http://www.cgm.org/themes/deveco/develop/nanofinal.pdf>

<sup>17</sup> [http://www.cnisf.org/biblioth\\_cnisf/etudes/Plan%20Nano.pdf](http://www.cnisf.org/biblioth_cnisf/etudes/Plan%20Nano.pdf)

<sup>18</sup> <http://www.cnisf.org/index.html>

<sup>19</sup> <http://www.emertec.fr/fond.php3?id=1>

<sup>20</sup> [http://www.competitivite.gouv.fr/IMG/pdf/Dossier\\_CIADT\\_II\\_Fiches\\_presentation\\_poles\\_.pdf?PHPSES\\_SID=e45a4e7ab78427e7ba578e2eadb25f5e](http://www.competitivite.gouv.fr/IMG/pdf/Dossier_CIADT_II_Fiches_presentation_poles_.pdf?PHPSES_SID=e45a4e7ab78427e7ba578e2eadb25f5e) see pp. 33 and all.

more dynamic, systemic approach which includes the cognitive, cultural and generally speaking societal impacts to be eventually brought by full and unregulated applied nanosciences and nanotechnologies in industry for trade and commerce on a worldwide basis.

The French government expressed its view in favour of the proposal made by the European Commission of a strategic plan for nanosciences and nanotechnologies in September 2004 and in favour of the action plan 2005-2009 released by the EC in may 2005.

In particular, there is a strong support from France to a structured international dialogue in the field of responsible nanotechnology development, whose characteristics should be transparent, democratic and inclusive, with a special attention to societal aspects.

5. *Horizontal connections in government, with private, NGO's and other organisations.*

- I. OPECST<sup>21</sup> is the French Parliament's agency for scientific and technical choices' evaluation. It has examined a report<sup>22</sup> on nanosciences and medical improvements and the proposals have been adopted by unanimity. As an independent delegation of 18 senators and 18 members of Parliament, it is assisted by a high level *scientific advisory body*. OPECST is member of the European Parliamentary Technology Assessment" (EPTA) network<sup>23</sup>.
- II. OMNT<sup>24</sup> Observatory for micro and nanotechnologies. This network provides strategic outlooks and organizes a range of seminars for its members and the public (academia, scientists, institutions, scientific press, industry, SBE...)
- III. ECRIN<sup>25</sup> is an association created by CNRS and CEA whose aim is to strengthening the industry-research relationships in a neutral and confidential place. It has been charged to organise technology transfers and international cooperation. Its nanomaterials project Nirv@na<sup>26</sup> is associated to the European program Nanosafe2. The association creates and supports clubs of members for nanomaterials and risk assessment<sup>27</sup>.
- IV. VIVAGORA is an association whose goal is to create debate between citizens and the scientists in the field of life science. It has initiated a debate about nanoparticles risk for the environment and health in 2005, and created a website<sup>28</sup> for the public dedicated to nanosciences and nanotechnologies. It will propose *upstream* dialogues in providing participation to seminars with C'Nnano Ile de France, the center of competences in Nanosciences of the Ile de France Region, and provide trans-disciplinary dialogues for responsible nanotechnologies in 2005 and 2006.

6. *International connections: agreements, advice and participation in international organisations.*

- i. G7 / Research Carnegie groups
- ii. OECD

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<sup>21</sup> <http://www.senat.fr/opecst/>

<sup>22</sup> <http://www.senat.fr/commission/offices/office040510.html>

<sup>23</sup> <http://www.eptanetwork.org/EPTA/epta/index.php3> 11 EU members parliaments and the European Parliament

<sup>24</sup> <http://www.omnt.fr/>

<sup>25</sup> ECRIN : [http://ecrin.asso.free.fr/ra04\\_doc/ra04\\_ecrin.pdf](http://ecrin.asso.free.fr/ra04_doc/ra04_ecrin.pdf)

<http://www.nanomateriauxetsecurite.fr/>

<sup>26</sup> Nirv@na Nouvelles Initiatives de Recherche pour le déVeloppement des Architectures Nanostructurées et adaptatives.

<sup>27</sup> <http://www.ecrin.asso.fr/nanomx/>

<sup>28</sup> VIVAGORA website on nanosciences and nanotechnologies  
<http://www.vivantinfo.com/index.php?id=82>

- iii. European Union / European institutions ( European Commission, CEN/WG 166 nanotechnology)
- iv. European Patent Office ( EPO/OEB is an intergovernmental european agency )
- v. ISO/TC 229 nanotechnology 2005 -
- vi. ISO 26000 ( Corporate societal responsibility) 2005-2008 via AFNOR
- vii. NSF Global Nanotechnology Network
- viii. IRGC
- ix. EPTA
- x. International Dialogue on responsible nanoscience and nanotechnology development ( Alexandria process)

#### 7. *Reports and communications concerning nanotechnology*

- Ø Speech on nanotechnologies, Claudie HAIGNERE, ministre de la recherche et des nouvelles technologies, 2003
- Ø Le financement des nanotechnologies et des nanosciences . L'effort des pouvoirs publics en France. Comparaisons internationales.
- Ø Rapport de l' IGAEN ( Alain BILLON , Jean-Loup DUPONT, Gérard GHYS) Janvier 2004
- Ø Nanosciences-Nanotechnologies  
Rapport de l'Académie des sciences sur la science et la technologie n°18 réalisé avec l'Académie des technologies  
Avril 2004
- Ø Les nanosciences et le progrès médical
- Ø Rapport de MM. Jean-Louis LORRAIN et Daniel RAOUL, sénateurs, mai 2004
- Ø Nanotechnologies, les promesses de l'infiniment petit.
- Ø Dossier des cahiers Industries n°101 janvier 2005. Ministère de l'industrie.
- Ø Nanotechnologies : éthique et prospective industrielle
- Ø Rapport de Jean-Pierre DUPUY, ingénieur général, et Françoise ROURE, inspecteur général , Conseil général des mines et Conseil général des technologies de l'information, février 2005

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

We should begin by discussing the “why” before coming to the “how”.

Nanotechnology risk is a complex issue involving the ways and means by which we do represent and imagine today the evolution of the *combination* of risks of different nature in the long run.

Nanotechnology risk should be seen beyond the physical aspects of toxicology for humans and living bodies, and ecotoxicology for the environment.

Nanotechnology risk should also be seen beyond the interaction between the human/living bodies and nanostructured systems enabling artificial performances

Nanotechnology risk should be addressed also for *non* physical aspects, i.e. cognitive, social, societal, legal, ethical ones involved by the new products and “services” that will come not only from nanotechnologies like carbon nanotubes, but from converging technologies, in particular **converging transformational nano-enabled technologies ( CoTNeTs).**

So to be addressed appropriately, we need to conceive and adopt collectively, and, following a democratic process, a common methodology for an on going dynamic and normative risk assessment<sup>29</sup>.

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<sup>29</sup> See on this topic, inter alia, “Living with uncertainty : towards an ongoing normative assessment of nanotechnology” Jean-Pierre Dupuy, Alexei Grinbaum  
<http://scholar.lib.vt.edu/ejournals/SPT/v8n2/pdf/grinbaum.pdf>

Organisational capacities to address technology risk should be given this methodology achievement the highest priority on the international agenda.

9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*

First of all, readiness for communication implies that there is a well defined, already available “message” to communicate. Taking into consideration the fact that observatories and research on physical risks just begin to deliver preliminary results, and taking into consideration the fact that there are no global networkings on the assessment of non physical risks, we do wonder how it would be possible to select an honest “message” to communicate on nanotechnology, but the simple explanation of what is going on in the laboratories and in the industrial plants.

One of the best approaches about how the risks can be best communicated is, in my opinion, expressed by the DEMOS See-through Science essay <sup>30</sup>in the following terms:

*“...The research team identified a deep cultural dislocation between that policy makers and the public frame relevant questions. Whilst the former tend to ask simply “what are the risks?” the latter ask in addition, “what might be the unanticipated effects? Who will be in charge of, and will take the responsibility for, the responses to such surprises and can we trust them?” Many public engagement processes, however well-intentioned, get caught in this trap. Questions of risk – the known uncertainties – can easily dominate proceedings and squeeze out broader discussion of unknown or unanticipated consequences”.*

Here comes the question of responsibilities, which I addressed in a working paper herein after, under the title “Between responsibility and game, converging technologies as a matter of choice”.

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

The classical cost/benefit approach is an interesting step when characterising the facts and impacts. It involves a rather causal, linear approach about the known uncertainties. But this kind of approach reaches limits quickly. I have developed those topics in a contribution to the European Science Foundation Nanotechnology forward look (April 2005).

First, it involves a static approach, not a systemic one: it focuses on linear causalities linking one “event” to its impacts (release of engineered nanoparticles and toxicity/ecotoxicity studies for example); adjustment over time as well as the complexity related to combinations do not fit the risk/benefit approach. Risk here is considered as the “known” uncertainty only. How to fund research on what “we don’t know we don’t know”, without crossing foresight and a systemic risk assessment methodology?

Secondly, it carries implicit values which we may want, or may refuse to share as such. In a competition-led approach, the hidden philosophy for action is “if you don’t know it, just try it”. The stakeholders are under pressure of fulfilling the expected rate of return on investment (ROI) which should be, for instance, no less than x%, within no more than (y) months or years. Unexpected impacts are being considered as externalities to be supported by the whole community. In a more balanced approach combining market efficiency with social welfare, the “norm” could be different.

Other values we may not want to share are, for instance, human performance whatever the ethical consequences might be. Converging technologies for improving human performances is the title of an annual event who takes place in the US. The question here is as follows: when convergence between nanotechnologies, information technologies, cognitive sciences and brain

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<sup>30</sup> [www.demos.co.uk](http://www.demos.co.uk) “ Why public engagement need to move upstream”. 2004, 67 p.

biology gives access to enhanced capacities, how do individuals and groups *consider the freedom/ ability to opt in favour of enhancement when confronted to competition, or opt out* if they are “fed up”, to refer to the analysis developed by Pr. Sheila Jasanoff of Harvard University, author of “Designs on nature”<sup>31</sup>?

The model suggested by M. William Sims Bainbridge at the NBIC 2004 event was the one of an Artificial intelligence personal advisor, for which an AI system provides personal advice to the individual by simulating a human friend or an advisor. This interaction requires *a significant degree of “personal capture” involving the user*. In this example of convergence, cognitive sciences provide design for judgment and decision-making; IT supplies AI information system; the artefact is based on emotional (physiological) responses and nanotechnology allows nano-enabled extreme portability. Appropriation of such “models” is rooted deeply in a societal bet: “if we build it so they will come...”

Confronted to such models *suggested* to scientifics by the orientation of R&D funding, one cannot avoid the neuroethics questions raised by Sonia Miller: “could the possibility to alter an individual’s thoughts and actions be used to forcibly control him in the future?” “Who decides and on what basis?” “What are the safeguards for protecting and disclosing the information?” I would like to add more fundamental questions around ownership, control and the social ends to which the converging technologies are being directed by those who determine and provide funds for scientific works; who benefits from it/ is potentially harmed by it; who denies or edits out unpredictable and social consequences in the long run; who “takes the floor”.

Pr. Alfred Nordmann, rapporteur of the high level expert group on “Foresighting the new technology wave” settled by DG R&D of the European Commission, wrote : “ the potential and limits of engineering *for* the mind and *engineering of* the mind need to be determined. Also, the effects on cognitive processes by technical environments should be investigated: if the video game culture has altered how students learn, pervasive artificial environments of the future will have a more profound effect”.

Pr. Jean-Pierre Dupuy elaborated on the paradox that the triumph of scientific humanism brings with it the obsolescence of man: “in mechanizing the mind, in treating it as an artefact, the mind presumes to exercise power over this artefact to a degree that no psychology claiming to be scientific has ever dreamed of attaining. The mind can now hope not only to manipulate this mechanized version of itself at will, but even to reproduce and manufacture it in accordance with its own wishes and intentions. Accordingly, the technologies of the mind, present and future, open up a vast continent upon which man now has *to impose norms* if he wishes to give them meaning and purpose. The human subject will therefore need to have recourse to a supplementary endowment of will and conscience in order to determine, not what he can do, but what he ought to do or, rather, what he ought not to do. These new technologies will require a whole ethics to be elaborated...”<sup>iii</sup>

Third criticism, it prevents from recycling immediately the increase in knowledge about effects and impacts. Significant factors which could influence the limits fixed by a given legal framework, such as the classification of scientific information related to strategic and safety issues, or the impact of patents governance, are not to be questioned in the classic risks/benefits assessment methodology.

In summary, the risk assessment approach based upon the balance between risks and benefits is far too limited to answer adequately the societal questions raised by converging transformational technologies, in particular between IT and nanotechnologies. This means that containing risk assessment to this methodology opens the door to disillusion and, unfortunately, to a loosen appointment with the great potentialities of nano and information technologies. Are we rich

enough to throw the baby with the bath's water? No, indeed. The ethical deadlock has to be broken in a context already characterized by the emergence of a public opinion trend (not already a "wave"), against all technologies *perceived* as privacy/liberty depriving ones.<sup>iii</sup>

We might want to move to a systemic, dynamic approach if risks, combining the physical and non physical risks, and involving all the stakeholders in the definition of the assessment methodology. We have recently ( 2005) observed in a survey made for the European standards agency ( CEN WG 166), *the wide ( widening ?) gap between industrial and institutional risk perception*, the former ones minimizing strongly their risk awareness as regards the latter ones. And this is a **matter of concern**.

11. *In your opinion how should the scientific and technological community be self-regulated?*

There is an implicit hypothesis in this question, i.e. the fact that self regulation could be the only way to contain unwanted impacts of nanotechnologies. In my opinion, awareness and social/societal responsibility are powerful levers of self discipline, self constraints. One cannot deny the existence of the civil society counterpowers, expressing itself by NGOs lobbies in favour of rating the corporate accountability as regards corporate social/societal responsibilities.

Even the European Economic and Social Committee adopted, as regards *Information and measurement instruments for corporate social responsibility (CSR) in a globalised economy*, the following opinion by 135 votes to 2 with 18 abstentions:

***“Enterprises are an integral part of human society, not just a component of the economic system. Their primary function is to produce goods and deliver services, thereby creating jobs providing incomes and paying taxes. Enterprises are, thus, an integral part of human society. The economic performance of undertakings has, for a very long period, been measured by means of management tools and accountancy instruments. These tools and instruments, which can be rendered more effective, are subject to regular adjustment.”***<sup>32</sup>

We believe that the ISO TC 26000 dynamics<sup>33</sup>, under the co-presidency of Brazil and Sweden, will achieve non mandatory regulation that will be used by all stakeholders, including capital and funds providers, in the field of nanotechnologies as in other ones.

When coming to academics and fundamental/ applied research, we would favour an international dialogue between ethical advisory committees, and full involvement of the civil society, beginning with members of Parliament and Senators.

We also believe that self regulation will not fulfil all the conditions required for obtaining trust and even support from individuals. It is the duty of institutions (national, regional in the meaning of the WTO, and supranational levels, to enter foresight exercises and be ready to regulate.

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

Yes, indeed, this kind of approach is necessary to avoid inertia involved by the rather long periods of time required by diplomacy to come to multilateral agreements.

One of the best good practices is the IPCC<sup>34</sup> (International Panel on Climate change), who was launched by the coordination of International Council of Scientific Unions (ICSU) and the United Nations Environment Program (UNEP).

<sup>32</sup> [www.corporate-accountability.org/docs/EESC-opinionCSR\\_5-2005.doc](http://www.corporate-accountability.org/docs/EESC-opinionCSR_5-2005.doc)

<sup>33</sup> <http://www.iso.org/iso/en/commcentre/pressreleases/2005/Ref953.html>

<sup>34</sup> [http://www.isuma.net/v02n04/bruce/bruce\\_e.shtml](http://www.isuma.net/v02n04/bruce/bruce_e.shtml)

The equivalent could be imagined as the CoTNeTs (see *supra*) present a real and lasting “long emergency” for the Millennium.

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

Without a structured international agreement, and in order to enter a cooperative process, we should be tempted to suggest the voluntary peers' reviews approach.

This would be a way to produce a first global governance evaluation methodology. It requires the coordination and networking of societal observatories dedicated to nanotechnologies and CoTNeTs, at local, national and global levels.

The High level expert group on Foresighting the new technology wave 2020 of the European Commission produced the following definition of a societal observatory for converging technologies:

“The primary mission of this observatory is to study social drivers, economic and social opportunities and effects, ethics and human rights dimensions. It would rely on a standing committee for real-time monitoring and assessment of international converging technologies research. This observatory also serves as a clearing house and platform for public debate. Working groups will deal in multidisciplinary collaborations with issues of patenting, the definition of commons and the allocation of property rights. The core members in the societal observatory represent policy and ethical perspectives while developing substantial technical and scientific expertise in converging technologies. They serve as intermediaries that bring societal concerns to the research community, and relate research visions to various public constituencies<sup>iv, 35</sup>.”

I had the opportunity to present this proposal to the European Commission high level expert group dedicated to “Foresighting the new technology wave”. It received full support from this group, and also from participants to the “Converging technologies for a diverse Europe” conference, which is heartening. Indeed, the European Commission is never committed to implementing recommendations from an expert group, but should consider the obvious welcome and election of this societal observatory recommendation among the others.

This idea could be disseminated around all continents and, provided that it receives public support, would allow international networking and may be the creation of a working party dedicated to *sorting out the relevant criteria* for a peers review evaluation methodology. A first presentation has been made at the 3<sup>rd</sup> Global NanoNetwork Conference in Saarbrücken, May 2005.

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

Not only can it, but it must be ensured at the international level, the most relevant of all.

International cooperation and information sharing use to be a powerful tool for the public evaluation of an existing legal framework, and can help strongly adapting the norms at international, national and local levels. “Adapting”, here, means to let the normative limits implemented in regulatory frameworks (including international laws of trade and commerce within the WTO), move towards harder or softer ones for individuals and entities, when and where appropriate.

<sup>35</sup> [http://europa.eu.int/comm/research/conferences/2004/ntw/index\\_en.html](http://europa.eu.int/comm/research/conferences/2004/ntw/index_en.html)

Since the launching of the Alexandria process in June 2004, the international dialogue gained momentum with the new and full participation of China in the second meeting in Brussels the 14<sup>th</sup> and 15<sup>th</sup> of July 2005<sup>36</sup>, but lost part of its meaning by the fact that the official position of the US since mid July 2005 is to mention no more the word “responsible” in the emerging international dialogue on nanotechnology. This has been interpreted by the whole institutional community as a step backward we wish will be only temporary.

Responsibility comes with a structured dialogue. It is a condition of trust and support from the society. We need to find the ways and means of a universally accepted framework for this structured dialogue. Otherwise we will threaten the institutional ability to secure the desirable outputs of nanotechnology.

Trust also requires transparency, democracy and inclusiveness. One must take into consideration the fact that, on two multilateral agendas, the civil society commitment has been obtained and secured: The World Summit for Information Society (WSIS), within the general responsibility of the UN Secretary, and ISO TC 26000 for Corporate Social responsibility. Being given the maturity and readiness of the society when it comes to discussing health impacts of GMOs, pesticides and chemicals, one cannot imagine the society to be left behind, as “ sleeping dogs not to be awakened prematurely”...

16. *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.*

Wealth of Nations might not mean Earth's paucity. Technology transfers and appropriate funding might guaranty equal and indiscriminate access to the knowledge and products useful to spare scarce resources like energy and contribute to the well being and decent living condition for all. Ethics should regulate what is patentable, opening access to private royalties, and what belongs to public missions and common good.

A cooperative approach, by grid computing simulations open to all researchers, should be supported to accelerate the dissemination of knowledge on properties of the new artificial nanoparticles and structures, as such and when confronted to a wide range of natural and artificial environments.

Military and security organisations might be given a right/duty to prevent proliferation of offensive technologies and products in the field of nanotechnologies, under democratic instruments to be imagined, discussed and eventually implemented on a multilateral basis.

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<sup>1</sup> JASANOFF Sheila, « Designs on Nature”, Princeton University Press, and Science in Society Forum, Brussels, 10<sup>th</sup> of March, 2005.

<sup>1</sup> MILLER Sonia. “ The convergence of C. Legal issues emerge as cognitive science and IT become one”. In NBIC Convergence 2004, February 25-27, 2004, New York, NY.

<sup>1</sup> DUPUY Jean-Pierre , « The philosophical foundations of nanoethics ». Arguments for a method”. Paper presented at the NanoEthics conference, University of South California, Columbia, SC, March 2-5, 2005.

<sup>1</sup> « La micropuce implantable à l'être humain », Signature JAMEH ( jamais avec la manipulation électronique de l'être humain, in <http://www.forum-social-tarnais.org/Telechargement/Micropuce.pdf> 10 p.

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<sup>36</sup> [ftp://ftp.cordis.lu/pub/nanotechnology/docs/intldialogue\\_chairman\\_conclusions.pdf](ftp://ftp.cordis.lu/pub/nanotechnology/docs/intldialogue_chairman_conclusions.pdf)

<sup>1</sup> NORDMANN Alfred, Rapporteur, “ Converging technologies – Shaping the future of European societies”. Report 2004, HLEG Expert group Foresighting the New technology wave/ European Commission DG R&D, 64 p.

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## QUESTIONNAIRE ANSWERS FROM GERMANY

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

The basic elements of the funding and R&D activities stated already in the Meridian questionnaire are still in force.

### Ø **Some additional remarks:**

An international comparison of the shares of publications and patents from the world's nation's shows that Germany's work in the scientific domains of nanotechnology largely remains separated from application and product-orientated areas of R&D. In other words, there is still a lot of catching up to do in the area of industrial implementation. This is where the development of products and systems based on nanotechnological advances and the integration of nanostructures in microscopic and macroscopic environments present an opportunity that must not be missed. In many areas of nanotechnology, Germany is still out in front of many other countries in terms of knowledge. This know-how, together with the production and sales structures needed for implementation and Germany's internationally renowned expertise in the area of systems integration, must be resolutely exploited in the marketplace.

This is exactly where the "German innovation offensive for nanotechnology" is taking up the challenge. On the basis of the white paper presented at the NanoDe congress in 2002 and intensive discussions with representatives from business and science, the BMBF's new approach to nanotechnology funding — starting from Germany's highly-developed and globally competitive basic research in sciences and technology — primarily aims to open up the application potential of nanotechnology through research collaborations (leading-edge innovations) that strategically target the value-added chain. In addition, the BMBF is working to counteract the danger of a shortage of qualified scientists and technicians through its education policy activities. For many of Germany's important industrial sectors — including the automotive business, IT, chemistry, pharmaceuticals and optics — the future competitiveness of their products depends on the opening up of the nanocosmos. Moreover, technology and innovation are increasingly becoming the deciding factors in the struggle to remain competitive in the face of the various challenges posed by low-wage countries. In other words, new technological trends such as nanotechnology will almost certainly have a powerful impact on the labour market of the 21st century — and thus on ensuring Germany's continuing prosperity.

### Ø **Present situation in science, business and politics**

The players on Germany's nanotechnology scene were among the world's first to address potential applications at an early stage, on the basis of solid and broad-based fundamental research. More than 100 companies in Germany have already recognised these innovation opportunities and are using nanotechnology know-how in their core business. Today, a total of about 400 to 500 companies in Germany are involved with nanotechnology and are becoming increasingly active in this field as product developers, suppliers or investors. These companies do not view nanotechnological R&D work as a short-lived fashion but are taking a long-term approach in addressing key elements for future innovation in industries with a large job-creation potential, primarily in the automotive and machine-construction industries, in chemicals and pharmaceuticals, in the optical industry, medicine and biotechnology, as well as in power generation and construction. Many small and medium-sized enterprises (SMEs) that can be ranked as pure nano businesses have sprung up in Germany. These flexible innovation companies occupy specific niches in the value-added chain and make an important contribution to know-how transfer from research to industry. SMEs consequently serve a key function in most

high-technology fields, and establishing innovative start-ups is therefore of enormous importance in the young nanotechnology industry too.

Ø **Project funding by the Federal Ministry of Education and Research (BMBF):**

<b>BMBF nanotechnology funding (in million €)</b>	<b>Core topic areas</b>	<b>1998</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
Nanomaterials	Nanoanalytics, nanobiotechnology, nanostructured materials, nanochemistry, CCN, new “nano talent” recruiting, nano opportunity		19.2	20.3	32.7	38.1
Production technologies	Ultrathin films ultraprecise surfaces		0.2	0.8	2.2	2.2
Optical technologies	Nanooptics, ultraprecision processing, microscopy, photonic crystals, molecular electronics, diode lasers, OLEDs		18.5	25.2	26	26
Microsystems technology	Systems integration		7	7	9.4	10.2
Communications technologies	Quantum structure systems, photonic crystals		4.3	4	3.6	3.4
Nanoelectronics	EUVL, lithography, mask technology, e-biochips, magnetoelectronics, SiGe electronics		19.9	25	44.7	46.2
Nanobiotechnology	Manipulation technologies, functionalised nanoparticles, biochips		4.6	5.4	5	3.1
Innovation and technology analyses	ITA studies		0.2	0.5	0.5	
<b>Total (in million €)</b>		<b>27.6</b>	<b>73.9</b>	<b>88.2</b>	<b>124.3</b>	<b>129.2</b>

Table 1: Expenditures on nanotechnology within various BMBF core topic areas

Since the late 1980s, the BMBF has been funding nanotechnology research activities in the contexts of its Materials Research and Physical Technologies programmes. Initial core topic areas included the production of nanopowders, the creation of lateral structures on silicon and the development of nanoanalytical methods. BMBF support was later expanded to also include other programmes with relevance to nanotechnology, for instance in the Laser Research and Optoelectronics programmes. Today, many projects related to nanotechnology are supported through a considerable number of specialized programmes. Examples include Materials Innovations for Industry and Society (WING), IT Research 2006, the Optical Technologies Sponsorship Programme and the Biotechnology Framework Programme. From 1998 to 2004, the volume of funded joint projects in nanotechnology has quadrupled to about €120 million. Table 1 lists BMBF expenditures on nanotechnology research in various core topic areas for the fiscal years 1998 and 2002 to 2005.

Ø **Project funding by the Federal Ministry of Economics and Employment (BMWA):**

In addition to BMBF-funded research, project-related investments are also financed by the Ministry of Economics and Employment (BMWA) in the Physikalisch-Technischen Bundesanstalt (PTB — the national metrology institute) and the Federal Institute for Materials Research and Testing (BAM), as well as nanotechnology-related projects in the PRO INNO innovation

competency programme for SMEs. These projects are funded to the tune of about €25 million annually.

∅ **Project funding by other funding organisations:**

<b>Institutional nanotechnology funding</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
Deutsche Forschungsgemeinschaft (DFG)	60	60	60	60
Wissensgemeinschaft G.W. Leibniz (WGL)	23.7	23.6	23.4	23.5
Helmholtz-Gemeinschaft (HGF)	38.2	37.1	37.4	37.8
Max-Planck-Gesellschaft (MPG)	14.8	14.8	14.8	14.8
Fraunhofer-Gesellschaft FhG)	4.6	5.4	5.2	4.9
Caesar	1.8	3.3	4	4.4
<b>Total (in million €)</b>	<b>143.1</b>	<b>144.2</b>	<b>144.8</b>	<b>145.4</b>

Table 2: Funds for nanotechnology research in the context of DFG funding and institutional funding.

∅ **Total expenditures for funding nanotechnology in Germany:**

<b>Nanotechnology funding in Germany</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
BMBF project funding	73.9	88.2	123.8	129.2
BMWA project funding	21.1	24.5	24.5	23.7
Institutional funding	143.1	144.2	144.8	145.4
<b>Total (in million €)</b>	<b>238.1</b>	<b>256.9</b>	<b>293.1</b>	<b>298.3</b>

Table 3: Public expenditure on funding for nanotechnology projects in Germany.

Not counting the industry's own contribution, Germany's public expenditures for nanotechnology funding in 2004 total about €290 million. This does not include the Federal States' expenditures on the universities' basic budgets, nor the industry's own funding of nanotechnology research *apart from* public funding.

∅ **Evaluation of the nanotechnology player scene in Germany**

In the field of nanotechnology, Germany can build on a well-educated corps of scientists, on a differentiated and networked R&D and industrial landscape, and on committed engineers and entrepreneurs. All of these players are aware that nanotechnology innovations require large investments but that they also create new job opportunities. The BMBF supports such innovative companies by funding collaborative projects, particular in those applications in which a dominant market position and high profit targets appear attainable. Both these forward-looking companies and public institutions are investing substantial sums in strengthening this discipline and the players in it. These efforts include both R&D work and an expanding array of supporting measures, such as the development of networked structures, the establishment of academic programmes in nanotechnology and other activities designed to ensure a pool of new talent, as well as the familiarisation of society with this subject.

2. Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.

The basic elements of the funding and R&D activities stated already in the Meridian questionnaire are still in force.

∅ **Some additional remarks:**

A focus will be laid on adapting existing legislation to match the requirements for a safe industrial use of nanoparticles and nanomaterials. The government can base its activities on a whole range of regulation tools already in place in the framework of chemical policy, worker safety regulation, consumer protection and handling of hazardous substances. A proactive approach will be taken to advance scientific knowledge, develop appropriate monitoring and warning systems and –if necessary- adjust existing legislation and regulation.

3. Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.

## Networks

### *BMBF-funded competence centres (CCN)*

In 1998, the BMBF established six competence centres with annual funding of approx. €2 million. In Phase 3, starting in the autumn of 2003, nine competence centres will begin or continue their work as nationwide, subject-specific networks with regional clusters in the most important areas of nanotechnology:

- Ultrathin functional layers (*Dresden*)
- Nanomaterials: Functionality by chemistry (*Saarbrücken*)
- Ultraprecise surface processing (*Braunschweig*)
- Nanobioanalytics (*Münster*)
- HanseNanoTec (*Hamburg*)
- Nanoanalytics (*München*)
- Nanostructures in optoelectronics — NanOp (*Berlin*)
- NanoBioTech (*Kaiserslautern*)
- NanoMat (*Karlsruhe*; established and financed by the FZK)

The purpose of the infrastructural activity of these competence centres is to optimise the conditions for bringing potential users and nanotechnology researchers together. The centres will efficiently focus the nanotechnological knowledge of their members and convert it into industrial development. Other tasks of the competence centres include in particular activities related to training and continuing education, collaboration on issues concerning standardisation and regulations, consulting and support of would-be entrepreneurs and public-relations work. The individual competence centres are organised along the subject-specific value-added chain in their respective fields. The entire network presently interlinks approximately 440 players from the academic sphere (29%), research institutions (23%), large corporations (12%), small and medium-sized enterprises (31%) as well as financial services, consultants and associations (totalling 5%). The information sharing supported by the competence centres is particularly helpful for small companies to keep them informed about current developments and what such developments mean to them. In the next three years, the centres intend to focus especially on training and continuing education, and on supporting start-up companies. In the future, BMBF funding will also be complemented by regional financing through the Federal States to the same amount.

### *Other networks*

Besides the competence centres that are directly supported by the BMBF, several other networks have evolved that pursue different goals and are therefore differently structured.

In contrast to networks with a (virtual) structure that is generally nationwide, several universities and research centres have consolidated their nanotechnological basic research activities through local — in some cases even internal — networks. Examples include CeNS (Munich), CINSAT (Kassel), CNI (Jülich) and CFN (Karlsruhe). The NanoBioNet in the Saarland region also has a strong regional focus.

The establishment of incubators founded by universities plays a very special part by supporting spin-offs in the academic environment. To meet this objective, CenTech GmbH in Münster, for example, has established its own start-up support centre.

### **Institutional research establishments**

In Germany, institutional research in nanotechnology outside the universities is pursued by the four large research associations: MPG, FhG, HGF and WGL. These associations maintain numerous research establishments or working groups whose range of activities includes nanotechnology research. What's more, these partners are also integrated into many collaborative research programmes and priority programmes of the DFG.

#### *Wissenschaftsgemeinschaft G. W. Leibniz (WGL):*

The institutes of the WGL (G.W. Leibniz Science Association) conduct basic and industrially orientated work in nanotechnology. Some of their principal efforts are focused on nanomaterials research, in which the Institutes for New Materials (INM, Saarbrücken), for Solid State and Materials Research (IFW, Dresden) and for Polymer Research (IPF, Dresden) rank among the leaders; and on surface technology, for instance at the Institute for Surface Modification (IOM, Leipzig) and at the Rossendorf Research Centre (FZR). Work at the Paul-Drude-Institut (PDI, Berlin) includes basic research in solid state electronics.

#### *Helmholtz-Gemeinschaft deutscher Forschungszentren (HGF):*

The HGF (Helmholtz Association of National Research Centres) also conducts work on issues related to materials and nanoelectronics. Especially noteworthy is the work at the two research centres in Karlsruhe (FZK) and Jülich (FZJ). R&D on nanomaterials and thin-film systems is also pursued at the research centre in Geesthacht (GKSS) and at the Hahn-Meitner-Institut in Berlin (HMI).

#### *Max-Planck-Gesellschaft (MPG):*

Work at the institutes of the MPG (Max Planck Society) is contributing fundamentally important knowledge towards new approaches in nanotechnology research. The Institute for Solid State Research and Metals Research in Stuttgart and the MPI for Microstructure Physics in Halle for instances have been active for many years in the fields of nanomaterials, characterisation methods and new functionalities. Internationally recognized R&D achievements have also been contributed by the Institutes for Polymer Research (Mainz), for Colloid and Boundary Layer Research (Golm), for Biochemistry (Munich-Martinsried), for Coal Research (Mülheim), and by the Fritz-Haber Institute (Berlin).

#### *Fraunhofer Gesellschaft (FhG):*

Since an industrial demand already exists in most areas of nanotechnology, many institutes of the FhG (Fraunhofer Society) conduct projects focused on specific applications jointly with industrial companies. Some of these efforts are focused on thin-film and surface technologies, a field in which the FhG has been supported by the BMBF for many years. The Institutes for Materials and Laser Beam Technology (IWS, Dresden), for Silicate Research (ISC, Würzburg), for Optics and Precision Mechanics (IOF, Jena) and for Boundary Layer Research (IGB, Stuttgart) have been very active in this subject area. Nanomaterials research receives high priority at the Institutes for Applied Materials Research (IFAM, Bremen), for Applied Solid State Physics (IAF, Freiburg) and for Chemical Technology (ICT, Pfinztal), among others. The Institutes for Silicon Technology (ISIT, Itzehoe) and for Production Technology (IPT, Aachen) are exploring the interface of microtechnology and nanotechnology. The Fraunhofer Institute for Reliability and Microintegration (IZM, Berlin) is making contributions in particular to assembly and interconnection technology. The Institute for Biomedical Technology (IBMT, St. Ingbert) is exploring links to nanobiotechnology. The Institute for Solar Energies (ISE, Freiburg) is investigating the contribution of nanotechnology to energy production.

## Universities and other research establishments

Nearly all German universities with a technical and scientific programme of studies are conducting R&D related to nanotechnology. At the same time, growing emphasis is given to developing an interdisciplinary understanding of the relationships in various areas of this field. At several universities, nanotechnology courses of study have already been established that are closely linked to current research topics. Examples of the comprehensive activities covering this subject area can be found in the academic centres of Karlsruhe, Aachen, Munich, Münster, Hamburg, Saarbrücken, Kaiserslautern, Berlin, Kassel, Würzburg, Freiburg and Marburg. Technical universities too are beginning to focus more sharply on this field of studies.

In addition to the aforementioned institutes, the strongly diversified R&D system in Germany also includes other establishments involved with nanotechnology, such as the NMI in Reutlingen, IMS-Chips in Stuttgart, AMICA Aachen, FBH Berlin, Bessy II Berlin, PTB Brunswick, CAESAR in Bonn and IPHT in Jena.

## Industrial R&D

The players in the nanotechnology field in Germany also include several hundred industrial companies. Research programmes in many large corporations such as Infineon, DaimlerChrysler, Schott, Carl Zeiss, Siemens, Osram, BASF, Bayer, Metallgesellschaft and Henkel include open questions in nanotechnology. For example, nearly all major chemical companies are working with nanoscale materials. These research activities vary in the way they are organised. While Henkel has spun off SusTech and Phenion in cooperation with the universities in Darmstadt and Frankfurt for the development and marketing of new nanotechnology applications outside the company in a university setting, Degussa has launched "Projekthaus Nano" at Creavis, a wholly-owned subsidiary, to research nanotechnological methods and products in-house to the point of their suitability for application with the support of universities. Some of these developments are currently being transferred to business units. A third available model is to entirely outsource the utilisation of the research results and of any related patents. Examples include spin-offs such as Sunyx (from Bayer AG) and Mildendo (from Jenoptik). Infineon AG is using yet another model to implement nanotechnology knowledge, by assigning responsibility for this area to an internal research department (Infineon-CPR Corporate Research) with a distinct focus on nanotechnology. In addition to sub-50-nm CMOS transistors for future nanoelectronics this organisation is also focusing on carbon nanotubes (CNTs) as possible connections between different chip levels (chip interconnects).

While large companies tend to be interested mainly in system solutions with prospects of large sales volumes, small and mid-sized enterprises are mainly concerned with production, analysis and equipment-related technologies. SMEs in this field include Nanogate Technologies GmbH (Saarbrücken), a company that supplies its nanomaterials for a variety of applications (easy-to-clean coatings, non-stick products, anti-graffiti protection, etc.). HL-Planar, a company that manufactures various sensors and also provides services in the field of thin-films for microsystems, is already using nanotechnology under a variety of conditions in manufacturing GMR sensors for the auto and machine-construction industry. Important players in nanotechnology in Germany also include many start-up companies (spin-offs of universities and research institutes) such as Nano-X, ItN-Nanovation, NanoSolution, Capsulation and so on. In addition to companies specialising in the production of nanomaterials, there are many others that are active in nanostructuring (such as Aixtron, NaWoTec, Team Nanotech, Nanosensors) or nanoanalytics (including Omicron Nanotechnologies, IoNTOF, NanoAnalytics, Nanotype, SIS and NanoTools).

4. Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.

As a far-reaching basic technology that touches on a wide range of areas of society — including technology, health, individuality and communication — nanotechnology also requires analysis in terms of innovation and technology. Efforts running parallel to technological development must examine possible social and environment consequences in order to develop options for action in terms of the socially desired use of nanotechnology. The somewhat visionary expectations associated with the design potential for creating entirely new materials and products at the atomic and molecular levels require an early public discussion of the question: What sort of effect could these new technologies have on the lives of people and the economy of Germany? This is why the German Ministry for Education and Research is promoting a dialogue among researchers, users and society about the opportunities and risks associated with nanotechnology.

*Measures to support the discussion about opportunities and risks:*

The BMBF will play an active role in directing a scientific/technological and social dialogue about the environmental, health, social and political aspects of nanotechnology. In particular, it will provide interested citizens with facts and figures as well as information about the technical and economic opportunities of individual areas and their recognizable risks. Based on the findings of these studies and on work initiated by the European Commission as part of the sixth EU Framework Programme, other research activities will be undertaken in order to provide political leaders with concrete recommendations for action.

Besides the discussion on the opportunities and risks presented by the use of nanotechnological techniques, the basic conditions governing the utilization of the results need to be optimised. Special standardisation processes play a major role in the diffusion of the results of innovation. Particularly in the area of nanotechnology — where the focus is on new size ranges, more sensitive process and verification management, and new functions — international competitiveness depends heavily on the ability to compare product characteristics. International standards also do much to intensify world trade. Only those who successfully conduct R&D and do not shut themselves off from international activities can have an impact on industrial standards and shape standards in a manner that promotes innovation.

The BMBF plans to increasingly support those cooperative efforts whose goal is to develop standards for nanotechnological manufacturing processes and characteristic values for surface coatings, layers, particles and chemical compositions. The opportunities offered by the large European domestic market must be explored and strategic alliances established with other economic regions.

The first of the standardisation tasks that accompany developmental activities will address the areas of analysis and metrology. In this regard, the BMBF is funding a collaborative project in which recommendations for processes capable of being calibrated are being compiled and discussed as part of international collaborative work. The BMBF will also include necessary standardization activities in the funding programme as part of other projects.

Patent activities are too an essential part of the effort to establish a strong competitive presence and a position of technological strength. Fundamental patents that grow out of innovative research serve as serious proof of accomplishment and win international respect. Particularly in the area of nanotechnology, a field filled with potential for discoveries, patents are a necessity for survival.

The ministry will also increasingly insist that existing patent utilisation opportunities should be exploited. A review will also be conducted into the question of whether a strategic patent initiative is necessary in areas that have high market potential or a pivotal character.

5. Please describe **“horizontal” connections in government, with private, NGO’s and other organisations**. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.

The core element of the horizontal connections between industrial enterprises and research institutions is the well proven cooperation in governmental funded joined projects, so-called “Verbundprojekte” of the BMBF. In these projects several R&D partners are sharing efforts to achieve a common development goal. These collaborative projects pursue a risky, application-oriented project goal with prospects for later market application. They should too include aspects of sustainability (economy, ecology, societal concerns). An industrial partner should be in charge of such industrial collaborative projects, to get directly links from science to industrial usage. If possible, and that is in case of risk topics in nanotechnology advisable, organisations, associations and control authorities representing the opinion of the public and the monitoring of product applicability should be implemented into the discussion in an early stage. This can be done via accompanying evaluation procedures, stakeholder dialogues and public discussion events.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.

In the age of market globalisation, an increased internationalisation of science and research is necessary. International research cooperation strengthens the strong economic relations that already exist between German companies and foreign business. Similarly, collaboration in the field of R&D — and the enhanced profile of German science and research that this entails — increases the attractiveness of Germany as a research and manufacturing location, which in turn creates incentives for foreign investment. In short, such international cooperation makes a significant contribution to bolstering German competitiveness.

International collaboration can take a variety of forms, including bilateral cooperation on joint scientific/technical projects with individual countries and multilateral cooperation programmes such as EUREKA and, in particular, the EU’s Sixth Framework Programme ([www.rp6.de](http://www.rp6.de)) for research, technological development and innovation. The latter aims to create a European Research Area (ERA) and, in so doing, turn Europe into the world’s most competitive and dynamic knowledge-based society by 2010. One of the prime objectives of European cooperation in the area of R&D is to develop common standards. In order to be able to influence and participate in the establishment of international standards in such rapidly developing markets, a thriving R&D environment is absolutely crucial.

A substantial increase in EU funds for nanotechnology in the Sixth Framework Programme (FP6) was resolved with the support of the German federal government. This offers a golden opportunity for Germany to cooperate with outstanding partners from throughout Europe and boost its profile as a location for science and innovation by participating in the Networks of Excellence (NoE), the Integrated Projects (IP) and other FP6 schemes for the promotion of research and development. In particular, the Integrated Projects introduced by FP6 provide — in a manner comparable to the forthcoming BMBF measures to support “leading-edge innovations” — a suitable instrument for promoting a stronger strategic focus for European nanotechnology, with an increased emphasis to be placed on applications in areas such as healthcare and medical technology, chemistry, energy technology, optics, the integration of nanotechnology into the development of new materials and new manufacturing technologies, the development of engineering processes for nanotubes and related systems, and nanobiotechnology. In the future, it will be increasingly important to harmonise national funding with European initiatives. In turn,

this means exploiting the advantages that Germany has on account of its funding system — orientated towards networked, interdisciplinary, project-based cooperation — with a view to bringing about a stronger strategic alignment with European nanotechnology research. Given that national funding for nanotechnology focuses on the applied potential of this field, this will include, in particular, a greater readiness on the part of German companies and research establishments to take on a leadership role within European projects. Alongside the national contact agencies ([www.vdi.de/vdi/j-technologien/nanotechno/index.php](http://www.vdi.de/vdi/j-technologien/nanotechno/index.php)), the competence centres could also play — given the network they form — a valuable role as mediator in the conception of such strategic projects.

The BMBF has established a national contact agency in order to assist German applicants wishing to participate in projects of the Sixth Framework Programme. This agency will serve to integrate the work done by the BMBF more closely into the current efforts to establish a European Research Area. Furthermore, scientific/technical cooperation (WTZ) and bilateral projects (e.g. with France) in nanotechnology will receive increased support when they can demonstrate that they are making a concrete contribution toward the fulfilment of the stated strategic goals in this field.

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

**- References:**

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  8. Nanotechnology competence centres in Germany; BMBF, VDI TZ GmbH [http://www.techportal.de/de/322/2/static\\_public\\_static\\_1103/](http://www.techportal.de/de/322/2/static_public_static_1103/)
  9. see also [www.nanotruck.de](http://www.nanotruck.de)
8. *In your opinion how is it possible to build organisational capability to address nanotechnology risk?*

A general discussion about the chances and risks of nanotechnology, without specifying problem or product oriented areas, seems not to be adequate. Due to the broadness and sometimes non-specific approaches to the nanoworld, a detailed work programme, comprising the hot topics and the appropriate players, with clearly formulated tasks seems to be more feasible. In spite of the increasing societal relevance of nanotechnological developments, society, politics, economy and science have to be sensitized for open mutual information, an attempt to find the accurate language to communicate with each other and to take actions if necessary.

9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*

For non-scientists it is often unclear what nanotechnology actually is, what special qualities nanoproductions may have, and what possible risks are. The manufacturing processes and operating mechanisms of nanotechnological products remain largely inscrutable to observers, users and consumers. This may lead to uncertainty and scepticism in society, especially if the various risk aspects become the subject of public discussion. Therefore, an open public dialog with citizens and consumers is advisable as a basis for an objective judgement on nanotechnology and to avoid baseless fears. This dialog can be done in a two-way process. Scientists, industrialists, and public servants need to understand the concerns of the general public. Conversely, the public should learn about the risks and benefits of nanotechnologies and participate fully in shaping nanotechnologies.

To fulfil these necessities the BMBF initiated the so called "nanotruck". This is a big lorry with several experiments able to explain to the general public the new functionalities based on nanostructures. Especially for pupils in the teen age BMBF commissioned the creation of internet based nano journeys, where future scientist can explore the tininess of the nanoworld in comparison to the real world around them. And there are more activities of the BMBF to bring the nanoworld to the people - brochures, presentations, exhibitions, ...

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

Risk assessment in general comprises several components including

- Ø hazard identification
- Ø hazard characterisation
- Ø exposure assessment
- Ø risk calculation

One the basis of a reliable risk assessment measures for risk management have to be undertaken comprising preventive measures, standardisation and regulation activities. The following figure gives an overview of different aspects and components, which have to be taken into account for the assessment and management of risks associated with industrial nanoparticle production and use.

<p><b>1 Hazard identification</b></p> <p><b>Particle Characteristics</b></p> <ul style="list-style-type: none"> <li>• Aspect-ratio</li> <li>• Diameter (particle/aggregate)</li> <li>• Surface area/ properties</li> <li>• Water solubility</li> <li>• Chemical composition</li> </ul> <p><b>Emission</b></p> <ul style="list-style-type: none"> <li>• Production volume</li> <li>• Material flows</li> <li>• Potential particle release (production, use, disposal)</li> </ul> <p><b>Health effects</b></p> <ul style="list-style-type: none"> <li>• Humans</li> <li>• Experimental animals</li> </ul> <p><b>Environmental effects</b></p> <ul style="list-style-type: none"> <li>• Persistence</li> <li>• Biomagnification</li> <li>• Long range transport</li> </ul>	<p><b>2 Hazard characterization</b></p> <p><b>Epidemiological Studies</b></p> <ul style="list-style-type: none"> <li>• Workers</li> <li>• Consumers</li> <li>• Exposed population</li> </ul> <p><b>In vivo studies</b></p> <ul style="list-style-type: none"> <li>• acute/chronic</li> <li>• different species</li> </ul> <p><b>In vitro studies</b></p> <ul style="list-style-type: none"> <li>• Human/ animal, different cell types</li> <li>• Models (lung, skin, systemic effects)</li> </ul> <p><b>3 Exposure assessment</b></p> <p><b>Exposure routes</b></p> <ul style="list-style-type: none"> <li>• Inhalation, dermal, ingestion</li> </ul> <p><b>Environmental monitoring</b></p> <ul style="list-style-type: none"> <li>• Biological uptake</li> </ul> <p><b>Occupational monitoring</b></p> <ul style="list-style-type: none"> <li>• Personal exposure</li> </ul>	<p><b>4 Risk calculation</b></p> <p><b>Susceptibility extrapolation models</b></p> <ul style="list-style-type: none"> <li>• high dose → low dose</li> <li>• animal → human</li> </ul> <p><b>Threshold value calculation</b></p> <ul style="list-style-type: none"> <li>• Intake, immission concentration, maximum workplace concentration</li> </ul> <p><b>5 Risk Management</b></p> <p><b>Preventive Measures</b></p> <ul style="list-style-type: none"> <li>• Personal protection equipment</li> <li>• Modification of processes</li> </ul> <p><b>Standardization</b></p> <ul style="list-style-type: none"> <li>• Measurement techniques</li> <li>• Toxicological assessment</li> </ul> <p><b>Regulation</b></p> <ul style="list-style-type: none"> <li>• Exposure/ immission standards</li> <li>• Production standards/restrictions</li> </ul>
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*Components and aspects of risk assessment and management associated with industrial nanoparticle production and use.*

It should be pointed out, that many of the aspects concerning nanoparticles have not been investigated yet and are still unknown. For the risk assessment it is useful to distinguish different

types of nanoparticulate materials, whether they are dispersed in gaseous, liquid or solid phase, whether they occur as single-particles or as agglomerates or whether they are untreated or surface modified.

Most critical with regard to potential health and environmental risk are nanoparticles dispersed in air (aerosols), because of their mobility and the possible intake into the human body via the lungs which represents the most critical exposure route for humans. On the other side nanoparticles dispersed in a solid matrix are much less likely to raise concerns because of their immobilisation. Aerosol nanoparticles tend to build larger agglomerates with sizes in the  $\mu\text{m}$ -range. So the question arises whether particle-size dependent phenomena like cell barrier crossing, etc. are still valid for engineered nanomaterials. To answer this question investigations have to be performed, e.g. if agglomerates can deagglomerate in the lung liquid or other biological liquids.

To sum up it has to be kept in mind when assessing risks of engineered nanomaterials that:

- Ø At present combustion processes from traffic and energy generation as well as mechanical abrasion processes contribute much more to anthropogenic nanoparticle emissions than industrial nanoparticle production
- Ø Industrial nanoparticulate materials usually build aggregates with sizes in the  $\mu\text{m}$ -range
- Ø Also natural aerosols contain huge amounts of particles with sizes  $< 100 \text{ nm}$

Nevertheless due to fact that the next few years will probably see a dramatic increase in the industrial generation and use of nanoparticles and entirely new substance classes like carbon nanotubes are released into the environment, a careful risk assessment of engineered nanomaterials is obviously necessary.

11. *In your opinion how should the scientific and technological community be self-regulated?*

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

International pooling of health related information and monitoring the development of nanotechnologies should be encouraged. Joint projects of industry and scientific organisations on international level should be fostered as well as international networks of excellence.

International standards (including a nomenclature for nanoparticles/ nanomaterials), and guidelines would facilitate scientific exchanges, use of existing data, and intercomparisons of experimental results, strengthen consumer and environmental protection, and improve market transparency and facilitate trade. This concerns nanoparticle specific detection and measurement techniques, toxicological and ecotoxicological testing methods, good-working-practises as well as emission standards, etc.

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 ensured at the international level?*

15. *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.*

## QUESTIONNAIRE ANSWERS FROM IRELAND

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

### Nanotechnology Research Groups in Ireland

#### The Tyndall National Institute

The Tyndall National Institute at University College Cork comprises the National Microelectronics Research Centre (NMRC) and the photonics communities within University College Cork and Cork Institute of Technology. It aims to be a national focal point for excellence in research in Microelectronics, Photonics and related technologies. For further details see support section below.

The Tyndall Nanotechnology Group undertakes research aimed at development and innovative exploitation of nanoscale materials and devices within emerging Information and Communication Technology (ICT) application areas. Special emphasis is placed on the development of novel hybrid methods for materials processing and device fabrication. Substantial use is made of combined methodologies, derived from microelectronics, chemistry and biology, for the rational assembly of nanostructures and nanodevices that exhibit novel electrical or optical properties. Within the area of nanophotonics, research is directed at the development of new nano-enabled device concepts and fabrication strategies such as, for example, use of metal nanocrystals for biological sensing, nanostructuring of organic photonic devices and self-assembly based integration of optoelectronic components. Corporate Collaborations include Avecia Ltd., Agilent Technologies, Jenasensonic e.V., MIP Technologies AB., NanoComms Ltd., Oswel Ltd., SONY International (Europe) GmbH., ST Microelectronics S.A., Thales TRT. and Unaxis Balzers Ltd.

Tyndall secures funding through a number of private, national and EU sources.  
Most successful academic performer in winning FP6 nanotech funding

#### Centre for Research on Adaptive Nanostructures and NanoDevices (CRANN)

CRANN is Ireland's first purpose-built Research Institute with a mission to advance the frontiers of nanoscience. Its four major research areas are Membrane-Fluid Interface, Nanoscale Organization and Self-Assembly, Nanoscale Contacts and Spin-Transport and Nanomagnetic Applications. Based at Trinity College Dublin in partnership with University College Cork and University College Dublin, key industrial partners include Intel Ireland Ltd., and several new Irish high-technology companies. The Centre received funding of €10 million from Science Foundation Ireland with a further €11 million going to Trinity College Dublin for the provision of a specialised nanoscience research facility.

#### National Centre for Sensor Research

The National Centre for Sensor Research (NCSR) at Dublin City University is a large-scale, multidisciplinary, sensor research centre focused on the science and applications of chemical sensors and biosensors. The research programme of the NCSR includes both fundamental and applied projects, ranging from basic studies of molecular interactions, for example, to prototype development for industrial partners. The application focus of the NCSR research programme is on areas of economic importance and societal concern, including medical diagnostics, food quality and environmental monitoring. The research structure of the NCSR focuses on three priority research themes: Photonics, Life Sciences and Health and Nanotechnology & Microsystems.

Nanotechnology and Microsystems interests include in-situ visualization of biomembrane activity, nanometre dimensioned electrodes and fibre optics, self-assembling molecular and polymer materials, biomaterials as linkers for self-assembling molecular electronics, security applications and multiplexed sensing, nanophase biolithography and polymer microfabrication.

The NCSR has received €12 million in funding under the Higher Education Authority's (HEA) Programme for Research in Third Level Institutions (PRTL). It has established 4 strategic research & education alliances with internationally recognised centres in identified key areas of Sensor R&D. They include Intelligent Polymer Research Institute, University of Wollongong, Australia, Sensors research Laboratory, Georgia Institute of Technology, Atlanta, US, VTT Electronics, Oulu, Finland and Cornell University Nanobiotechnology Centre.

#### **Sami Nasr Institute for Advanced Materials Science**

The Sami Nasr Institute of Advanced Materials Science brings together staff and students from the departments of Physics, Chemistry and Electronic Engineering within Trinity College Dublin. The research work undertaken by the Institute seeks to provide an improved understanding of inter-relationships among synthesis, processing, and performance of materials, and a description of their structure, composition and properties at the atomic, molecular, microscopic and macroscopic levels.

The current co-ordinated interdisciplinary programme is "Nanomaterials and Nanoscience". This project is funded by the Higher Education Authority (HEA) under the Programme for Research in Third Level Institutions (PRTL; €14.6 million). The project encompasses nanostructured materials and nanoscale processes with the potential of laying scientific foundations for future electronic technology. The subject areas include: semiconductor science, magnetic and spin electronic domain and self-assembling and organic nanostructures. The range of tasks within these subject areas involve the collaboration of internationally respected members of the associated departments, with the common aim of developing novel structured materials and exploring new device concepts.

Deerac fluidics, a company specializing in nanofluidic delivery systems spun out of a nanoscience research group in TCD.

The Sami Nasr is undertaking long term collaborative nanotech research with Intel and Dow Corning, and short to medium term research with indigenous SMEs mainly in the diagnostics, electronics and plastics sectors.

#### **Materials and Surface Science Institute**

The Materials and Surface Science Institute (MSSI) at the University of Limerick provides a world class centre of excellence generating state-of-the-art fundamental research on topics of industrial significance in the fields of surface science and materials. The Institute focuses on research in the areas of the fundamental technical requirements of the materials of the future, from ultra-thin films and coating used in electronic circuits and sensors, to plastics and polymers used in structural and biomedical materials, to the mechanical and electrical properties of ceramics, bio ceramics and magnetic materials, to the biochemical and rheological properties of pharmaceutical compounds and selected foods and the chemical and mechanical properties of heterogeneous catalysts. MSSI was formally established in 1998 and was awarded grants totalling €16 million from the HEA PRTL.

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development.** Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

There are no nanotechnology specific laws or regulations in Ireland to date.

General legislation covers research and development activities (for further information relating to health, safety and environment see <http://www.hse.ie/> and <http://www.epa.ie/> respectively.

Ireland's approach to implementation of European Commission legislation is generally positive but precautionary. European directives related to biotechnology (patentability of biotechnology inventions, use of GMOs, commercialisation of GMOs) have been adopted in a timely fashion. Unlike other EC directives, the commercialisation of GMOs has provoked controversy arising mainly from the final users.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

#### **Science Foundation Ireland**

Science Foundation Ireland (SFI) was established in 2000, as a sub-board of Forfás, to administer Ireland's Technology Foresight Fund. SFI provides awards to support scientists and engineers working in biotechnology and information and communications technology development. SFI is investing €646 million between 2000-2006 in academic researchers and research teams who are most likely to generate new knowledge, leading edge technologies, and competitive enterprises. SFI also advances co-operative efforts among education, government, and industry that support its fields of emphasis and promotes Ireland's ensuing achievements around the world. As a state agency operating under the auspices of the Department of Enterprise, Trade & Employment, SFI contributes actively to national policymaking.

In parallel to funding a number of principal investigators in nanoscience-nanotechnology related areas, SFI has recently supported the establishment of Ireland's first purpose-built research institute with a mission to advance the frontiers of nanoscience the Centre for Research on Adaptive Nanostructures and NanoDevices at Trinity College Dublin.

SFI supports technologies that enable/underpin new developments in ICT and biotech one of these technologies being nanotechnology.

#### **Higher Education Authority**

The Higher Education Authority (HEA) is committed to supporting the provision of core capacity and capability for the Irish third level sector to conduct research and development. An increasing emphasis of the research programmes funded by the HEA, is enabling and encouraging collaboration between institutions and between disciplines in the conduct of research for the benefit of Ireland. The HEA Programme for Research in Third-Level Institutions was launched in 1998 following the success of a pilot programme in science and technology. The programme provides integrated financial support for institutional strategies, programmes and infrastructure and ensures that institutions have the capacity and incentives to formulate and implement research strategies, which will give them critical mass and world level capacity in key areas of research. To date, €605m has been allocated to third level institutions under this competitive programme for research. The HEA contributes to national policymaking through its parent department, the Department of Education.

Investment in recent years in new centres of excellence particularly in nanoscale science & technology, electronics, sensors and materials, ensures that Irish companies have access to world-class research and a highly trained workforce for the future.

#### **Enterprise Ireland**

Enterprise Ireland (EI) is the Irish state development agency focused on accelerating the development of world-class Irish companies. Its vision is to transform Irish companies into businesses that are market focused and innovation driven. EI focuses on achieving export sales, investing in research and innovation, competing through productivity, starting up and scaling up and driving regional enterprise. As a state agency operating under the auspices of the Department of Enterprise, Trade & Employment, EI contributes actively to national policymaking.

EI is actively working with companies to ensure early adoption of nanotechnology. In particular, the agency is helping companies to use the technology to meet market demands and to achieve competitive advantage in the areas of Engineering, Electronics, Construction, Medical Devices, Medical Plastics and General Plastics. Enterprise Ireland supports collaborative research between academics with expertise in nanotech and Irish companies. In 2002 Enterprise Ireland established the Irish Nanotechnology Association, a network to bring Irish researchers and companies together to promote the uptake of nanotechnologies in industry. The Association hosted the World NanoEconomic Congress in Dublin in 2005.

#### **Environmental Protection Agency**

The Environmental Protection Agency (EPA) aims to protect and improve the natural environment for present and future generations, taking into account the environmental, social and economic principles of sustainable development. The EPA's Environmental Research, Technological Development and Innovation (ERTDI) Programme involves a budget of €32m over seven years, and has supported over 230 projects to date. The research focuses on key areas such as air quality and climate change, cleaner production, water quality and eutrophication (over-enrichment).

This year the EPA issued a call for new technologies to assist water and air remediation (call €3M). Nanotechnology solutions to environmental problems were specifically requested. This call is currently open.

#### **Irish Research Council for Science, Engineering & Technology**

The Irish Research Council for Science, Engineering & Technology (IRCSET) provides direct financial support for researchers and research students. Its programmes do not target research projects with an industrial or economic focus but instead aim to support researchers in exploring ideas and bringing vision to reality. Through its programmes, IRCSET strives to stimulate internationally recognisable excellence in research across the sciences, engineering and technology. The emphasis is on innovative, original and exploratory research, aimed at generating new knowledge and energising Ireland's future growth, development and national competitiveness.

IRCSET has funded a variety of projects in nanoscience and nanotechnology to date.

IRCSET is currently the Irish partner in ERACHEM, a chemistry ERANET whose first call is for projects in nanostructured materials.

#### **The Tyndall National Institute**

The Tyndall National Institute has been recently established as a distinct legal entity by the Irish Government Department of Enterprise, Trade and Employment and University College Cork, with the objective of creating a truly National Institute capable of operating at a world-class level. The Institute which initially comprises the National Microelectronics Research Centre (NMRC) and the photonics communities within University College Cork and Cork Institute of Technology aims to be a national focal point for excellence in research in Microelectronics, Photonics and related technologies. Tyndall currently has a substantial research infrastructure, including several fabrication laboratories (e.g. CMOS, Compound Semiconductor & Microsystems) along with an extensive suite of characterisation, analytical and test laboratories.

Tyndall provides access for researchers to research facilities and equipment, funded by Science Foundation Ireland, with consequent benefits for research quality, innovation and economic competitiveness. The programme is open to all Irish based research staff and post graduate students of Irish academic institutions. The NMRC has a demonstrable track record as a strategic European host site for providing access for small and medium enterprises to advanced technologies for improved product development and enhanced product innovation through a number of EU programmes. As an EU designated research infrastructure, NMRC provides European academic researchers access to advanced analysis and characterisation facilities to support their R&D programmes.

### European Commission 6<sup>th</sup> Framework Programme

Ireland has demonstrated substantial success in the European Commission 6<sup>th</sup> Framework Programme *nanotechnologies and nano-sciences, knowledge-based multifunctional materials and new production processes and devices* initiative. The majority of funding has gone to researchers in higher education with substantial representation by the Tyndall National Institute. Industry participation has been strong with both Irish and foreign owned industries equally well-represented and accounting for over 20% of funding to date. While the foreign owned multinational companies are representative of the pharmaceutical, medical device and information technologies industries, the Irish owned companies include several high tech and nanotechnology-specific SMEs.

European Commission funding forms a core part of the support measures available to the nanotechnology communities in Ireland and is increasingly considered in an integrative manner with the national support measures listed above.

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

Ireland is currently developing a strategic policy intelligence capability, which includes Technology Assessment (TA), across the Irish national innovation system. In this context Ireland is piloting this strategic capability development using nanotechnology in its NanoIreland project. The approach being adopted, i.e. TA, is a systematic, multi-disciplinary research and structured communication process which integrates expert knowledge (national and international) regarding emerging nanotechnology characteristics, development pathways and potential long-term socio-economic impacts. The TA process will enable Ireland to generate robust and fact-based analysis on which public and private investment decisions can subsequently be based.

NanoIreland, managed by Forfás and advised by a high level Task Force, chaired by Mike Devane, CEO, Lucent Ireland and three integrated scenario building panels in the areas of NanoBiotechnology, NanoMaterials and NanoElectronics. Both the Task Force and Panels are currently investigating issues such as risk in detail.

Ireland is also actively participating in the development of the European Strategy for Nanotechnology and considers this a core element in national strategy deliberations given the European Council invitation to Member States to reinforce national research in the field of nanotechnology and to engage in an international dialogue with a view to establishing a framework of shared principles for the safe, sustainable, responsible and societally acceptable development and use of nanotechnology.

5. *Please describe "**horizontal**" connections in government, with private, NGO's and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

In June 2004 the Irish Government established a Cabinet Committee on Science and Technology, supported by an Inter-Departmental Committee and the appointment of Ireland's first Chief Science Adviser (<http://www.c-s.ie/>), thus placing research and development at the centre of Government policy at the highest level to date and initiating the mechanism to ensure effective oversight and review of the investment underway, and to provide strategic direction and coherence to that investment.

The Office of Science and Technology (OST; <http://www.entemp.ie/science/technology/>) is responsible for the development, promotion and co-ordination of Ireland's Science, Technology and Innovation policy; and Ireland's policy in European Union and international research activities. The OST is advised by Forfás (<http://www.forfas.ie/>) in accordance with its statutory remit and the Advisory Council for Science Technology and Innovation, established as a sub-board of Forfás.

Figures 1 & 2 (see Appendix) illustrate the connections within government and between government and private, NGO's and other organizations. All of the organizations play a role in initiation and influencing of public and government decision making (both formally and informally) with certain organisations playing stronger roles in this process. For example, government departments rely heavily on the knowledge and expertise accrued by the research and development agencies during implementation of their funding programmes. In turn, these agencies aspire to have strong representation at Inter Departmental Committee level within Government to ensure adequate placement and representation within a coherent coordinated national innovation system. Following recent trends at European level, the role of industry in policy development is under review and recent initiatives have comprised substantial industry input or indeed, have been industry led.

The NanoIreland TA, which is chaired by a leading Irish-based industrialist, will feed directly into the Inter Departmental Committee. This mechanism is seen as most appropriate to the interdisciplinary, cross-sectoral nature of nanotechnology which makes it appropriate that no one scientific discipline or policy field will monopolise it generally, or from a policy perspective.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organization(s), and briefly describe how it works and your participation in it.

Ireland is represented on all European and OECD activities relevant to its national strategies. Nanotechnology-specific examples include:

#### **European Commission 6<sup>th</sup> Framework Programme Nanosciences & nanotechnology Initiative**

Ireland is represented by a National Delegate (ND) and facilitates access to the initiative through its National Contact Point (NCP). Both access the ND/NCP network across Europe and beyond. Representatives of other parts of FP6 also play a role as necessary e.g. in the New & Emerging Science and Technology initiative and in the Horizontal Programme Committee. All representatives play a central role in policymaking.

Ireland's success in FP6 to date has resulted in our researchers having access to extensive higher education and industry research networks across Europe.

#### **European Commission 7<sup>th</sup> Framework Programme**

Like all Member States, Ireland is actively involved in shaping the next Framework Programme. In this context Ireland is currently participating in the preliminary planning stages of the proposed European Strategic Technology Platforms. Dr Alastair Glass, Director of the Tyndall Institute is a member of the NanoElectronics Platform high-level group. Intel Ireland is a member of the Scientific Advisory Group and Enterprise Ireland is represented on the PA Advisory Group.

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

Statement on Nanotechnology

The Irish Council for Science, Technology and Innovation (ICSTI)

July 2004

The Statement assesses Ireland's current capabilities in the field of nanotechnology, maps out specific areas of opportunity for the Irish economy and presents a sustainable vision and strategy for the promotion, development and commercialisation of nanotechnology in Ireland. It can be downloaded at:

[http://www.forfas.ie/icsti/statements/icsti040714/icsti040714\\_nanotech\\_statement.pdf](http://www.forfas.ie/icsti/statements/icsti040714/icsti040714_nanotech_statement.pdf)

Enterprise Ireland Strategy Document for Nanotechnology, 2003-2008.

Enterprise Ireland

December 2002

This document sets out a medium term strategy for the development of nanotechnology capability in Ireland and how best to leverage the technology to the benefit of Irish industry. Clear targets and deliverables are set out with appropriate phasing of investment and measurement of results to ensure impact and value for money. The main impacts of the strategy will be: **(i)** the development and application of nanotechnology by existing clients i.e. up to 40 companies to apply the technology to yield products which offer a significant competitive advantage, **(ii)** a doubling in the number of researchers from 130 to 260 with Science Foundation Ireland supporting new basic research centre(s) of excellence, and **(iii)** the creation of 8 new start-up companies over the next 3 years.

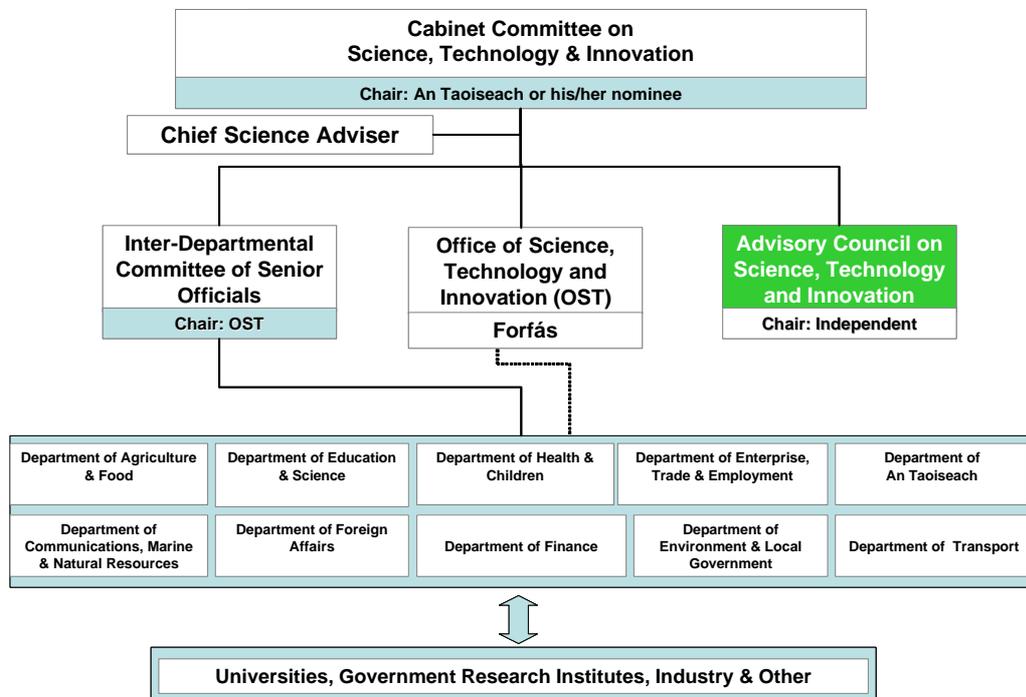
8. *In your opinion how it is possible to build organisational capability to address nanotechnology risk? Identify best practice in other countries. An initial step might be to build risk and ethical studies into large R&D projects such as CSET, SFI fellowships, ILRP similar to FP6 NMP projects. Under the NanoIreland project a national expert group in this field could link with similar groups and international projects worldwide.*
9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated? A single agency/organisation to take responsibility for coordinating information from all projects. Full and transparent disclosure of positive and negative results in order to avoid some of the mistakes made in the past with GMO research.*
10. *In your opinion what are the potential risk prevention approaches?*
11. *In your opinion how should the scientific and technological community be self-regulated? Self-regulation is difficult full stop. This question though very topical in nanotech is wider than just the nanotech field for example stem cell research.*
12. *In your opinion how can international expert bodies provide advice for critical issues worldwide? It's often the same critical issues arising in several countries. An International expert body has the means to create a knowledge database that can be accessed by all.*
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 ensured at the international level? Improved interactions between the various DGs in Europe, for example there are common nanotech related issues in both DG research and DG Health. ENIAC (Nanoelectronics TP) is already working with Japan and the US to identify areas where all 3 regions can work together to make significant inroads into the technology but also to avoid spending millions of Euro individually trying to tackle the same problems, or dealing with*

generic health, safety and risk issues. In ENIAC's case the responsible development of nanotech is being addressed with a narrow sectoral focus – future electronics.

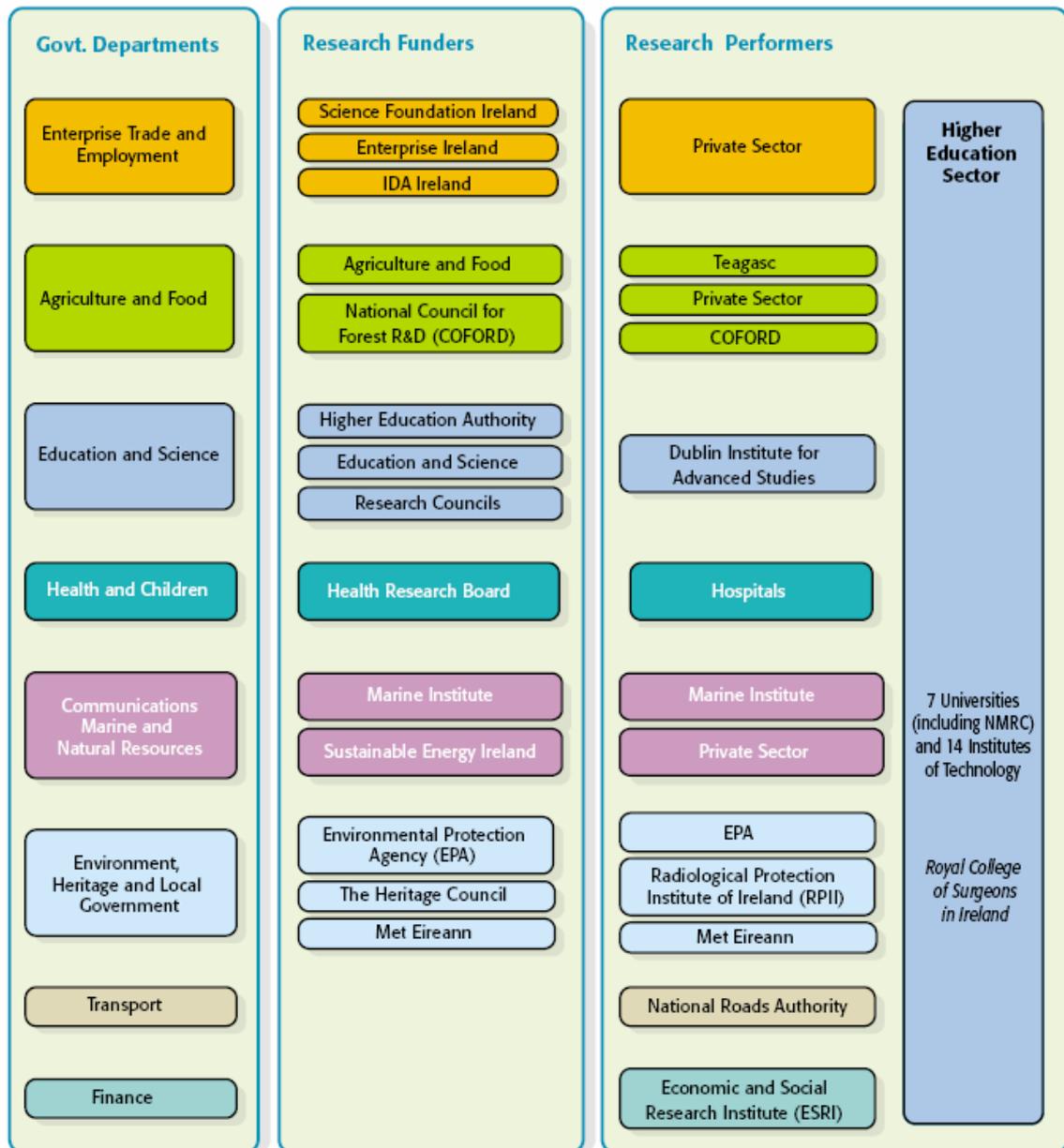
15. Please provide suggestions on how to ensure that we take advantage of nanotechnology in key areas (such as water, energy and materials) of global importance for sustainable development, and how to achieve a balanced distribution of benefits among countries and regions.

**FIGURE 1.**

**Administrative Structure of Government-funded Science and Technology in Ireland**



**FIGURE 2.**  
**Public Sector Research Structures.**



Source: Forfás

## QUESTIONNAIRE ANSWERS FROM ITALY

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

The 2001-2003 National Research Programme (NRP), approved by the Government on December 2000, has allocated funds for € 85 million for the integrated development of nanotechnology, microtechnology and advanced materials. This money has been made available through FIRB, the Fund for Investment in Basic Research, and more than 50% of it has been used to finance projects in the field of nanoscience and nanotechnology at universities and public research organizations. Nanotechnology is a specific priority of the new NRP, but there is not a specific single programme on it. In 2004 the funding for R&D in nanotechnology totalled about € 40 million.

The research in the field of nanotechnology involves in Italy all the major public research organisation. The National Research Council (CNR), the National Institute of Structure of the Matter (INFN), the Inter-University Consortium for Material Sciences and Technologies (INSTM), the National Institute for Nuclear Physics (INFN), the National Agency for New Technologies, Energy and Environment (ENEA). Besides them there are also several large companies and some SMEs.

The research refer to the most relevant topics: atomic and molecular physics, nanooptics and photonic devices, nanoelectronics, supramolecular and nanodimensional systems, nanostructured surfaces and powders, nanocomposites, biomaterials, biosystems, for applications in the medical sector, ITC, transportation, energy.

Recently the creation of a technological district focused on nanotechnology (Veneto Nanotech) has been financed by the Veneto Region and the Ministry for Education, University and Research (MIUR) to promote and support R&D in this field and for building a nanofabrication facility (NFF).

Post graduated courses (Masters and PhD's) on nanotechnology are offered by the Universities of Padua, Perugia, Rome, Padua, the Polytechnics of Turin and Milan.

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

No specific laws that apply to nanotechnology development have been introduced so far. Environment and worker safety are regulated by current laws regulating handling and disposal of harmful substances that follow the indications of the European Commission.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

All public resarch institutions (indicated above) include now nanotechnology among the priorities of their research activity. These institutions contribute to the definition of national research policies and decisions.

**Nanotec IT** (the Italian Centre for Nanotechnology) was created in 2003 as an autonomous division of AIRI (Italian Association for Industrial Research), it is a private non-profit organisation,

with the objective to provide a national focal point for nanotechnology and contribute to make more effective the activities undertaken in Italy in this field, so helping to translate this commitment into a competitive advantage for the Country.

Nanotec IT provides a permanent monitoring of the situation in the field at national and international level with reference to R&D results and trends, applications, research infrastructures and facilities, market data and forecasts, national and international programmes. It disseminates this information using its web site ([www.nanotec.it](http://www.nanotec.it)), a newsletter, written documents and reports, organizing dedicated scientific events, conferences and workshops. Nanotec IT works in close contact with enterprises, the research community, government structures to raise the awareness toward nanotechnology and it is active in promoting contacts between industry and public research as well as among enterprises to build up nanotechnology related actions and trans-national links. It gives assistance to SMEs to gain contacts and to enter national and international research programmes in this field. In 2004 Nanotec IT has undertaken the first census on nanotechnology in Italy. An implementation of the information collected is planned to prepare a national data base on the subject. Nanotec IT has links with other similar organizations and research institutions in Europe. It coordinates EU cofinanced projects on nanotechnologies (Nanoroadmap, Naomitec) and is trying to enlarge these contacts on a world-wide scale. Nanotec IT participates at the Global Nanotechnology Network (GNN) which has the risk governance issues associated with nanotechnology and the sharing of their benefits on world-wide base among its specific aims.

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

Nanotechnology is in Italy essentially at a R&D stage and the problem of risk, risk assessment, monitoring and management is not yet a major concern for the public. There are not yet initiatives specifically dedicated to address these problems in a organic way, nevertheless these issues are gaining an increasing attention among the research community (public and industry) and policy makers. Very recently by the Office of the Presidency of Ministry has been set up a Bionanotechnology Working Group to address safety and ethical issues associated with this field. Nanotec IT (with me) is present in this group.

5. *Please describe "**horizontal**" connections in government, with private, NGO's and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

In Italy no NGO has expressed opinion or studies on nanotechnology.

6. *Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.*

The Istituto Superiore Sanità (ISS) is participating (Dr. Achille Marconi; [marconi@iss.it](mailto:marconi@iss.it)) at a OECD Working Group on potential implications of manufactured nanomaterials for human health and environmental safety.

7. *Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).*

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

As the present survey indicates, the assessment of nanotechnology risk is on the agenda of several national, international and supranational organizations. All initiatives should converge and find a common ground since there is the need of a global risk governance approach which requires:

- Ø International coordination on regulatory schemes;
- Ø Agreement on definitions and nomenclature;
- Ø Development of common assessment methodologies and testing protocols.

All key stakeholders must be involved in the process. A supranational body should finally “set” and guarantee rules to be accepted worldwide.

9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*

Independent research, with no links with vested interests and/or pressure groups, should be the main source of information about the risks (and benefits) associated with nanotechnology which must be supported by sound, documented, proofs. Transparency and completeness of research results on these matters must be the rule both for academia and industry while information must be correctly and timely divulged to the public to gain a conscious acceptance of nanotechnology and nanotechnology-related products. Proper and accurate labelling for the latter products will be also necessary.

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

Include the evaluation of the potential risks from the very beginning of the research, as a safeguard for the researcher in first place, and then tailoring the investigation to the specific features of the possible final applications taking into consideration besides safety (for the human health and the environment) also societal and ethical issues. Public funding of R&D projects in nanotechnology should be linked to the presence in the project of a specific attention to the above issues. Sharing of information and exchange in this sector must be favoured and promoted

11. *In your opinion how should the scientific and technological community be self-regulated?*

See above answer 9.

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

Workshops, dedicated documents, articles in the press (but with sound scientific evidence), gathering and dissemination of information are the principal instruments for providing advice. A clear evidence of independence of the expert bodies is fundamental to be trustworthy.

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 ensured at the international level?*

Clear rules valid worldwide and a supranational body to supervise them, strict requirements for the access to funding and market, possible labelling of some consumer-sensible nano-related products.

*15. 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.*

Assure that a significative share of research at universities and public research centers as well as that of public funding for R&D in nanotechnology is funnelled toward key ares and companies step up the social responsibility attitude. To make the emerging (poor) countries share the advantages deriving from nanotechnology the access of information in this field should be facilitated as well as participation to cooperative projects and access to research facilities and equipments. Specific exchange programmes for education and training should be promoted.

## QUESTIONNAIRE ANSWERS FROM JAPAN (DR MASAFUMI ATA AND DR. KAZUNOBU TANAKA)

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

Many programs exist. The following are representative examples; Nano Bio Industry Project-Nano Drug Delivery (This project has started in FY 2004 involving four ministries, and direct aim is development of DDS medicine.), Standardization of Nanoparticles Safety Assessment (This project has just started in FY2005, and expected to establish assessment method. National Institute of Advanced Industrial Science and Technology is in charge of the research. )

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

There is no directly applicable law in Japan. But existing laws and regulations could be applied to nano materials. One of those laws is the chemical screening and regulation law that controls production, import and use of chemical materials.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

The Science and Technology Basic Plan (FY2001-2005) is the most basic institutional support of nanotechnology, in which nanotechnology is, along with materials, one of the four prioritized fields. Many ministries, agencies and research organizations are involved such as National Institute of Advanced Industrial Science and Technology, National Institute for Materials Science, National Institute for Environmental Studies and National Institute of Health Science and so on.

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

Japan took stopgap measures for risk governance for a long time, but has started to shift in precautionary measures, though still seeking a way that fits nanotechnology well.

5. *Please describe "**horizontal**" connections in government, with private, NGO's and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

There is few NGO involvement in Japan so far, but government and private organizations are cooperating closely especially in the field of standardization.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.

Correspondence to international move for nano standardization, Japanese government has established a research committee on standardization of nano materials. Government is also eager to participate in international cooperative works. The representative examples are UK/Japan Workshop on Health, Environment and Societal Issues of Nanotechnology and the Asia Nanotech Forum.

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

The representative examples of reports are;

- Ø “Research on Safety of Nano Materials” issued by New Energy and Industrial Technology Development Organization (FY2003)
- Ø “Prescription for Achieving Value Creation by Nanotechnology”
- Ø Ministry of Economy, Trade and Industry (FY2003)

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

Lowering the organizational barriers and facilitate smooth cooperation among ministries and agencies as well as government, industry and academia.

8. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*

Rational and transparent risk assessment is required. That is secured by combine hazardous property assessment that is consisted of understanding particle character and action mechanism and exposure assessment. Then, enforce risk management in accordance with demonstrated risk.

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

Appropriate risk prevention approach consists of standardization of nano technology, risk communication and sound risk governance. Respond to this request, many programs on standardization and risk assessment have started current fiscal year in Japan.

10. *In your opinion how should the scientific and technological community be self-regulated?*

Researchers should realize that accountability is thought to be an integral part of R&D and that without responding to this expectation, getting in the international arena would be difficult.

11. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

Basically technical advice should be provided based on unified criteria, however in some situation, like an advice for policy making, flexibility would be required.

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

Incorporate informal approach, like workshops that open to public, into formal approach to promote scientific communication with society that is essential for sound growth of nanotechnology R&D.

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

Implement rational risk assessment and share information with society would be able to mitigate groundless anxieties, if they can not wipe it out.

*14. 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.*

Develop referable guidelines for research organizations to distribute benefit from nanotechnology R&D in an equitable manner, just like business organizations are able to refer the concept of corporate social responsibility that is now under standardization in ISO.

## QUESTIONNAIRE ANSWERS FROM JAPAN (DR TATSUO MARIMOTO)

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

cf. attached file "R&D Programs FY2004" (available upon request)

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

The laws and regulation that apply to nanotechnology development are not enacted especially in Japan.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

- Ø AIST [http://www.aist.go.jp/index\\_en.html](http://www.aist.go.jp/index_en.html)
- Ø NIMS <http://www.nims.go.jp/eng/index.html>
- Ø RIKEN <http://www.riken.go.jp/engn/index.html>
- Ø NCVC <http://www.ncvc.go.jp/english/indexe.html>
- Ø NCC <http://www.ncc.go.jp/index.html>
- Ø NIES <http://www.nies.go.jp/index.html>
- Ø NFRI <http://www.nfri.affrc.go.jp/english/new/>
- Ø NEDO <http://www.nedo.go.jp/english/index.html>
- Ø JST <http://www.jst.go.jp/EN/>
- Ø JSPS <http://www.jsps.go.jp/english/index.html>

Questions 4-7

cf. attached files "S&TPolicyJapan" (available upon request)

### Manuscript of presentation

(Slide 1)

Today, I'm going to make a presentation about Japan's science & technology policy on nanotechnology. I am very pleased to have an opportunity to speak on Japan's nanotech policy.

(Slide 2)

Here I show you the outline of today's presentation. First, I am going to talk about a basic framework and scheme of Science and Technology Policy in Japan. I will talk about governmental system of science and technology policy, and also the fundamental legal framework. Second, I'd like to show you Japan's Nanotechnology strategy and current programs. I would talk about a 5-year R&D promotion strategy of nanotechnology, and how it was decided and it has been promoted. I will also show how nanotech budget has changed since 2001. Third, I will show you

several topics on science and technology policy in Japan. And I will summarize my presentation in the end.

(Slide 3)

This slide shows the promotion system of science and technology policy in Japan. In cabinet office, the Council for Science and Technology Policy, so called “the CSTP” was established in January 2001. The CSTP’s role is to assist the Prime minister and Cabinet on generalizing matters relating to science and technology. The mission of the CSTP is:

1. To conduct investigations and deliberations on Science and Technology Basic Policies and Programs, assign allocation guidelines of budgets, personnel and other resources in every year.
2. To evaluate nationally important Research and Development for Science and Technology.
3. Convey its opinions or views related these issues to the Prime Minister.

All the ministries concerning to Science and Technology R&D are under the coordination of the CSTP. The CSTP is expected to serve as a brain for promotion of science and technology policy under the leadership of the Prime Minister and the Minister of State for Science and Technology, and to eliminate vertical divisions among those ministries you can see in the lower half of this slide.

(Slide 4)

This is the members of the CSTP. The Prime Minister Junichiro Koizumi is the Chair of the CSTP. The following 6 ministers, namely: Minister of State for Science and Technology Policy, Chief Cabinet Secretary, Minister of Internal Affairs and Communications, Minister of Finance, Minister of Education, Culture, Sports, Science & Technology, and Minister of Economy, Trade and Industry. They are the CSTP member from the Cabinet. There are other 7 Executive Members from Academia and Industries. Dr.Hiroyuki Abe is in charge of nanotechnology promotion. Two women members are included in Executive Members. Dr. Kurokawa, President of Science Council of Japan is also a member of the CSTP. These 15 members are common members of the CSTP. In addition to the 15 members, we sometimes have other cabinet members such as Minister of the Environment, Minister of Health, Labor and Welfare, Ministry of Agriculture, Forestry and Fisheries, and Minister of Land, Infrastructure and Transport.

(Slide 5)

This picture shows the CSTP meeting. The meeting is held once a month or two months in the Official Residence. They discuss about critical issues of Japan’s science and technology policy, and make decisions on them. In the picture below, you can see the Prime Minister Junichiro Koizumi and the right side person is the Minister of Science and Technology Policy Yasubumi Tanahashi. They lead the CSTP meeting.

(Slide 6)

From now on, I would like to talk about the fundamental framework of science and technology policy in Japan. The Japan’s Parliament made the Science and Technology Basic Act in 1993. The Cabinet is required to plan and implement the whole governmental science and technology policy in accordance with the Act. The Act also requires the Cabinet to make the Science and technology Basic Plan every 5 years. The 2nd Science and Technology Basic Plan has started at the beginning of 2001 fiscal year, which is April 2001, and will finish in 2005 fiscal year. So, the next basic plan that starts from April 2006 has to be prepared within 2005. In the 2nd Basic Plan, 4 R&D areas are set as the most prioritized areas. The 4 prioritized areas are Life Science, Information & Telecommunication Technology, Environmental Science, and Nanotechnology & Materials. As you can see, Japan prioritized “Nanotechnology” together with “Materials”. We recognize that Japan is traditionally strong in material science. And in the nanotechnology area, Japanese scientists also made excellent scientific achievement in nano-material development, For example, Dr. Iijima discovered and developed carbon nano-tubes and Dr, Fujishima

developed photo-catalysts with titanium oxides. One of basic concepts of Japan's S&T policy is "Make strong points stronger". This is why Japan prioritized as "Nanotechnology and Materials."

The 2nd S&T Basic Plan also requires the CSTP to establish an R&D promotion strategy for each prioritized area. In the several slide hereafter, I'd like to show you the R&D promotion strategy on the "Nanotechnology and Materials" area.

(Slide 7)

R&D Promotion Strategy for prioritized areas is established in September 2001 by the CSTP. For each prioritized area, the strategy determines several important R&D sub-areas and goals, and promotion measures. In the strategy of Nanotechnology and Materials area, 5 important R&D sub-areas and 4 directions of promotion measures are decided in the Strategy. The next slide shows more details of the 4 directions.

(Slide 8)

Here I show you the 4 directions of R&D promotion measures for Nanotechnology and Materials area. First is to introduce competitive environment in R&D activities by increasing competitive research funds, promoting inter-agency, inter-program cooperation and reinforcing strategic patents. Second is to promote cooperation among scientists with different backgrounds. To do that, we support cooperative approach among scientists and make effort to establish network among researchers of different fields and among research institutes. The third direction is to enhance the collaboration among industry, academia and government, as well as to introduce methods for promoting industrialization. The Promotion Strategy proposes (1) to enhance technology transfer from academia to industry, (2) to introduce incentives for industry, academia and government collaboration such as prioritizing in research funds, and then (3) to increase the number of the researchers who migrate from industry to academia or vice versa. The last direction is to improving and reinforcing education and training systems of scientists and engineers so that talented human resources increase.

(Slide 9)

5 prioritized sub-areas in Nanotechnology and Materials are shown in this slide. There are three areas that are intended for the application of Nanotechnology and Materials, namely (1) Nano-devices and Materials for Next Generation Information and Telecommunications, (2) Microsystems and Materials for Medical Applications and Nano-biology base on Biomechanics and (3) Materials for environmental Conservation and Efficient Energy Consumption. The other two sub-areas are Fundamentals of Nanotechnology. The one of them is Instrumentation, Evaluation, Processing and Computational Simulation. And the other is Innovative Material Technology to realize superior material properties.

(Slide 10)

Here are several examples of R&D Projects done by various ministries and national research organizations. In Nano-devices and materials for Information and telecommunications, we have MIRAI project, which aims to develop next generation semiconductor. We also have a R&D project of EUV source for semiconductor lithography and of Quantum Info-communication technology. In Materials for the environment and energy, we have material development project for fuel cells, which might revolutionize energy supply structures. In the Medical application area, we have several R&D projects for drug delivery system and nano-medicine. In the two fundamental sub-areas, we have MEMS project, Ultra-steel project.

(Slide 11)

Here I am going to talk about budgets. As you can see the budget for Nanotechnology and Materials R&D has been increasing gradually during the second Basic Plan from 2001 to 2005. In the first year, government expenditure to Nanotechnology and Materials was approximately 80 billion yen, which is approximately 750 million US dollars or 600 million Euros. In the fifth year, total amount has increased up to 97 billion yen, 900 million US dollars or 700 million Euros.

(Slide 12)

This figure shows S&T Budget share of the 4 most prioritized areas and the secondary prioritized areas namely Energy, Societal Infrastructure, and Frontier such as Outer space and Oceans and Manufacturing technology. The share of “Nanotechnology and Materials” area has slightly but steadily increased during the recent 5 years from 4.2 % in 2001 to 4.9% in 2005.

(Slide 13)

Here is another figure which shows budgets. This is nanotech and materials budget by ministries. As is shown in this figure, Ministry of Education, Culture, Sports, Science and Technology, MEXT, has as much as about 75% share of the total. They tend to more focus on basic or scientific research rather than commercialization or industrialization of nanotechnology. Other ministries, on the other hand, tend to spend their budgets on more application R&Ds. For example, Ministry of Economy, Trade and Industry, METI, focuses on application for manufacturing. Ministry of Health, Labor, and Welfare tend to conduct R&Ds for medical application.

(Slide 14)

Finally, I am going to talk about several topics on Japan's Science and Technology policy. First is “the Coordination Program of Science and Technology Projects”. It will start late in this month. The purpose of the Coordination Program is to implement nationally critical S&T projects more effectively and more efficiently by eliminating vertical divide between ministries and by enhancing inter-ministerial coordination. The CSTP selected 8 themes for the program, which are very important for Japan's society and economy. As for nanotechnology, “Nano-biotechnology” and “Hydrogen Utilization and Fuel Cell” are included. The Prime Minister will appoint a coordinator for each theme, and the coordinator will lead the program.

(Slide 15)

The second topic is the 3rd Science and Technology Basic Plan. As I mentioned before, the Third Science and Technology Basic Plan will start from 2006 fiscal year. In the last December, the CSTP established an Expert Panel to discuss on the next 5-year Basic Plan. The chair person of this Panel is Dr. Hiroshi Abe, one of Executive Members of the CSTP. So far, we have held the Expert Panel meeting almost every month and discussed on several issues, such as priority areas, human resource development and policy goals. The next meeting will held on June 16. In this meeting, chair-person's draft of the Expert Panel report will be shown and discussed about. It has not been decided yet whether Nanotechnology and Materials will be prioritized in the next plan as well as in the current Basic Plan, but many Expert Panel members show their opinion that the 4 most prioritized areas including “Nanotechnology and Materials”, should be also prioritized in the next 5 years. I expect so because “Nanotechnology and Materials” are still believed to be Japan's strength and to have a big impact on our society and industry. The last topic is “Responsible development of Nanotechnology”. Unfortunately, several technologies, such as nuclear energy and chemical substances, have negative images. This is partly because of inherent danger of these technologies, but largely it can be attributable to policy failure. In order not to make the same failure on nanotechnology, science community and governmental organizations must address the responsible development of nanotechnology. In Japan, several national research institutes, such as National Institute of Advanced Industrial Science and Technology, National Institute of Material Science, conduct research on environmental and health impacts of nano-materials. We recognize this issue should be addressed not only by one country but by an international community. Japan will continue to cooperate with the US, Europe and other countries to address this issue.

(Slide 16)

In my presentation, I talked about several basic points of Japan's S&T policy and told you that Nanotechnology is the most prioritized together with other 3 areas. Nanotechnology is prioritized together with Materials because Japan has traditionally been strong in material science. The CSTP made an R&D Promotion Strategy on Nanotechnology and Materials area, which states 4 directions of R&D promotion, and 5 important sub-areas. Nanotech budget has increased by about 20% during the 2nd Science and Technology Basic Plan. The Coordination Program of

S&T Projects is a new challenge for Japan's S&T policy, and will start soon. The 3 Science and Technology Basic Plan are now being discussed about, and Nanotechnology and Materials is likely to be prioritized again in the next Basic Plan.

*Answers for questions 8-15*

### **A Personal View of the Social Impact of Nanotechnology**

- ∅ Nanotechnology offers techniques for controlling structures and functions at the molecular and atomic level. It plays a role in the most advanced developments in virtually every scientific and technical field, ranging from information and telecommunications, life sciences, environmental sciences and energy, to manufacturing technology. In other words, nanotechnology is of absolutely crucial importance for the future of humankind and for the continued protection of the earth and the nature upon it. No other technology can replace it.
- ∅ Consequently, as the utilization of nanotechnology continues to grow, it becomes essential that we take measures to preclude any negative effects on human beings and on society. Japan experienced misfortune in the past when the unforeseen effects from certain chemicals resulted in the tragedy of organic mercury poisoning. In order to avoid repeating that kind of experience, we must promptly address these issues and we must make maximum use of current scientific knowledge in doing so.
- ∅ There is yet another perspective of importance in connection with the effects of nanotechnology. That is, the possibility that as humankind extends science and technology down to the nano scale, we may bring about unforeseen effects, in the form of unfavorable changes as well as positive contributions, which take place rapidly and have an impact on ethics, society, and the economy. In order for humankind to enjoy the benefits of nanotechnology, we must analyze and study this technology from social science, natural science, and other perspectives before it begins to spread and be used. We must correctly evaluate its social and economic effects, and make an effort to point out better avenues for its future use by humankind and society. This is crucially important, and the time to begin is right now.
- ∅ There are aspects of this problem that will have to be addressed through measures taken autonomously by individual countries, and others to be addressed by action through international cooperation.
- ∅ Important measures taken at the national level include improving and disseminating an appropriate understanding of nanotechnology. For instance, there are nanoparticles that are generated as byproducts, such as the particulates included in automobile exhaust. There are also nanoparticles created deliberately, such as fullerenes and carbon nanotubes. These should be handled in clearly differentiated ways, and suitable measures should be devised for each. To do so, however, we need to have a proper understanding of the structure and properties of nanoparticles.
- ∅ Specific measures for improving and disseminating understanding on the national level include rigorous advance studies of the effects of nanotechnology, and education and training for the safe, effective use of nanotechnology. These measures should be given priority.
- ∅ Issues to be addressed by international cooperation, on the other hand, include information sharing and joint programs for developing more specific measures. Countries where the dissemination of nanotechnology has advanced due to international Cooperation will be capable of taking prompt precautions and precise measures. These countries are likely to provide guidelines in the future to other countries that begin to achieve progress in this field.
- ∅ Nanotechnology is presently on the verge of recognition as an essential technology for society and entry into widespread use. As countries that are advanced in nanotechnology forge ahead in this field, their critical task will be to proceed with responsibility to society.

## QUESTIONNAIRE ANSWERS FROM PR CHINA

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programme on nanotechnology** made in your country, including the annual budget. Please provide the name of the program, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

The support to the activities of nanoscience and nanotechnologies come from many government agencies, especially from R & D related funding agencies, such as State Commission for Development & Reform, Ministry of Science and Technology (MOST), Ministry of Education, the Chinese Academy of Sciences (CAS), National Natural Science Foundation of China (NSFC). In 2000, National Steering Committee for Nanoscience and Nanotechnology was created to oversee national policy of nanoscience and nanotechnology. The committee is formed by Ministry of Science and Technology, State Development and Planning Commission, Ministry of Education, the Chinese Academy of Sciences, Chinese Academy of Engineering, National Science Foundation of China and so on.

The funding for nano-related activities can be traced back to the mid-1980s when the developments of scanning probe microscopy and functional ceramics lead by researchers in the Chinese Academy of Sciences (CAS) were supported by National Natural Science Foundation of China (NSFC) and Ministry of Science and Technology (MOST). Several projects on nanomaterials were implemented since 1990. The State Science and Technology Commission (SSTC) of China approved the 'Climbing up' project (10-year project from 1990 to 1999) on nanomaterial science. In 1999, the Ministry of Science and Technology started a national key basic research project 'Nanomaterial and Nanostructure' to continually support the basic research on nanomaterials such as nanotubes. The National High Technology Plan also established a series of projects for nanomaterial applications. The supported areas include nanomaterials, nanodevices, nanobiology and medicine, detection and characterization, theory, modelling and simulation etc (Figure 1). From 1999 to 2001, nearly 550 national projects were implemented. In addition, NSFC granted nearly 1000 projects in that period of time. Appreciable differences of overall level still exist between China and other developed economies, especially in the area of nanoscale devices and industrialization. Even though the magnitude of support is relatively small as compared with developed economies, the output and impact are well received.

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

The effort to set up measurement standard for nanostructures has resulted in the initiation of a technical committee on nanotechnology standardizations-**National Technical Committee 279 on Nanotechnology of Standardization Administration of China**. Second, a national special committee has been created for laboratory accreditation under the auspice of China National Accreditation Board for Laboratories (CNAL)-**Technical Committee Nanotechnology Subcommittee of China National Accreditation Board for Laboratories**. This effort is aimed at strengthening the detection capabilities of the research facilities in public institutions as well as manufacture sectors engaged in nanotechnology.

SAC/TC279 will be serve as the coordinating body for the purposes of drafting fundamental standards regarding nanotechnology, including terminology, methodology and safety in the fields of nano-scale measurements, materials, devices and scale biomedicine.

On April 1, 2005, China has established the first national standards for nano-scale materials in the world. Initially, seven standards have been issued, including a glossary, four standards for the

nano-scale products nickel powder, zinc oxide, titanium dioxide, and calcium carbonate, and two standards for testing the specific surface area and pore size distribution of powdered or solid materials via gas adsorption BET and the granularity of nano-sized powders. A range of research on nanomaterial standards is currently underway.

The nanomaterial standards are expected to lay ground for the establishment of market access and for other technical standards. The standards are also expected to assist in regulating the market, the proper application of tech-intensive nanomaterials, and the healthy development of the sector.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

The support to the activities of nanoscience and nanotechnologies come from many government agencies, especially from R & D related funding agencies, such as State Commission for Development & Reform, Ministry of Science and Technology (MOST), Ministry of Education, the Chinese Academy of Sciences (CAS), National Natural Science Foundation of China (NSFC).

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*
5. *Please describe "**horizontal**" connections in government, with private, NGO's and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

National Steering Committee for Nanoscience and Nanotechnology was created in 2000 to oversee national policy of nanoscience and nanotechnology. The committee is formed by Ministry of Science and Technology, State Development and Planning Commission, Ministry of Education, the Chinese Academy of Sciences, Chinese Academy of Engineering, National Science Foundation of China and 21 leading scientists from institutes and universities. The National Steering Committee for Nanoscience and Nanotechnology will provide planning, coordinating, consulting nano projects in China at national level.

6. *Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.*

Tens of international and national conferences have been organized in China since 1990 covering a wide range of topics in the related fields. It was clearly realized by all participants that international collaborations should be an important segment in building the infrastructures in this area. The strengthened international collaborations can be seen from setting up joint research projects, research groups, bilateral symposiums etc.

Recognizing the great potential and importance of scientific and technological cooperation in the field of nanotechnology, basing on the present R&D level and the characteristic of nanotechnology, China has agreements with several countries for the international cooperation, holding bilateral seminars on nanotechnology including US, France, Germany, Korea, and other countries every year, exchanging students and post doctor, etc., and also recently the multilateral

meeting International Declaration for the Responsible Development of Nanotechnology in Brussels on July 12 2005.

7. *Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).*

“Report on Nanotechnology Development” is a monthly published report by Ministry of Science and Technology, edited by office of National Steering Committee on Nanoscience and Nanotechnology. The website of the report is <http://nano.br.gov.cn/mag.asp>.

**Answers to Questions 8-15:**

8. *In your opinion how it is possible to build organisational capability to address nanotechnology risk?*
9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*
10. *In your opinion what are the potential risk prevention approaches?*
11. *In your opinion how should the scientific and technological community be self-regulated?*
12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*
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 ensured at the international level?*
15. *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.*

Building an organization like International Risk Governance Council to address nanotechnology risk is helpful for the nanotechnology development. And international communication and cooperation research will also be helpful to share the basic data related to nanotechnology, such as safety of nanomaterials and nanobiotechnology. Scientists and engineers should obey all the rules related to human health and environmental safety for the sustainable development of the whole society. Government and other funding organizations may support some fundamental research to study the different risk situation of nanotechnology.

## QUESTIONNAIRE ANSWERS FROM SOUTH KOREA

1. Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.

### § Research

- Frontier Program: Nanodevices, Nanomaterials, Nanomechatronics: \$10M each/year for 10 years
- Nano Challenge Program: \$8M/year
- Nanofusion program: \$6.4M/year
- Others:

### § Facility

- National NanoFab. Center: \$100 M
- Application Specific NanoFab. Center: \$50M
- National NT Cluster Centers:\$75M

2. Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.

### Nanotech promotion law

- Obligation of Government (there are no indicative goal):
  - Fund raising
  - Establish national master plan
  - Monitoring activities
  - Report national activity to national science and technology committee
  - Education, facilities
- No other regulations

3. Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.

- KOSEF(Korea Science and Engineering Foundation): Managing all the NT funding provided by Ministry of Science and Technology, Cultivation of research and promotion of science education
- KISTEP(Korea Institute of science and technology evaluation and planning): Charged with national science and technology evaluation and planning for Government, Providing foresight and roadmaps
- ITEP(Institute of industrial technology evaluation and planning): Charged with research policy, R&D management and technology assessment. NT R&D management funded by ministry of commerce,industry and energy
- Korea Nanotechnology Research Society: Functioning as a think tank made of scientists for NT-related problems and a network to exchange information,
- Nano Technology Research Association: Functioning as a think tank made of industries

4. Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.

Our law should designate an institute responsible for the study of NT implications on societal, environmental and ethical problems and provide the outcome from the study for NT master plan. KISTEP as a designated Institute reported the results in 2004. and is now doing the investigation to provide the information for the inclusion in the NT master plan which is under revision. The study groups are consisted of NGOs, scientists, social scientist, et al.

5. Please describe "**horizontal**" **connections in government, with private, NGO's and other organizations**. Please provide a brief description of organizations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.

There are many NGOs to influence our NT R&D policy. Now, two NGOs are actively participated in the study of NT implications. They are Green Korea United and Citizen's Coalition for Economic Justice. Representatives from two NGOs join in the study group.

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organization(s), and briefly describe how it works and your participation in it.

We have many agreements with foreign countries to cooperate NT research. As a result, we have Koera-US Nanoforum, a focalpoint program between Korea and UK, Korea-Japan Nanoforum regularly. These activities are operated by scientists. Especially, I actively participated in GNN and responsible NT held in Alexandria and Brussels

7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

- Ø Overview of Nanotechnology in Korea-10 years blueprint, by Jo-Won Lee in Journal of Nanoparticle Research vol 4, P473 (2002)
- Ø Current Status of Nanotechnology in Korea and Research into CNT, by Jo-Won Lee and Wonbong Choi, in Nanotechnology- Global Strategies, Industry Trends and Application, edited by J. Schulte, P25, Wiley (2005)
- Ø Nanotechnology R&D Activities in Korea, by Hanjo Lim, IUMRS Facets vol 4, NO2, P8 (2005)

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

We should form an international committee to deal with the risks. This committee should be made on the voluntary basis. Under the committee, working group of scientists should tackle the problems on the scientific base.

9. In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?

The regular working group workshop will be very helpful to communicate and exchange the information.

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

We do not know what kind of risks we face in the future yet. Do research first and disseminate the results through the workshop or conference.

*11. In your opinion how should the scientific and technological community be self-regulated?*

We do not have to regulate research except human clone by nanotechnology and any experiment using human body. Those two things are regulated by government.

*12. In your opinion how can international expert bodies provide advice for critical issues worldwide?*

We can raise the critical issues through UN and OECD

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

In formal case, we do not have to worry. For informal case, many issues without scientific evidence are rapidly permeated into the public. We need the public education.

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

This is only possible through international dialogue like expert group's workshop, conference and regular papers.

*15. 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.*

To achieve the sustainable development, NT is only solution. We should pursue the fund through UN and OECD or seek donation from people worldwide. That fund should be given to expert group composed of many countries to do research. The outcome through the research should be shared and given to the developing countries without any payment.

**QUESTIONNAIRE ANSWERS FROM UNITED KINGDOM (UK)**

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

Please refer to Meridian document (2004): The Research Councils collectively account for some \$2.2 BN out of a total of \$10.9 BN, of UK Government investment in R&D. The first real dedicated investment in Nanotechnology was made in 1986 through the UK DTI's National Initiative in Nanotechnology (NION), this was quickly followed by the then, Science & Engineering Research Council.s (SERC) own directed Programme. Recently there has been a renewed interest in the potential of technologies at the nano scale and through a variety of Research Council funding routes, such as responsive mode,

PhD and MSc training programmes have led to substantial investment in nanoscience and nanotechnology at UK universities, central laboratories and Research Council institutes. The investment has fostered the development of key centres of research and postgraduate training activity each possessing a critical mass.

Using a broad definition of nanotechnology it is possible to estimate current expenditure across the Research Councils as depicted in Table 1.

<b>Expenditure</b>	<b>2002/03 Direct</b>	<b>2002/03 Underpinning</b>
<b>BBSRC</b>	<b>£14.5M</b>	<b>£35M</b>
<b>EPSRC</b>	<b>£32.2M</b>	<b>£147M</b>
<b>MRC</b>	<b>£21.3M</b>	<b>–</b>
<b>Total</b>	<b>£68M (\$ 115M)</b>	<b>£182M (\$ 308M)</b>

**Table 1: Current Expenditure by UK Research Councils relevant to Nanotechnology (excluding NERC & CCLRC)**

The centre piece to the current investment are the two Interdisciplinary Research Collaborations (IRCs) in nanotechnology. These are intended to be virtual centres of excellence possessing a critical mass of researchers, a concentration of advanced instrumentation and excellence in research and training in an interdisciplinary environment.

The IRC in Nanotechnology is led by University of Cambridge with core partners including the University of Bristol and University College London. The main objectives of this IRC are to: fabricate complex 3-dimensional structures with molecular precision, to control growth and assembly of soft layers by directed self assembly on patterned substrates and to produce architectures for new devices in biomedicine and information technology.

The IRC in Bio-Nanotechnology is led by Oxford University with core partners including University of Glasgow, University of York and the National Institute for Medical Research. This IRC aims to investigate bio-molecular systems, from the level of single molecules to complex molecular machines, to establish their function; and apply this knowledge to produce artificial electronic and optical devices.

A third joint Research Council IRC carries out research relevant to Bio-nanotechnology in the area of Tissue Engineering. This is based at the Universities of Manchester and Liverpool.

A joint Research Councils. programme in Basic Technologies has also been established within the UK. This is another cross-Council activity which is aimed at building up the UK.s means to acquire capability in fundamental technology which will underpin the next generation of scientific endeavour. Well over half the projects are relevant to Nanotechnology representing a total investment of \$13M

A listing of key centres of research activity in nanotechnology in the engineering and physical sciences domain are detailed in the attached briefing note.

2. *Please provide an overview of your country's **laws and regulations which apply directly, or could be applied to nanotechnology development**. Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

Please refer to Meridian document (2004): Explicit UK regulation covering nanotechnology development is still in the formative stage. However existing legislation exists covering aspects of research and development involving the use of chemicals, animals and aspects of *in-vivo* studies. Key legislation includes (not an exhaustive list)

- Ø UK Health and Safety at Work Act
- Ø UK Animal Scientific Procedures Act 1986
- Ø Medical Research Council (Terms and conditions cover legislative requirements for research involving animals and humans)
- Ø Research Councils. Good Scientific Practice (each Council has a publication)
- Ø REACH Chemicals Legislation 2003 (European Union)

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

**The Research Councils(RCs)** fund basic and applied research at Universities and Research Institutes in Nanotechnology in the UK(see table 1 of the Meridian document).The RCs that are primarily involved are:

BBSRC: Biotechnology and Biological Sciences Research Council  
 EPSRC: Engineering and Physical Sciences Research Council  
 MRC: Medical Research Council  
 ESRC:Economic and Social Research Council  
 NERC:Natural Environment Research Council

Organisationally the RCs are administered by the **Office of Science and Technology (OST)** which is part of the **DTI(Department of Trade and Industry)**. OST is headed by the **Chief Scientific Adviser** who provides advice to the Government on science, engineering and technology (SET) matters. The **Director General of Research Councils** advises on the allocation of the UK science budget.

The DTI itself directly funds pre competitive research at Universities, Institutes and Industrial concerns principally via the Micro and Nano Technology initiative but also by means of their Technology Programme. It is the intention of the DTI's programmes is to lever additional funding from local government(**Regional Development Authorities**) who may also directly fund Nanotechnology research.

4. *Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.*

At the government's request The Royal Society and the Royal Academy of Engineering produced a report in 2004 (Nanoscience and Nanotechnologies: Opportunities and Uncertainties. The government gave a detailed response to the recommendations of this report and set up the **Nanotechnology Issues Dialogue Group (NIDG)**,in the Office of Science and Technology,

chaired by the Chief Scientific Officer(CSO)(currently Sir David King) with the following terms of reference:

1. Co-ordinate Government activities described in its response to the report by the Royal Society and the Royal Academy of Engineering: ‘Nanoscience and nanotechnologies: opportunities and uncertainties’;
2. Provide a platform to monitor progress and delivery of the commitments of the Government, and provide evidence to inform the Council for Science and Technology’s two and five-year independent reviews of progress;
3. Ensure that the work of the **Nanotechnology Research Co-ordination Group (NRCG)** is integrated with other parts of the programme of work set out in the Government’s response.

The actions derived are being led by the government **Department for Environment, Food and Rural Affairs (DEFRA)**.

DEFRA has set up the Nanotechnology Research Coordination Group (NRCG) which reports to the NIDG. The role of the NRCG is to:

1. Develop and oversee the implementation of a cross-Government research programme into the potential human health and environmental risks posed by free manufactured nanoparticles and nanotubes to inform regulation and underpin regulatory standards;
2. Establish links in Europe and internationally to promote dialogue and to draw upon and facilitate exchange of information relevant to the Group’s research objectives;
3. Consider the outputs of dialogue between stakeholders, researchers and the public (as integrated with the Nanotechnology Issues Dialogue Group’s (NIDG’s) wider plans for stakeholder and public dialogue) with a view to enhancing and informing research decisions.
5. *Please describe “horizontal” connections in government, with private, NGO’s and other organisations. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.*

There are informal connections with learned societies who supply many of the members of government panels and are asked by the government to comment on policy matters which may concern them. The main societies concerned with nanotechnology are:

The Royal Society  
The Royal Academy of Engineering  
The Royal Society of Chemistry  
The Institute of Physics  
The Institute of Materials, Minerals and Mining

6. *Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations.** Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.*

EPSRC takes part in the ESF Eurocores programme in Self Organised Nano-Structures and there are many Nanotechnology collaborations with European partners through the Framework programme.

There is also a joint research programme with the NSF.

General agreements on research exist with many nations: Korea, Japan, China some of which may concern nanotechnology.

7. *Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).*

- Ø Theme Day in Nanotechnology (EPSRC 1999)  
<http://www.epsrc.ac.uk/website/commonpages/downloads.aspx?CID=3811&ZoneID=6&MenuID=696>
- Ø Opportunities for Industry in the Application of Nanotechnology (DTI/IoN 2000)  
Nanotechnology: Mechanical and Electronic Systems on a Molecular Scale (IoP 2000)  
<http://www.nano.org.uk/contents.htm>
- Ø Nanotechnology: its impact on defence and the MOD (MOD 2001)  
<http://www.mod.uk/issues/nanotech/contents.htm>
- Ø British Council Briefing Sheet 13: Nanotechnology 2002 <http://www.britishcouncil.org/science-publications-briefing-sheets.htm>
- Ø New Dimensions for Manufacturing: A UK Strategy for Nanotechnology (DTI 2002)  
<http://www.dti.gov.uk/innovation/nanotechnologyreport.pdf>
- Ø Foresight - Materials: Shaping our Society (DTI 2000) <http://www.foresight.gov.uk/>
- Ø Nanotechnology: Commercial Opportunities (Evolution Capital Ltd, 2001)
- Ø 'UK invests in the Nanoworld' nanotoday, Materials Today supplement (Elsevier 2003)  
<http://www.materialstoday.com/nanotoday.htm>
- Ø The Social and Economic Challenges of Nanotechnology (ESRC 2003)  
<http://www.esrc.ac.uk/ESRCContent/DownloadDocs/Nanotechnology.pdf>
- Ø Towards a European Strategy for Nanotechnology, European Commission(2004)  
<http://www.cordis.lu/nanotechnology/src/communication.htm>
- Ø House of Commons Science Committee Report: Nanotechnology(2004)  
<http://www.publications.parliament.uk/pa/cm200304/cmselect/cmsctech/56/5602.htm>
- Ø Royal Society/Royal Academy of Engineering nanotechnology report(2004)  
<http://www.nanotec.org.uk/>

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

By identifying needs through stakeholder engagement and review and funding the necessary capability to identify those needs.

9. *In your opinion how can the risks (both positive and negative) of nanotechnology best be communicated?*

Through the channels appropriate to the level of knowledge of the recipient of the communication.

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

Engagement with stakeholders through the NIDG to evolve risk identification and amelioration activities.

11. *In your opinion how should the scientific and technological community be self-regulated?  
In the UK there should be engagement of these communities in NIDG.*

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

By engaging with government bodies and by disseminating information via normal channels: media, conferences and journals.

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

Channelling these through national coordinating bodies.

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

Possibly by an international committee that includes bodies such as the NIDG from all countries.

*15. 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.*

Engagement of international nanotech coordinating committee with UN, OECD, G& and other concerned international bodies.

## QUESTIONNAIRE ANSWERS FROM UNITED STATES OF AMERICA (US)

1. *Briefly describe your country's nanotechnology **research and development programmes and other investment programmes on nanotechnology** made in your country, including the annual budget. Please provide the name of the programme, the name(s) of organisation(s) involved, a brief description of the programme's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to provide.*

### **Reply: R&D programs and other investment programs on nanotechnology in US**

Nanotechnology R&D is supported by the Federal Government (about \$1B in FY 2004 [1]), state governments and local organizations (various commitments [2]), and industry and private organizations (about \$1.7B in 2004 [2]).

The National Nanotechnology Initiative (NNI) is a long-term Federal R&D program that currently coordinates nanotechnology-related efforts at 24 federal agencies, and develops partnerships with states, industry and local organizations. The program was announced in January 2000 and started formally in October 2000 (Fiscal year 2001). It has adopted a **specific definition for nanotechnology**: Working at the atomic, molecular and supramolecular levels, in the length scale of approximately 1 – 100 nm range, in order to understand, create and use materials, devices and systems with fundamentally new properties and functions because of their small structure. This definition implies three conditions: the ability to measure, control and modify the structure at the nanoscale; exploiting specific phenomena, properties or functions that occur at that scale; and integrating nanostructures into larger microscale and macroscale structures while maintaining the specific properties and functions. NNI was motivated by a long-term scientific, technological and societal vision: **the ability to systematically control the matter at the nanoscale that would lead to a technological and industrial revolution**. It was the result of the bottom-up proposal of an interagency group on nanoscale science and engineering that got started in 1996 [3, 4, 5]. The National Science Foundation funded the first program on high rate synthesis and processing of nanoparticles in 2001, established the National Nanofabrication User Network in 1994 (that become National Nanotechnology Infrastructure Network ten years later in 2004), and sponsored the multidisciplinary program Functional Nanostructures in 1997-1998. The DOD funded several earlier projects and recognized the importance of nanotechnology in 1997 with the creation of a strategic research area in nanoscience. The Federal nanotechnology investment per agency since the beginning of NNI in FY 2001 is given in Table 1.

The activities of the NNI have been coordinated by the U.S. Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC). The main goals of NNI are:

- Ø Maintain a world-class research and development program aimed at realizing the full potential of nanotechnology through extending the frontiers of nanoscale science and engineering through support for research and development; and establishing a "grand coalition" of academe, industry and government to realize the that potential
- Ø Facilitate transfer of the new technologies into products for economic and public benefit
- Ø Establish a balanced and flexible infrastructure, including educational resources and a skilled workforce
- Ø Support responsible development of nanotechnology, including investment policies, assessment of societal implications, and measures for environmental, health and safety issues

Table 1. Contribution of key federal departments and agencies to NNI investment\*

Federal Department or Agency	FY 2000 Actual (\$M)	FY 2001 Actual (\$M)	FY 2002 Actual (\$M)	FY 2003 Actual (\$M)	FY 2004 Actual (\$M)	FY 2005 Estimate (\$M)	FY 2006 Request (\$M)
National Science Foundation (NSF)	97	150	204	221	256	338	344
Department of Defense (DOD)	70	125	224	322	291	257	230
Department of Energy (DOE)	58	88	89	134	202	210	207
National Institutes of Health (NIH)	32	40	59	78	106	142	144
National Institute of Standards and technology (NIST)	8	33	77	64	77	75	75
National Aeronautics and Space Administration (NASA)	5	22	35	36	47	45	32
National Institute for Occupational Safety and Health (NIOSH)						3	3
Environmental Protection Agency (EPA)	-	6	6	5	5	5	5
Homeland Security (TSA)	-	-	2	1	1	1	1
Department of Agriculture (USDA)	-	1.5	0	1	2	3	11
Department of Justice (DOJ)	-	1.4	1	1	2	2	2
<b>TOTAL</b> (% of FY 2000)	<b>270</b> (100%)	<b>465</b> (172%)	<b>697</b> (258%)	<b>862</b> (319%)	<b>989</b> (356%)	<b>1,081</b> (400%)	<b>1,054</b> (390%)

\* Each Fiscal Year (FY) begins October 1 of the previous year and ends September 30 of the respective year.

Between 1997 and 2000, the NNI completed: a long-term vision statement and strategic plan for research and development (Nanotechnology Research Directions, 1999 [3]), an international benchmarking study of nanotechnology in academe, government and industry [4], and a program solicitation "Functional Nanostructures" (NSF) that provided feedback from the academic community (1997-1998). Other milestones included a plan for the US government investment for fiscal year (FY) 2001 [5], a brochure explaining nanotechnology for the public in 1999 [6], and a workshop and a report on the societal implications of nanoscience and nanotechnology in 2000 [7].

In August 2000, the White House changed the Interagency Working Group on Nanoscience, Engineering and Technology (IWGN), which had been in existence since October 1998, to the level of Subcommittee on Nanoscale Science, Engineering and Technology (NSET) with the charge of implementing the NNI. The National Nanotechnology Coordinating Office (NNCO) was established as a secretariat office to NSET in January 2001.

**The annual implementation plans for FY 2001-2005** (corresponding to the first strategic plan) have been balanced between five programmatic areas: fundamental research, nine Grand Challenges, centres of excellence and networks, infrastructure, and societal and educational implications of nanotechnology. An example of a program solicitation is "Nanoscale Science and Engineering" (NSF, FY 2001-2005; see [www.nsf.gov/nano](http://www.nsf.gov/nano) and [www.nseresearch.org](http://www.nseresearch.org)).

**A second strategic plan was prepared in December 2004** [8] following a series of twelve supporting workshops with the scientific and engineering community, and will be implemented beginning with FY 2006 [1] (beginning on October 1, 2005). The program is organized around seven Program Component Areas (PCAs). One PCA is focused on societal dimensions of

nanotechnology and includes: (a) Environmental, health and safety (EHS) issues, (b) Education, and (c) Ethical, legal and other social issues (ELSI). Two examples of program solicitations focused on the new generation of nanotechnology R&D are “Active Nanostructures and Nanosystems” (NSF, for FY 2006) and “Nanotechnology Research Grants Investigating Environmental and Human Health Effects of Manufactured Nanomaterials,” (a joint research solicitation of EPA, NSF, NIOSH, and NIEHS for FY 2006; see the FY 2006 NNI Implementation Plan [9]).

In addition, state, local, and private organizations have regional nanotechnology investments in infrastructure, education, and support for business.

**Since FY 2001, about 10% of the NNI budget has addressed issues, including basic research, applications, and implications, related to environment, health, and safety.** These efforts are funded by several agencies, including NSF, EPA, NIH, DOE, NIOSH, USDA, and DOD:

- ∅ NSF has a focus on nanoscale processes in the environment and on societal implications in its programs since August 2000. A list of 100 grants, including abstracts, is available on [http://www.nsf.gov/home/crssprgm/nano/nni01\\_03\\_env.htm](http://www.nsf.gov/home/crssprgm/nano/nni01_03_env.htm). The support for social, ethical and economic implications is an area of growing interest. Information on two grants of over \$1 million each with a focus on the interaction with the public and the creation of databases is available on <http://www.nsf.gov/od/lpa/news/03/pr0389.htm>. In 2005, NSF has established the network “Nanotechnology in Society” with an annual budget of about \$3 million. All 16 NSF’s Nanoscale Science and Engineering Centers (NSEC), the National Nanotechnology Infrastructure Network (NNIN) and Network for Computational Nanotechnology (NCN) are required to have research and education components addressing the environmental and societal implications.
- ∅ Three federal agencies have a program to study the potential risks of exposure to nanomaterials: the National Toxicology Program (NTP) - established in the Department of Health and Human Services, NIOSH, and EPA. The NTP studies are focused on the potential toxicity of nanomaterials, beginning with titanium dioxide, several types of quantum dots, and fullerenes. The first studies will be of the distribution and uptake by the skin of titanium dioxide, fullerenes and quantum dots. The NTP is also considering conducting inhalation studies of fullerenes, and is exploring ways to assist NIOSH in the development of inhalation exposure capability for carbon nanotubes.
- ∅ The NIOSH provides research, information, education and training in the field of occupational safety and health. In 2004, NIOSH initiated several research projects focused on nanotechnology, including a five-year program to assess the toxicity of ultrafine and nanoparticles. In 2005 NIOSH established coordinating Nanotechnology Research Center which developed Strategic Plan for NIOSH Nanotechnology Research ([http://www.cdc.gov/niosh/topics/nanotech/strat\\_plan.html](http://www.cdc.gov/niosh/topics/nanotech/strat_plan.html)). The plan identifies a list of critical topics associated with possible occupational safety and health issues arising from nanotechnology. The 10 topic areas are guiding NIOSH in addressing knowledge gaps, developing strategies and providing recommendations to ensure worker protection. Also in 2005 NIOSH developed workplace “Approaches to Safe Nanotechnology: An Information Exchange with NIOSH” ([http://www.cdc.gov/niosh/topics/nanotech/nano\\_exchange.html](http://www.cdc.gov/niosh/topics/nanotech/nano_exchange.html)), which raises awareness of potential safety and health concerns from exposure to nanomaterials, and announced the formation of an interdisciplinary field team of NIOSH researchers, which will assess and obtain insight on materials, processes, worker exposures, work practices, control procedures and medical monitoring in operations where nanomaterials are developed or utilized.
- ∅ EPA is funding research at universities to examine the toxicity of manufactured nanomaterials such as quantum dots, carbon nanotubes, and titanium dioxide (\$0.5 million annually in FY 2004 and 2005). In addition, current and past work in ultrafine particulates at EPA labs and funded through the extramural program at EPA can help

inform the effects of nanoparticles on human health and environment. A joint program solicitation on effect of manufactured nanoparticles on health and the environment has been funded jointly by EPA, NSF and NIOSH in FY 2005.

- ∅ Scientists funded by the NIH also are studying the chemistry, biology, and physics of nanoscale material interactions at the molecular and cellular level addressed in vitro experiments and models. The National Cancer Institute has established a five year initiative (NCI Alliance for Nanotechnology in Cancer) with a total award of about \$145 million ([www.nano.cancer.gov](http://www.nano.cancer.gov)) with the mission of “eliminating suffering and death from cancer”. It will include four major programs: Centers of Cancer Nanotechnology Excellence, Multidisciplinary Research teams, Nanotechnology Platforms for Cancer Research, and the Nanotechnology Characterization Laboratory (NCL, [www.ncl.cancer.gov](http://www.ncl.cancer.gov)).
- ∅ DOE has included nanoscience in the environmental research performed at several National Laboratories such as Oak Ridge in Tennessee and Environmental Molecular Sciences Laboratory in Washington State.
- ∅ The Department of Defense is supporting a Multidisciplinary University Research Initiative (MURI) program to investigate the interaction of nanomaterial and cellular responses. The research studies the effect and response of cells following interactions with nanoscale particles, including the size, shape, charge, and composition of the nanoparticle and their influence on the cellular, sub-cellular, and biomolecular levels. This research is creating a significant body of knowledge of nanoscale materials reactions with biological materials.
- ∅ SBIR/STTR awards related to nanoscale processes in the environment have made by NSF and DOD since 1999 when nanotechnology was specifically targeted in the annual program announcements. EPA supported an SBIR solicitation on “Nanomaterials and Clean Technology” in 2004. NNI invested over \$70M in SBIR in FY 2004.

2. *Please provide an overview of your country’s **laws and regulations that apply directly, or could be applied to nanotechnology development.** Please provide the name of the regulatory instrument, and briefly describe what it regulates (e.g. environmental impacts, worker safety, etc.) and how it applies to nanotechnology.*

#### **Reply: Laws and regulations that apply directly to nanotechnology development**

On December 3, 2003, the President signed into law the 21st Century Nanotechnology Research and Development Act (Public Law 108-153) [15]. A section of that Law is dedicated to societal implications. The law requires R&D for addressing societal dimensions. DOD participation in the NNI is separately established by Public Law 107-314. NIH has special legislation from Congress.

Congress issues authorization laws and funding appropriations for nanotechnology R&D by federal agencies participating in NNI each year. The number of participating agencies has increased from six agencies in FY 2001 to 24 agencies in FY 2005.

**Organizations with primary responsibility for implementing regulations and guidance in areas relevant to nanotechnology materials and products are:**

- ∅ Environmental and Protection Agency (EPA)
- ∅ Food and Drug Administration (FDA)
- ∅ National Institute for Occupational Safety and Health (NIOSH)
- ∅ Occupational Safety and Health Administration (OSHA)
- ∅ US Department of Agriculture (USDA)
- ∅ Consumer Product Safety Commission (CPSC)
- ∅ National Institute of Science and Technology (NIST)
- ∅ US Patent and Trade Office (USPTO)
- ∅ DOC (export/import regulations)
- ∅ American National Standard Institute (ANSI, private) for standards

- Ø Various States, such University of California, which may have active regional programs often more stringent than the Federal Government

**Research to establish the knowledge base** that is used by regulatory agencies to inform their decision-making process is performed by federal agencies, including NSF, NIH, NIST, EPA, FDA, NIOSH, OSHA, USDA, DOE, and DOD. Industry (including DuPont and Intel) and other private sector research institutions contribute to R&D for EHS as a function of their respective interests, and collaborate with NNI through joint working groups with chemical and electronic industries. Professional societies (including ACS, ACC, CIIT, ILSI, ASME, and AIChE) and NGOs (including Pew Foundation, Woodrow Wilson Center and Environmental Defense) provide support in various studies, workshops and reports.

**The materials and products based on nanotechnology are regulated today within the existing network of statutes, regulations, rules, guidelines, and other voluntary activities.** Nanostructures are generally evaluated as chemicals with new uses or as new chemicals when new properties are identified as compared to bulk. In some cases, pre-market review and approval is required (e.g. drugs, food regulated by FDA, food packaging, medical devices, and new chemical compounds). In other cases, post-market surveillance and monitoring applies (e.g., cosmetics and most consumer products). The existing regulatory network will be modified, if necessary. Examples of regulatory laws and standards applicable to nanoparticles and other nanostructures include:

- Ø Product specific:
  - Toxic Substance Control Act (TSCA) for industrial chemicals, administered by EPA.
  - Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) for pesticides, administered by EPA
- Ø Media specific (air, water, soil):
  - Clean Air Act for particulate matter, which could include ultrafine particles in the future, administered by EPA
  - Clean Water Act, administered by EPA
  - Waste disposal acts, --Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), administered by EPA
- Ø In the work place (aerosol-based standards based on existing health risk data)
  - Permissible Exposure Limits (PELs), established by Occupational Safety and Health Administration (OSHA)
  - Recommended Exposure Limits (RELs), established by National Institute for Occupational Safety and Health (NIOSH)
  - Threshold Limit Values (TLVs), established by the American Conference of Government Industrial Hygienists (ACGIH)
  - Personal Protective Equipment to reduce exposure, established by OSHA and ASTM (American Society for Testing and Materials)
- Ø In consumer (personal) products
  - Nanoparticles for drugs to be metabolized in human body, for diagnostics or therapeutic medical devices (such as quantum dots); regulated by FDA
  - Nanostructured particles/substances. to be incorporated into food; FDA, EPA and USDA share the regulations (such as food additives, food colouring); FIFRA sets standards for acceptable levels of pesticides in food
  - Substances incorporated into consumer products; regulated by Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act. A focus is on protection of children, who are more susceptible and who sometimes put objects in their mouth that were not intended for that purpose.

Under NSET coordination, the EPA, FDA, CPSC, OSHA (Occupational Safety and Health Agency), NIOSH (National Institute for Occupational Safety and Health), NIST, USDA, Export Administration, and other agencies are reviewing existing rules and procedures to determine how

to use the existing statutes and regulations to review products of nanotechnology, as these products are developed. Where new nanotechnology products differ from existing products and present unique concerns for the environment or public health, modification or extension of rules will be considered. This is particularly important for the new generations of nanoproducts including active nanostructures and nanosystems.

3. *Please describe the **key institutions which support nanotechnology** in your country. Please provide the name(s) of organisation(s) involved, a brief description of their focus and scope, how they are able to influence policies and decisions, and any other information you would like to provide.*

**Reply: Key institutions which support nanotechnology in the US**

**Table 2. List of federal departments and agencies participating in the NNI during 2005**

<b>Federal agencies and departments with R&amp;D budgets dedicated to nanotechnology research and development</b>
Department of Agriculture (USDA) Department of Defense (DOD) Department of Energy (DOE) Department of Homeland Security (DHS) Department of Justice (DOJ) Environmental Protection Agency (EPA) National Aeronautics and Space Administration (NASA) National Institute of Standards and Technology (NIST, Department of Commerce) National Institute for Occupational Safety and Health (NIOSH, Department of Health and Human Services) National Institutes of Health (NIH, Department of Health and Human Services) National Science Foundation (NSF)
<b>Other participating agencies and departments</b>
Bureau of Industry and Security (BIS, Department of Commerce) Consumer Product Safety Commission (CPSC) Department of Agriculture, Forest Service (USDA/FS) Department of Education (DOEd) Department of State (DOS) Department of Transportation (DOT) Department of the Treasury (DOTreas) Food and Drug Administration (FDA, Department of Health and Human Services) International Trade Commission (ITC) Intelligence Technology Innovation Center, representing the Intelligence Community (IC) Nuclear Regulatory Commission (NRC) Technology Administration (TA, Department of Commerce) U.S. Patent and Trademark Office (USPTO, Department of Commerce)

- a. Participating organizations in the National Nanotechnology Initiative (Federal government) are listed in Table 2, and the FY 2006 planned agency investments by Program Component Area in Table 3. Key federally funded user facilities for nanotechnology research infrastructure are listed in Table 4. Examples of investments made by states and local organizations are given in Table 5.

**Table 3. FY 2006 planned agency investments by program component area**

	FUNDAMENTAL NANOSCALE PHENOMENA AND	Nano-materials	Nanoscale Devices and Systems	Instrumentation Research, Metrology, and Standards for Nanotechnology	Nano-manufacturing	Major Research Facilities and Instrumentation Acquisition	Societal Dimensions	NNI Total
NSF	95	75	54	12	24	24	60	<b>344</b>
DOD	35	83	99	3	2	6	2	<b>230</b>
DOE	48	33	5	11	0	109	1	<b>207</b>
HHS (NIH)	46	17	67	6	0	1	8	<b>144</b>
DOC (NIST)	5	1	2	39	19	8	1	<b>75</b>
NASA	4	17	10	0	1	0	0	<b>32</b>
USDA	1	2	6	0	1	0	1	<b>11</b>
EPA	0.5	0	0.5	0	0	0	4	<b>5</b>
HHS (NIOSH)	0	0	0	0	0	0	3	<b>3</b>
DOJ	0	0	0	0	0	0	2	<b>2</b>
DHS (TSA)	0	0	1	0	0	0	0	<b>1</b>
<b>Total</b>	<b>236</b>	<b>228</b>	<b>244</b>	<b>72</b>	<b>47</b>	<b>148</b>	<b>70</b>	<b>1051</b>

**Table 4. Federally funded user facilities for nanotechnology research infrastructure**

Facility	Agency	Lead Institution	PI	Partner Institutions
National Nanotechnology Infrastructure Network	NSF	Cornell University	Tiwari	Cornell, Howard, Stanford, Penn State, UCSB, Georgia Tech, Harvard, NC State, U. of Michigan, U. of Minnesota, U. of New Mexico, U-T Austin and U. of Washington
Network for Computational Nanotechnology	NSF	Purdue University	Lungstrom	Illinois, Stanford, Florida, Texas, Northwestern, Morgan State
Center for Functional Nanomaterials*	DOE	Brookhaven National Laboratory	Hwang	
Center for Integrated Nanotechnologies*	DOE	Sandia/Los Alamos National Laboratories	Michalske	
Center for Nanophase Materials Sciences*	DOE	Oak Ridge National Laboratory	Lowndes	
Center for Nanoscale Materials*	DOE	Argonne National Laboratory	Bader	
Molecular Foundry*	DOE	Lawrence Berkeley National Laboratory	Alivisatos	
Center for Neutron Research	NIST & NSF	NIST	Rowe	

\*under development

## b. States and local organizations:

- ∅ About 20 states in the US invest in nanotechnology infrastructure (Examples of funding activities by states are shown in Table 5 [10])

**Table 5. Examples of R&D infrastructure investments at the state-level (State and Federal funding) [9].**

State	Recipient	Description	Commitment	Initiative Model
AZ	Nano-bio research center	Research infrastructure	\$5 million/yr for 20 yrs	University-state partnership
CA	California Nanosystems Institute	Building infrastructure	\$100 million over 4 yrs	Metropolitan-state
CO	Denver University	Federal earmark	\$250,000	
FL	Center at University of South Florida	Faculty recruitment and infrastructure	\$5 million	University-state partnership
GA	Center at Georgia Tech	Building & research infrastructure	\$90 million	
IL	Nanoscience Centers (NU, U of IL, ANL)	Building & research infrastructure	\$63 million	AtomWorks Metro-regional partnerships
IN	Nanotechnology Center at Purdue	Building infrastructure	\$5 million	
NJ	Support at NJIT and photonics consortium			NJ Nano-initiative Fab Shop with Lucent
NY	Nanoelectronics Center, Albany	Building & research infrastructure	\$50 million (initial), \$400M over 5 yrs	University-state partnership
OK	NanoNet	EPSCoR	\$3 million/yr for 5 yrs (40% state match)	University-region partnership
OR	ONAMI – Oregon Nano-Micro Interface Institute	Research infrastructure	\$20 million over 5 years	University-industry partnership
PA	Nanotechnology Center		\$37 million	BFTP & Penn State NMT
SC	NanoCenter	Building infrastructure	\$1 million	
SD	Center for Accelerated Applications at the Nanoscale	Research infrastructure	\$2.5 million over 5 years	University-state partnership
TX	Four universities: Rice, University of Texas at Austin, Dallas, and Arlington	Federal earmark for SPRING Initiative	\$10 million Federal, \$0.5 million private	Corporate venture
VA	Various institutions & Luna Innovations	Research matching & infrastructure	\$4 million for research matching, \$8 million for bldg infrastructure	University-state partnership
WA	University of Washington, Washington Tech Center	Clean Room Maintenance	\$3 million over 3 yrs	University-state partnership

∅ About 100 universities (such as Cornell University, University of California, MIT, Northwestern University, University of Illinois, and Rice University) and various foundations (such as Beckmann Institutes)

- c. Various industry and regional associations supporting technology transition, including NanoBusiness Alliance, AtomWorks, Texas Nanotechnology Initiative, Chesapeake Nanotechnology Initiative, Council of Chemical Research, Semiconductor Industry Association and Semiconductor Research Corporation.

4. Please describe your country's **governing approach to nanotechnology**. Please provide a brief description of your country's approach to nanotechnology (e.g. precautionary, developmental etc.), how risks are perceived, how decisions are made and conflicts resolved, how risks are assessed, monitored and managed, and any other information which you would like to provide.

**Reply: Governing approach to nanotechnology in the US**

Key characteristics of the Federal NNI governing approach are:

- ∅ R&D planning, coordination and management of NNI is performed at three levels: national (NSET Subcommittee in the National Science and Technology Council; OSTP, Office of Management and Budget), the principals in the participating agencies, and R&D programs within those agencies. Three time scales are used: (1) the long-term vision and strategic plan that is revisited about every five years (strategic plan), (2) agency planning each year (annual plan centralized by the U.S. Office of Management and Budget, OMB), and (3) organizational measures for the implementation of the programs each month (NSET monthly meetings and program decisions).
- ∅ The NNI activities are periodically reviewed by external, peer groups comprised of the main stakeholders: the NNI is reviewed at the (1) national level
  - by the President's Council of Advisors on Science and Technology (PCAST) (In July 2004, PCAST was designated to serve as the National Nanotechnology Advisory Panel (NNAP) called for by the Act);
  - Triennially by the National Research Council (NRC);
  - Congress (through required annual reports)
  - OMB crosscut, since 2001),
- ∅ and (2) each agency and (3) at the R&D program level by evaluation using input from the stakeholder communities (Committees of Visitors, Advisory Boards).

The 21<sup>st</sup> Century Nanotechnology Research and Development Act calls for triennial external review by NRC. The NRC reviewed the National Nanotechnology Initiative previously in 2002. The report from that study, *Small Wonders, Endless Frontiers* [11], included a series of ten recommendations for strengthening the initiative. These recommendations, as well as the provisions of 21<sup>st</sup> Century Nanotechnology Research and Development Act, were essential inputs to the development process for the NNI Strategic Plan, which NSET delivered to Congress in December 2004.

In accordance with the terms of the Act, PCAST, in its role as the NNAP, will have ongoing responsibilities for providing a comprehensive assessment of and reporting on the NNI. The NNAP has published its first of assessment of the initiative in May 2005 *The National Nanotechnology Initiative at Five Years* [12] (see [www.nano.gov](http://www.nano.gov)).

Currently, each Federal Agency involved in nanotechnology regulation and oversight considers how nanoscale materials fit within the current laws and regulations administered. For additional information, one may refer to web sites listed later in this document. Recent developments include the 2005 NIOSH best practices statements on their website and the 2005 TSCA public meeting to consider voluntary programs for reviewing nanoscale materials which would be considered industrial chemicals.

- ∅ The NNI supports a broad spectrum of research to understand and evaluate the **environmental, health, and safety implications of nanotechnology** for researchers, workers, consumers, and the public. Both positive and negative implications of the application of nanotechnology are considered. The level of support for such research has increased as NNI and other research has led to the discovery of new nanostructures and nanomaterials and to the development of new nanotechnology products. Among the efforts in this area are:

- Studies of potential health risks of nanomaterials by the following six Federal agencies: the National Institute of Environmental Health Sciences (including the National Toxicology Program); the National Institute for Occupational Safety and Health; the EPA; the Department of Defense; the Department of Energy; and the NSF. In addition, NIST is supporting this work through the development of relevant standards. Examples of NNI supported projects on toxicity and environmental research are listed in Table 6 and Table 7, respectively.
- Coordination among the member agencies to identify and prioritize research needed to support regulatory decision-making and to promote better communication among the Federal Government, industry, and researchers at universities and other institutions. These activities are coordinated by an NSET subgroup, the Nanotechnology Environmental and Health Implications Working Group (NEHI WG), with membership from agencies that support nanotechnology research as well as those with responsibilities for regulating nanotechnology-based products.
- Continue international dialogue on environmental, health, and other societal issues. NSET/NSTC has established the National Nanotechnology Coordinating Office (NNCO) in 2001 as its secretariat with one of its role to coordinate monitoring of potential unexpected consequences of nanotechnology.

An important concern is **the applicability of existing laws and regulations to responsible development of nanotechnology**. In U.S., the corresponding efforts are covered by:

- (a) Research Agencies. The U.S. government agencies that fund scientific research already have in place various policies to address ethical, health and safety considerations related to the research they are funding or performing in their laboratories. Applicants for NSF research funding are required to certify in writing that they are in compliance with various NSF policies and relevant sections of the U.S. Code of Federal Regulations with respect to, for example, recombinant DNA, human subjects, and use of animals in research. NSF has broad authority to suspend or terminate ongoing research grants if grantees fail to comply with grant regulations, or for “other reasonable cause<sup>37</sup>.” NSF program officers conduct regular site visits to review ongoing research, where they have an opportunity to see if there are any problems that might justify such actions. Other research agencies have comparable mechanisms.
- (b) Regulatory Agencies. For research and product development not funded by the government, other statutory and practical controls apply. The many existing statutes and regulations addressing commercial products also apply to nanotechnology-based products and materials. For example, the Consumer Products Safety Act of 1972 (administered by the Consumer Products Safety Commission<sup>38</sup>) requires that manufacturers of consumer products assure that their products are safe, and holds them liable if they are not; CPSC can require the recall of products in cases where it has evidence that they are not safe. The Occupational Safety and Health Act of 1970 (administered by the Occupational Health and Safety Administration, OSHA, within the Department of Labor<sup>39</sup>) provides for Federal regulation of safety in the workplace, including both public and private research laboratories. The National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control<sup>40</sup> conduct research and training to inform OSHA regulatory decisions. NIOSH now is leading an effort within the government to maintain an updated set of recommended safe handling practices for nanomaterials, for both research and commercial production facilities released under the title of “Approaches to Safe Nanotechnology: An Information Exchange with NIOSH” ([http://www.cdc.gov/niosh/topics/nanotech/nano\\_exchange.html](http://www.cdc.gov/niosh/topics/nanotech/nano_exchange.html)). The Toxic Substances

<sup>37</sup> See the NSF Grant Policy Manual: <http://www.nsf.gov/pubs/2002/nsf02151/>, in particular Chapter VII, “Other Grant Requirements” and the sections in Chapter IX on research misconduct and on termination policies and procedures.

<sup>38</sup> <http://www.cpsc.gov>.

<sup>39</sup> <http://www.osha.gov>.

<sup>40</sup> <http://www.cdc.gov/niosh/>.

Control Act of 1976 (administered by the Environmental Protection Agency<sup>41</sup>) regulates the manufacture, importation, and use of both new and existing chemical substances. Several other statutes administered by the EPA (e.g., the Clean Air Act, the Clean Water Act) also may come into play with respect to nanotechnology. The National Institute of Environmental Health Sciences within the National Institutes of Health<sup>42</sup> also conducts health-related research that informs regulatory decisions by other agencies. The Federal Food, Drug and Cosmetic Act (originally enacted as the Pure Food and Drug Act in 1906, administered by the Food and Drug Administration within the Department of Health and Human Services<sup>43</sup>) requires prior testing and review of pharmaceutical and medical products under strictly controlled conditions. Under most of these statutes, any adverse effects of new products or processes that are uncovered as a result of privately-funded research must be reported to the government. These and many other statutes and accompanying regulations provide an ample basis for both criminal and civil legal action against any private organizations that produce or import products or services that may be deemed hazardous to the public. All of the agencies and institutes listed above are coordinating their nanotechnology-related activities through their participation in the NSET Subcommittee and its NEHI Working Group.

In order to clarify how these existing statutes and regulatory structures apply to nanotechnology, both scientific and legal research efforts are underway to clarify how they will be interpreted for this new field. For example, NSET member agencies now are working with universities, industry, and standards development organizations to develop a clear system of nomenclature for classifying new nanomaterials. This nomenclature standard is needed to facilitate both appropriate regulation of nanotechnology and its commercial development. In another example, EPA held a public hearing in the summer of 2005 to inform discussion of how TSCA should be applied to nanomaterials, starting with a voluntary pilot program (See U.S. Federal Register notice: May 10, 2005, Volume 70, Number 89, Page 24574-24576 (<http://www.gpoaccess.gov/fr/index.html>)).

For nanotechnology R&D specifically, the 21st Century Nanotechnology Research and Development Act includes a number of additional measures to ensure adequate oversight of the interagency NNI activity. One of the stated purposes of the Act is to “[ensure] that ethical, legal, environmental, and other appropriate societal concerns...” are properly addressed. Specific measures provided for in the Act to accomplish this include oversight of the NNI by the President’s National Science and Technology Council, a separate National Nanotechnology Advisory Panel, and a triennial review of the NNI by the National Academy of Sciences. All three of these oversight bodies are charged in the Act with addressing the responsible development of nanotechnology. In short, within the United States, not only are the mechanisms for minimizing any misuses of nanotechnology in place, but they are already working to assure the responsible and safe development of nanotechnology.

The **Nanomaterials Environmental and Health Implications (NEHI) working group** was informally established in August 2003 to address environmental, health and safety (EHS) issues, including risk assessment, identification and prioritization of EHS research needs, and communication of information pertaining to the EHS impacts of nanomaterials to researchers and others who handle and use nanomaterials. During the fiscal year 2005, the Nanoscale Science, Engineering, and Technology Subcommittee formally established the Nanotechnology Environmental and Health Implications (NEHI) Working Group [13] to:

- Provide for exchange of information among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts (defined as engineered nanoscale materials, nanostructured materials or nanotechnology-based devices, and their by-products);

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<sup>41</sup> <http://www.epa.gov>.

<sup>42</sup> <http://www.niehs.nih.gov>.

<sup>43</sup> <http://www.fda.gov>.

- Facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research and development, utilization, and oversight of nanotechnology, including research methods of life-cycle analysis; and
- Promote communication of information related to research on environmental and health implications of nanotechnology to other Government agencies and non-Government parties.

The NEHI Working Group assists in the development of information and strategies as a basis for the drafting of guidance toward safe handling and use of nanoproducts by researchers, workers, and consumers. The group also is working to support development of nanotechnology standards, including nomenclature and terminology, by consensus-based standards organizations. Other activities of the NEHI WG are:

- Proper selection of R&D priorities for a balanced and equitable development of nanotechnology that includes research into its potential economic, social and legal implications
- Identifying environmental, health and safety implications associated with nanostructured materials. While natural nanostructured materials and nanostructured process-by-products are of high concern, the unique characteristics of engineered nanoparticles and nanostructured surfaces present particular challenges to understanding and controlling environmental and health implications
- Coordinates preparation of best practices statements for handling and use of engineered nanomaterials, particularly in industrial or manufacturing environments and research laboratories
- Coordinate preparation of best practices statements for protection and handling natural and process-by-product nanomaterials, such as those from combustion engines or welding

Other related topics that are addressed by NSET are:

- Best mechanisms for communicating with the public (by the Nanotechnology Public Engagement Group of NSET)
- Avoiding possible adverse EHS (environmental/health/safety) aspects of nanotechnology by practicing green chemistry (clean processes and processing) and environmentally benign manufacturing.
- Identifying ethical aspects related to EHS implications on individual rights (such as privacy) and on various groups,
- Using nanotechnology to understand, measure, and reduce/control pollution from our current processes

**Table 6. Examples of NNI projects supporting toxicity research**

<b>Project</b>	<b>Agency, Institution</b>
National Toxicology Program	NIH/NIEHS, FDA/NCTR, NIOSH
Particle Characterization for Health and Safety	NIOSH
Nanotechnology Characterization Laboratory	National Cancer Institute
Multidisciplinary University Research on Nanoparticle Toxicity	Department of Defense supported center, U. Rochester
Molecular function at the Nano-Bio Interface (component on nanostructures and cell behaviour)	NSF/NSEC U. Pennsylvania

Nanomanufacturing Center for Enabling Tools (component on safe manufacturing)	NSF/NSEC Northeastern University
Size Dependent Neural Translocation of Nanoparticles	NSF/SGER Rochester University
Reverse Engineering Cellular Pathways from Human Cells Exposed to Nanomaterials	NSF/SGER Houston
Biochemical, Molecular and Cellular Responses of Zebrafish Exposed to Metallic Nanoparticles	NSF/EPA/NIOSH University of Florida Center for Environmental and Human Toxicology

**Table 7. NSF environmental interdisciplinary groups with research and education at the nanoscale (examples).** Other programs related to environment are supported by EPA, NIOSH, NIH, DOE and DOD.

Centers and interdisciplinary groups	Institution
Fundamental Studies of Nanoparticles Formation in Air Pollution	Worcester Polytechnic Institute
Center for Advanced Materials for Water Purification	University of Illinois at Urbana
Center for Environmentally Responsible Solvents and Processes	University of North Carolina at Chapel Hill
Nanoscience in Biological and Environmental Engineering (NSF's Nanoscale Science and Engineering Center, NSEC) (estimated 50% in environment)	Rice University
Environmental Molecular Science Institute	University of Notre Dame
Institute of Molecular Science and Engineering	University of Washington
NIRT (Nanoscale Interdisciplinary Research Team): Investigating Nano-carbon Particles in the Atmosphere: Formation and Transformation	University of Utah
NIRT: Nanoscale Processes in the Environment - Atmospheric Nanoparticles	Harvard University
NIRT: Nanoscale Sensing Device for Measuring the Supply of Iron to Phytoplankton in Marine Systems	University of Maine
NIRT: Combustion-generated Nanoparticles: The role of Transition Metals in Nanoparticles and Pollutant Formation	Louisiana St. University
NIRT: Nanoparticle-environment Interfaces: Interactions in Natural Systems	University of Michigan
NIRT: The Role of Nanoscale and Molecular Structures in Dictating Environmental Reactivity	University of Alaska, Fairbanks
NIRT: Response of Aquatic and Terrestrial Micro-organisms to Carbon-based Manufactured Nanoparticles	Purdue University

For more information about environment and health safety related to the NNI, see:

- Ø [Specific Projects on Environmental and Health Implications](http://www.nano.gov/html/society/EHS2.htm)  
(<http://www.nano.gov/html/society/EHS2.htm>)
- Ø [National Institute for Occupational Safety and Health](http://www.cdc.gov/niosh/topics/nanotech/)  
(<http://www.cdc.gov/niosh/topics/nanotech/>)

- Ø [U.S. Environmental Protection Agency](http://es.epa.gov/ncer/nano/) (http://es.epa.gov/ncer/nano/)
- Ø [U.S. Food and Drug Administration](http://www.fda.gov/nanotechnology/) (http://www.fda.gov/nanotechnology/)
- Ø [NCI Nanotechnology Characterization Laboratory](http://nano.cancer.gov/about_alliance/nanotech_characterization_lab.asp) (http://nano.cancer.gov/about\_alliance/nanotech\_characterization\_lab.asp)
- Ø [National Science Foundation](http://www.nsf.gov/nano) ([www.nsf.gov/nano](http://www.nsf.gov/nano); http://www.nsf.gov/crssprgm/nano/activities/nni01\_03\_env.jsp)

5. Please describe **“horizontal” connections in government, with private, NGO’s and other organizations**. Please provide a brief description of organisations which are able to initiate and influence public and government decision making (both formally and informally), the extent of their participation, and the process through which they are able to do so, and any other information which you would like to provide.

**Reply:** “Horizontal” interactions among organizations at similar levels from various activity sectors and R&D disciplines have been advanced since 2000 as an essential approach for promoting collaborations and enhancing interdisciplinarity particularly important for nanotechnology R&D. Examples are:

- Ø Partnerships and collaborations among NSET federal agencies are being developed continually.
- Ø Partnerships between federal agencies and other stakeholders (industry, states, educational groups, NGOs) have been advanced (for example with Environmental Defence, Wilson Center for International Scholars, Environmental Law Institute, Semiconductor Research Corporation). In another example, a NSET working group on Nanotechnology Innovation and Liaison with Industry (NILI) is developing Consultative Boards for Advancing Nanotechnology (CBAN) that is open to participation by those interested.
- Ø Sponsoring workshops and reports prepared by multiple stakeholders in industry, academe, government and professional societies (see list of workshop, reports and list of workshop participants on www.nsf.gov)

6. Please provide an overview of your countries **international connections: agreements, advice and participation in international organisations**. Please provide the name(s) of agreements, advisory body(s) (both formal and informal) and international organisation(s), and briefly describe how it works and your participation in it.

**Reply: Illustration of international connections, US**

- Ø The U.S. has over 30 bilateral, government-to-government Scientific and Technological Cooperation agreements that establish frameworks to facilitate the exchange of scientific results, provide for protection and allocation of intellectual property rights and benefit sharing, facilitate access for researchers, address taxation issues, and respond to the complex set of issues associated with economic development, domestic security and regional stability (including Japan, EU, Germany, France, Korea, Australia). The U.S. is not currently a party to any formal agreements specifically addressing nanotechnology.
- Ø Planned nanotechnology activities with the EC for FY 2006 include:
  - Public Engagement Meeting and
  - R&D program solicitations on potential implications for health and the environment
- Ø Numerous implementing arrangements and agreements have been negotiated under these S&T Umbrella agreements to carry out joint research projects and agendas. No specific arrangements involving joint nanotechnology development have yet been carried out under this intergovernmental mechanism; however, the framework to do so exists.

- ∅ Cooperative nanotechnology research is being carried out on an Agency to Agency basis. (Examples: EPA and NIOSH with UK counterparts; EPA and NSF and EC counterparts)
  - ∅ Center-to-center and researcher-to-researcher cooperation is generally encouraged and widespread.
  - ∅ The U.S. participates in several international export control regimes (e.g. Wassenaar Arrangement, Australia Group, MTCR) restricting the movement of sensitive military and dual use technologies.
  - ∅ The U.S. is a party to a variety of international intellectual property and trade-related agreements and is a member of the World Intellectual Property organization and the WTO.
  - ∅ The U.S. organized an International Dialogue bringing together 25 governments plus the EU in Alexandria, VA in June 2004 to discuss nanotechnology development. The second dialogue was hosted by the EC in Brussels, Belgium in July 2005. Japan has agreed to host the third dialogue meeting in 2006.
  - ∅ Conducted worldwide survey of nanotechnology R&D (1999); expert panel visited many leading international researchers; draft report reviewed by site report hosts; report published by Kluwer Academic and full text available online for public use: <http://www.wtec.org/loyola/nano/>.
  - ∅ The U.S. is a member of numerous international entities such as OECD (June 2005 meeting in Paris; planned December 2005 meeting in U.S.) and APEC that have or are developing nanotechnology interests.
  - ∅ The U.S. has hosted or participated in numerous international conferences. Example: Taiwan International Conference on Nanotechnology and the Environment
  - ∅ Contribute to ISO standards and nomenclature (through ANSI, ASTM, IEEE, and ASME).
7. Please provide information on **reports and communications concerning nanotechnology** which have been produced by your government and other key stakeholders in your country. Please provide the name of the report(s) and producing organisation(s).

**Reply: Reports in the US**

The following is a list of reports on workshops that were organized or supported by the agencies participating in the National Nanotechnology Initiative between 2001 and 2005 with the objective of gathering input for NNI strategic planning.

**a. Workshops: Completed Reports**

- ∅ Nanotechnology: Opportunities and Challenges. Regional Workshop of the National Nanotechnology Initiative, hosted by the University of California at Los Angeles, September 2001. Los Angeles, CA. <http://wtec.org/nanoreports/FinalUCLAnanoRpt0302.pdf>
- ∅ NSF-EC Workshop on Nanomanufacturing and Processing. Summary Report from the National Science Foundation workshop, January 2002. San Juan, Puerto Rico. [http://www.nsf.gov/mps/divisions/dmr/research/nsfec\\_workshop\\_report.pdf](http://www.nsf.gov/mps/divisions/dmr/research/nsfec_workshop_report.pdf)
- ∅ From the Laboratory to New Commercial Frontiers. A Regional Workshop of the National Nanotechnology Initiative hosted by Rice University, May 2002, Houston, TX. <http://wtec.org/nanoreports/ACF64.pdf>

- ∅ Nanotechnology Innovation for Chemical, Biological, Radiological, and Explosive (CBRE): Detection and Protection. Final report of the NNI Grand Challenge Workshop, May 2002. Monterey, CA. J. Murday, J. Baker, R. Colton, H.S. Gibson, M. Grünze, S. Lee, K. Klabunde, C. Martin, T. Thundat, B. Tatarchuk, and K. Ward. <http://www.wtec.org/nanoreports/cbre/>
- ∅ Chemical Industry R&D Roadmap for Nanomaterials by Design: From Fundamentals to Function. Final report of the Vision 2020/NNI Grand Challenge Workshop, Baltimore, MD, September / October 2002. Chemical Industry Vision 2020 Partnership. <http://www.chemicalvision2020.org/nanomaterialsroadmap.html>
- ∅ Nanoscience Research for Energy Needs, Report of the National Nanotechnology Initiative Grand Challenge Workshop, March 2004. Alexandria, VA. R. Hwang and E. Williams, eds. [http://nano.gov/nni\\_energy\\_rpt.pdf](http://nano.gov/nni_energy_rpt.pdf)
- ∅ NNI Workshop on Regional, State, and Local Initiatives in Nanotechnology, September 30–October 1, 2003, Washington, DC, S. Murdock, S. Crosby, B. Stein, and N. Swami, eds. <http://nano.gov/041805Initiatives.pdf>
- ∅ Nanomaterials - a Risk to Health at Work? First International Symposium on Occupational Health Implications of Nanomaterials, October 12-14, 2004, Buxton, UK. [http://www.hsl.gov.uk/capabilities/nanosymrep\\_final.pdf](http://www.hsl.gov.uk/capabilities/nanosymrep_final.pdf).

#### **b. Workshops: Final Reports in Preparation**

- ∅ Buildings for Advanced Technology Workshop, National Institute of Standards and Technology, Gaithersburg, Maryland, January 14-16, 2003. Overview available at <http://www.nanobuildings.com/bat/overview/default.htm>.
- ∅ NNI Grand Challenge Workshop: Nanoscale Processes for Environmental Improvement, Arlington, VA, May 8-10, 2003.
- ∅ NNI Grand Challenge Workshop on Nanomaterials, National Science Foundation, June 11-13, 2003.
- ∅ National Nanotechnology Coordinating Office Interagency Research Meeting/Workshop — Nanotechnology and the Environment: Applications and Implications, Arlington, VA, September 15-16, 2003. Summary available at <http://es.epa.gov/ncer/publications/nano/index.html>.
- ∅ NNI Workshop on Nanobiotechnology, Arlington, VA, October 9-11, 2003.
- ∅ NNI Workshop on Societal Implications of Nanoscience and Nanotechnology, National Science Foundation, Arlington, VA, December 3-5, 2003 [14]
- ∅ NNI Grand Challenge Workshop on Instrumentation and Metrology for Nanotechnology, National Institute of Standards and Technology, Gaithersburg, MD, January 27-29, 2004.
- ∅ NNI Grand Challenge Workshop on Nano-Electronics, -Photonics, and -Magnetics, Arlington, VA, February 11-13, 2004.
- ∅ NNI Workshop on Nanotechnology for Space Exploration, Palo Alto, CA, August 24-26, 2004.
- ∅ National Nanotechnology Initiative Research Directions II Workshop, Washington, DC, September 8-10, 2004.
- ∅ NNI Workshop on X-rays and Neutrons: Essential Tools for Nanoscience Research, Washington, DC, June 16-18, 2005.

**c. Earlier workshops and reports on societal and environmental implications** are listed in Table 8. The 21<sup>st</sup> Century Nanotechnology R&D Act is given in [15]. Other reports were prepared by individual agencies such as NSF, DOE, DOD and NASA.

**Table 8. Earlier workshops and reports on societal and environmental implications**

<b>Workshop, conference</b>	<b>Sponsor</b>	<b>Dates</b>
Societal implications of nanoscience and nanotechnology (I)	NSF	September 2000
Nanoparticles in materials and environmental sciences	NSF, EC	September 2000
Converging technologies for improving human performance	NSF, DOC	December 2001
Societal implications of nanotechnology	NSF, EC	January 2002
Nanoparticles and the environment (grantees meeting)	NSF	July 2002
Nanotechnology and the environment applications and implications" (grantees meeting)	EPA	November 2002
Symposium on nanotechnology implications in the environment	ACS	March 2003
Global societal impacts of nanoscience	NSF, EC, Japan	March 2003
Vision for environmental implications and improvement	NSET, EPA, NSF	May 2003
Interagency grantees meeting	NSET, EPA, NSF, DOE, FDA, NIST	September 2003
Vision for nanobiosystems in biology and medicine	NSET, NIH, NSF, FDA, USDA, others	October 2003
Societal Implications of nanoscience and nanotechnology (II)	NSET, NSF, EPA, NIH, DOD, others	December 2003
2 <sup>nd</sup> International Symposium on Nanotechnology and Occupational Health	NIOSH, DOD	October 2005

**d. NAS/NRC reports**

- Ø Small Wonders, Endless Frontier (2002)
- Ø Implications of Emerging Micro and Nanotechnology (2002)
- Ø Implications of Nanotechnology for Environmental Health Research (2005)
- Ø NASA Capability Roadmap Review: Nanotechnology Panel – Project profile
- Ø National Academies Call for Applications for Nanotechnology Conference (2004)
- Ø Nanotechnology for the Intelligence Community (2005)

**e. State/Local**

- Ø Nanotechnology: A Technology Forecast (Implications for Community and Technical Colleges in the State of Texas, April 2003)  
<http://system.tstc.edu/forecasting/reports/nanotechnology.asp>

**f. Industry**

- Ø - ITRS (by Semiconductor Industry Association)

**g. Three related papers recently published are:**

- Ø "Environmentally Responsible Development of Nanotechnology: How the U.S. Government is dealing with the intermediate and long-term issues of this new technology", American Chemical Society, March 2005 [16]
- Ø "The emergence and policy implications of converging new technologies integrated from the nanoscale", J. Nanoparticle Research, May 2005 [17]

Ø "Nanoscale Science and Engineering: Unifying and Transforming Tools", AIChE Journal, 2004 [18]

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

Several approaches are:

- a. Support R&D for better understanding of environment, health and societal implications of nanotechnology. This assumes the existence of government agencies, corporate groups, and NGOs, with formal funding programs for addressing social issues related to nanotechnology (of which risk is only one issue). There must be commitment from both governmental and nongovernmental sources to fund a wide range of such groups, including:
  - Institutions with the capacity to carry out substantive, long-term, formal, public assessments of not only risks but also broader societal dimensions of nanotechnology.
  - Development of fundamental knowledge on societal dimensions of nanotechnology that can be used as a basis for sound, informed, and well-reasoned public assessments and policy choices.

- b. Coordination of government organizations covering the multiple aspects that provide essential services to serve and protect the public. NSET and NNCO provide communication and coordination within U.S.

- c. Develop partnerships, promote dialogue involving both government and non-governmental organizations (NGOs), and be inclusive. Promote two-way interactions with the public at the local, national, and international levels. Use informal science education outlets, such as museums, science centres, expositions, print and electronic media. Committees comprising scientists and citizens can discuss issues.

Promote exchange of information on the results of R&D on environment, health, and societal implications of nanotechnology. For illustration, NSF sponsored the first workshop on Societal Implications of Nanoscience and Nanotechnology in 2000, and a joint EC-NSF workshop on the same topic was held in 2002. Follow-on to the 2000 workshop was held in December 2003, and several NNI grantees and research direction meetings were held in 2001-2004.

- d. Facilitate and provide support to non-governmental organizations that create alternative ideas, involve all shareholders, including international. It includes building capacity within professional societies. A key challenge is to allow both a multiplicity of approaches but also provide some non-directional (non-targeted) coordination. For example, in the United States, at least four separate NSF-funded "networks" exist to explore aspects of social and ethical issues (the societal and environmental issues component of NNIN (2003- ); the "Nanoscale Center for Learning and Teaching" at Northwestern (2004- ), the "Nanotechnology Informal Science Education" network (2005- ), and the "Center for Nanotechnology and Society" (2005- ). The Center of Nanotechnology in Society will establish formal mechanisms for interacting among the centres and networks (besides various informal links already existing). Similarly, at the international level, some coordinating mechanisms would be useful for bringing together government institutions, corporate members, NGOs, and others with formal existence. Establishment of such a coordinating body would need to be funded, perhaps by governments, perhaps by foundations.
- e. Internationally recognized norms and standards for nanotechnology (under ISO) and global acceptance of them.
- f. Evaluate various issues in the broader societal context and from an international perspective:
  - Prepare best practices statements for handling and use of engineered nanomaterials, particularly in industrial or manufacturing environments and research laboratories

- Prepare best practices statements for protection and handling of natural and process-by-product nanomaterials, such as those from combustion engines or welding
  - Disseminate precompetitive research results and develop collaborative activities in order to advance broader goals such as water purification; energy conversion, storage, and transmission; and treatment of chronic illnesses
- g. Build capacity for integrating risk governance across a range of distinct but inter-related domains (e.g., environment, product safety, biological safety and efficacy, societal values). Other areas of emerging technology, such as genetic engineering and new reproductive technologies demonstrate the weaknesses (in terms of both under and over-regulation) of addressing the multiple dimensions of risk in piecemeal fashion.
  - h. Strengthening the capacity of legislative institutions to respond effectively to new and emerging technologies, so that the courts no longer serve as the only first responder in government regulation of technological risks.
9. *In your opinion how can the unexpected consequences (both positive and negative) of nanotechnology best be communicated?*
- a. Transparency and openness to all shareholders, presenting a balanced view of the benefits and risks
  - b. Consultation with stakeholders from the beginning; that is, from planning (workshops for input) through the selection of the investments (peer review) through implementation of the projects
  - c. Periodical evaluation of the higher risk applications and dissemination of the results to the public
  - d. A crucial point here is that "communication" is (at least) a two-way process. It is not appropriate only for an elite group to define the implications (positive and negative) and then "communicate" them to others. Rather, the very process of defining what constitutes a risk must be a collaborative process, engaging actors from throughout society. Among the actors to be engaged: scientists, engineers, community activists, community government leaders, business leaders, social science and humanities researchers, organized labour, political leaders. Special efforts should be made to engage representatives of traditionally disenfranchised or disaffected groups, whether national minorities within countries or less-developed countries in an international context.
  - e. Consider nanotechnology as a key component of converging technologies [19]. The risks of biotech, information technology, and other products/causes of globalization are just as important, even if nanotechnology plays an important role because it works at the foundation of matter and is a general base technology. One may consider using nanotechnology as a test-bed for broader experimentation in how to create organizational mechanisms for addressing science-and-technology-based concerns that interact with challenges posed by globalization.
  - f. Stakeholder workshops in which there is adequate time and energy devoted to full articulation of the rationale for characterizing and managing risks associated with nanotechnology. In some settings it may be appropriate to require procedures that ensure meaningful informed consent before parties are exposed to risk, for instance laboratory risk at workplace.
    - Risk communication must be done in an open framework in which the risks as well as the current and potential benefits must be conveyed. Risk communication must address perceived risks as well as documented risks, and information must be appropriate for the level of technical understanding of the audience.

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

There is a need for multiple, overlapping approaches:

- a. First, one must characterize risk, beginning with developing knowledge specific for nanotechnology for the first generation of products (passive nanostructures, currently in production) and second generation (active nanostructures and systems, mostly in the concept phase).
- b. Green design and clean manufacturing – nanotechnology offers a unique opportunity, given its relative infancy, for incorporating sustainable development principles from the outset in the design of nano-products and nano-manufacturing processes. Green chemistry and engineering (for cleaner production) and environmentally benign manufacturing principles can be used to prevent risk in the manufacture of nanomaterials. Industrial ecology approaches can be used to inform where risks might occur in a nanoproduct life cycle.
- c. Bionanotechnology and medical R&D should be investigated from the beginning in the long-term societal context, with simultaneous consideration of both positive and negative effects. In fact, virtually all biomedical research conducted in the United States (certainly all of that supported by the U.S. Government, primarily the National Institutes of Health, NIH) follows a standard methodology where toxicology testing and assessment of possible side-effects is included as part of the research in the first place. The U.S. Food and Drug Administration (FDA) requires further testing and validation of both safety and efficacy of new biomedical therapies and devices before they are allowed for human use. The Centers for Medicare & Medicaid Services (CMS) also requires additional testing for efficacy and cost-effectiveness before biomedical innovations can be approved for reimbursement under Medicare and Medicaid. All three of these agencies within the U.S. Department of Health and Human Services are working together to improve the efficiency and effectiveness of the biomedical innovation process, for example, to design research methodologies and testing protocols for the original NIH-funded research that will *also* meet the requirements for FDA and CMS approval from the start, avoiding the need for additional tests and the delay and expense that this entails.
- d. All NSF and DOE nanotechnology centres are required to address long-term societal implications of nanotechnology, with a focus on the nanotechnology research done in the respective centres.
- e. Nanotechnology research that is not in the biomedical domain could also be conducted more in the vein of biomedical research as described in point (c) above or of the management approach adopted by nanotechnology centres as described in point (d), e.g., safety testing could be built in to the research methodology from the start, so that new nanotechnology-based products are developed with environmental, health, safety, and even other societal dimensions accounted for during the development process.
- f. Adopt or develop current norms, standards and regulations for nanotechnology. Unfortunately, prospects for future legislation are made more difficult by the wide range of different classes of technologies encompassed by the label nanotechnology. Also, the standards and regulations for the second generation of nanotechnology products (such as active nanostructures and nanosystems) are more difficult because of many unknowns.

Note: There is a very large existing body of environmental, safety, and efficacy legislation and regulations in the United States governing air, water, and solid waste, pharmaceuticals, new chemicals, pure foods and drugs, consumer products, workplace safety, conduct of research involving human subjects and various types of radiation, etc., that can be applied to

nanotechnology-based products and services (as shown in reply to question #4) with little or no adjustments.

- g. Use technological and social science's scenario analyses to evaluating long-term implications
- h. Engage all stakeholders earlier in the R&D process, including the public. Develop instructional materials that make the issues comprehensible to the public.

Recognize that many decisions are not "technical" but rather are value judgments about the investment of resources, social priorities and risk perceptions. Those decisions and others that will be made by corporations and government because of authorities conferred to them, as well as decisions to be made by consumers, will be better decisions if they are informed by fully open discussions, even where decision-making authority over technology-related decisions is disputed. That doesn't mean decision-making authority—a formidable power—won't be exercised, but if more people have been involved and taken seriously in the process leading up to the exercise of authority, then those of us who believe that more information leads to better decisions can at least have some hope that such authority will be exercised more wisely. In addition to attempting to characterize and control risks, some resources should be devoted to large-scale studies that examine how government institutions, corporations, researchers, and expert bodies try to assess and manage risk.

Successful communication about nanotechnology risks will entail the development of sustained capacity in civil society for dialogue about new and emerging technologies. This need not necessarily entail all citizens, but might include the development of dedicated citizens' groups that are invited to wrestle with the challenges of new and emerging technologies on a sustained basis. Without this kind of capacity, efforts at risk communication are likely to be unidirectional (from science or the state to the public), to go unheard, to address issues that fail to concern publics while ignoring issues of great importance to publics, and to risk public backlash.

Robust discussion of uncertainties is essential in any risk communication. A strong role for citizens and stakeholders in defining and framing the concerns of risk assessment and communication is also essential for ensuring robust engagement on the part of the public in the communicative exercises, for establishing sufficient reflexivity in the process, and for identifying tacit assumptions and values embedded in risk frames that escape unexamined within elite science and policy communities.

- i. Anticipatory governance, implying careful thought and reflection at the front lines of scientific and technological research that recognizes the importance of the societal dimensions of new and emerging technologies as a central element in the deliberative activities of science and engineering laboratories – perhaps through innovative partnerships between the natural and social sciences, policymakers, and citizens.
- j. Transparency in science and engineering. Risk prevention is most effective when a range of diverse stakeholders are in a position to call into question issues of risk associated with particular avenues of development in science and technology. In that situation, there is an opportunity for a robust dialogue and evaluation of those critiques. This entails significant transparency within the scientific enterprise that enables a range of diverse stakeholders to see and track scientific and technological research and development as it is occurring. This also entails stakeholder capacity to participate in such exercises and mechanisms for both closing off debate and re-opening debate, where appropriate.
- k. "Prevention" is only one approach. In some instances, it may be appropriate after a full evaluation of potential impacts, positive and negative, simply to accept a risk. In others, it may be more appropriate either to develop mechanisms for compensating parties who bear

risk or suffer harm, or for allowing individuals or groups to apply personal or differential standards for accepting or rejecting risk.

- I. Risks are likely to vary considerably across nanotechnology products and processes.

11. *In your opinion how should the scientific and technological community be self-regulated?*

In one sense, research community is self-regulated already. Scientific findings are subject to peer review. In another sense, the scientific community is regulated by governments, corporations, and others who provide funds. One should consider the following aspects:

- a. Self-regulation in the general societal and international context has the potential to be extremely important in new and emerging technologies, as scientists and engineers are both at the forefront of their fields and, often, the most knowledgeable about new and emerging technologies.

However, the strong trend toward public-private partnerships, which often places scientists and engineers as innovators and entrepreneurs who may profit significantly from their innovations, raises questions about the potential limits of self-regulation. Universities are already seeing the emergence of significant conflicts of interest, especially in areas of high profit potential.

One approach that is potentially significant is to encourage science and engineering laboratories to dialogue internally and to critique regarding the societal dimensions of their work. Inviting non-scientists to become involved in the work of the laboratory could prove beneficial as well. A number of nanotechnology labs are already pioneering this approach, and its potential should be evaluated and publicized.

- b. Professional organizations should develop guidelines for R&D and reviewing the publications and encourage dialogue and debate about the nanotechnology. Mechanisms such as peer review are essential.
- c. Independent, multidisciplinary review groups should be formed to evaluate the implications of nanotechnology. Citizen ombudsmen could be recruited to react to R&D plans.
- d. We need to be careful that we don't defend the actions of a community in this way in detriment to others, but look forward to what is effective for society at large. But ultimately, the scientific community needs to recognize that self regulation has become an increasingly insufficient. The importance of science and technology is so great that democratic societies have legitimate interests in public accountability for scientists and participation in the governance of science. In addition, commercial science is tightly controlled by corporate needs. The image of the "gentleman scientist" accountable only to his peers no longer matches the modern world. The question is really how to move beyond simplistic notions, such as self regulation, to *building systems of accountability and governance that are conducive to appropriate expansion of both science and democracy*. A first step might be for the scientific community to recognize that it IS a community, and therefore operates according to social norms and institutionalized practices, not purely "rational" processes. Therefore, discussions of power, of compromise, of ethics, of funding, etc., are not "extraneous" to how the community operates, but are fundamental to how it operates. To recognize this requires substantial education, including resources (both in time and money) allocated to the process.
- e. Nanotechnology researchers should implement ongoing and iterative processes for involving a wide spectrum of stakeholders into their research planning activities. For example, a given team or lab might hold an annual workshop involving members of the public or representatives from NGOs. They might conduct a monthly seminar in which experts on

societal issues, ethics, regulation or risk communication are invited to share and discuss their research. They might employ outside consultants to perform performance reviews on their projects. They might attach a team of social science researchers to their team. They might designate an ombudsman to interact with the public, the media and other stakeholders.

Universities, scientific organizations and national labs might organize annual meetings to discuss, evaluate and promote effective models for accomplishing the above mentioned tasks.

12. *In your opinion how can international expert bodies provide advice for critical issues worldwide?*

Several suggestions are:

- a. Provide and prioritize the foundational knowledge. Provide models for solutions and examples of “best practices” and recommendations for standards.
- b. Provide consultative expert advice upon request, particularly for higher risk implications. Convene open discussions with full ranges of participants and create clear documentation of how positions are arrived at. Simultaneously recognize the need for informal links with powerful individuals in national and international bodies.

Several international expert bodies offer one experimental approach to pursuing this objective. The most prominent institutional model at present is an issue-specific expert advisory committee, often but not always established by a treaty, which produces periodic and ad hoc reports detailing current state-of-the-art knowledge and answering specific technical questions. Examples include the Intergovernmental Panel on Climate Change and the Millennium Ecosystem Assessment. An alternative model, illustrated by the InterAcademy Panel, offers one-off reports on a broad range of topics in response to specific requests from states, intergovernmental institutions, or others who might wish to commission a study.

One key element in the operation of these organizations is the quest for political authorization, which raises the political profile of the institution and helps gain standing for its activities among global policymakers.

Another important aspect of the operation of these organizations is the recognition of their potentially powerful influences in international governance and that, therefore, they ought to be subject to careful consideration regarding issues of legitimacy and accountability. In short, democratic reform in international governance needs to pay as much attention to expert advisory processes (as, for example, Stiglitz makes clear in his critique of the International Monetary Fund) as to voting and decision-making procedures.

The long-term value of such institutions stems from their capacity to help foster the expansion of reasoned dialogue in international governance and from their ability to inject particular factual claims into the debate (which tends to dominate the thinking of some of these organizations). As a consequence, careful attention should be given to the capacity of these institutions to a) broaden participation in international governance to marginalized groups whose knowledge and ideas might otherwise not acquire voice in global policy disputes, b) critique knowledge claims made by powerful actors in global society, whose justificatory rhetorics might otherwise go unchallenged, and c) negotiate and set standards for the production and validation of knowledge used as the basis for policies made on behalf of and that will impact the globe in its entirety.

Bodies of experts can conduct periodic reviews of both technical and socio-ethical standards and state of the art for nanotech risk research.

- c. There is a strong need to shift from the old model of international diplomacy among states pursuing their own self-interest to a more enlightened model of international politics in which reason and dialogue guide the legitimacy of policy choices that impact the globe as a whole.
  - d. Collect information in order to avoid duplication of effort.
  - e. International consultative expert may propose models and analyze scenarios. It is difficult to evaluate if the risk is worth taking. There is low expertise in that domain; it must be determined democratically.
13. *In your opinion how can formal and informal approaches for (governance of, that includes planning, managing, working with public, taking decisions, involving stakeholders) research and development be combined and implemented for nanotechnology?*

Formal and informal approaches for governance are useful for inclusiveness of the stakeholders and flexible implementation:

- a. The governance of nanotechnology is too complex for effective formal top-down analysis and decision making in all situations. Informal activities are useful for situations such as long-term forecasting, interaction with stakeholders, getting input from professional societies, promoting collaborations, and addressing exploratory research issues.
- b. Formal and informal governance approaches for open-ended issues may be combined through **input suggestions/reports** from professional organizations and various publics; through surveys; and through support for parallel projects in government and private sector.
- c. One interesting possible model to look at that involves both formal and informal approaches for research and development is the **open-source software development model** (see <http://www.opensource.org/> and <http://www.fsf.org/>). It may bear examination as an example of how informal collaboration in development of complex S&T innovations can be combined with structured processes for filtering and validating innovations to assure maximum public benefit, efficacy, and reliability of the resulting innovations. This group is a formal non-profit corporation, and that one of the key services it provides is to run a software certification program. Several other similar organizations exist, more or less co-existing in a collaborative atmosphere. Starting from a single idea by Linus Torvald to implement the original Berkeley UNIX instruction set on very small, affordable Intel processors, Linux has now blossomed into a worldwide movement. There are both commercial and non-profit “flavours” of Linux, but they all implement the open source concept to some extent. Interestingly, the “core” of the Linux operating system, the “kernel” is still reputedly controlled by Torvald himself – he and a close-knit group of associates monitor developments in the Unix world, detect problems that are tied to the code in the kernel itself, and periodically put out new releases to enhance the functionality of the Linux OS, address problems related to new hardware, etc. Hundreds of thousands of programmers around the world then take the new kernel and build complete operating systems around it, independently developing modules and applications that run under that kernel. Private companies (e.g., Red Hat) and non-profit organizations (e.g., Debian) then organize extensive testing and compatibility efforts to make sure that all these modules work correctly together, before assembling them into packages that consist of complete new “releases” of their respective “flavours” of the Linux operating system. There is in fact a great deal of “self regulation” that takes place through this process, with users commenting on their websites as to what works and does not work, what needs to be fixed in the next packaged release or the next kernel, etc.

This example is a microcosm of **how science and technology have been progressing** at an accelerating rate through increasing worldwide collaboration, both informal and formal, over the past several centuries. A key “informal” means of collaboration among scientists worldwide is the process of publishing technical journal articles documenting recent research

accomplishments. A more formalized process involved is the peer review process, by which journal editors decide which articles are worthy of publication. Successful papers in the nanotechnology era are often the result of collaborations among researchers from multiple institutions. Highly cited, "seminal" papers may in turn result in invitations to international conferences, out of which additional collaborations may emerge. When ethical or safety issues with respect to research innovations come to light, research journals and websites serve as fora for discussing them, and groups of concerned scientists may self-organize to decide on ethical standards for conduct of further research, as was the case at the dawn of the biotechnology era, with the organization of the Asilomar Conference in 1975. It is noteworthy that the voluntary standards that resulted from that conference were then largely adopted by the U.S. government in the form of regulations issued by NIH in the following year for the conduct of government-funded research involving recombinant DNA.

- d. Formal and informal may be interpreted as code words for scientific and lay notions of risk. The Danish consensus conference model is particularly effective in this area as it combines scientific risk analysis with public debate.

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

Several suggestions are:

- a. Enhanced communication and exchange information on R&D on EHS issues, medicine, etc.
- b. Joint development of standards and nomenclature, as well as their international acceptance. Trade and regulatory bodies should consider risk assessment and acceptability from the beginning.
- c. Education, knowledge and people exchanges
- d. Focus on R&D topics of global interest (N-S, E-W) such as energy conversion, water filtration, reducing pollution, and sharing materials and instrumentation. Joint international development of cyber tools for advancing nanotechnology.
- e. Governance should include a combination of "self-regulation" (as discussed above) and formal outside regulation by governments. Treaties, UN conventions, or some other mechanism may be appropriate way to address differing needs and cultural contexts. Coordinated planning for transporting nanomaterials across boundaries (there's an interagency working group being led by Mark Weiss in NSF/SBE and George Atkinson at State Dept on this)
- f. New and emerging technologies, which represent for many the possibility of rapidly creating future wealth, stand as a key area where competitive pressures will encourage countries to cut corners with respect to responsible R&D. A paraphrase of a developing country Commerce Minister offers the spirit of this attitude: "If the West is too squeamish to take advantage of the tremendous economic potential of stem cell technologies, we will have no qualms about leapfrogging them to become the economic power of the 21st century."
- g. These pressures, as well as competing cultural valuations of new and emerging technologies and competing cultural traditions of risk assessment, have made efforts to write treaties addressing the ethical regulation and control of new and emerging technologies exceedingly difficult, even when opposition is fairly widespread, as in the case of human cloning.
- h. A future development could be the creation of an institution that takes a more technology-by-technology approach to ethical considerations, that generates dialogue and discussion among global elites, as well as among global civil society, about the trajectories of specific

technological domains. While it is hard to imagine such an institution being granted regulatory authority today, that authority might accrete over time or be stimulated by an accident. Having an institution already in place that is seen as authoritative and credible would be a significant boost toward the possibility of future regulatory authority should developments warrant widespread concern among global publics; an institution already committed to a technology-by-technology evaluative approach could help mediate against a backlash to a negative incident transforming into a blanket prohibition on a whole class of technologies. Examples of such approaches include the Recombinant DNA Advisory Council in the US (which was probably too narrowly construed as an expert body) and the Human Fertility and Embryology Authority in the UK, which has a much more diverse membership and has specific authority to rule on the appropriateness of proposed experiments with new reproductive technologies. Such an agency would need the visibility and resources of an intergovernmental organization to be fully effective, but I might be wrong on this score. Regardless of the source of support, reaching heterogeneous global publics with meaningful dialogue about new and emerging technologies will entail significant resources.

- i. Apply conflict resolution models to create capacity for preventing conflict and mediate that which could occur
  - j. Although there are many international bodies that could provide a forum for international dialog on responsible development of nanotechnology, the United Nations is probably the most inclusive of these, and so the U.N. may need to play a role in coordinating conflicting national policies on these issues, even to the extent of cajoling “rogue” nations that refuse to abide by internationally accepted norms of ethical behavior with respect to scientific and technological research.
  - k. While the U.N. and other organizations do play key roles as international deliberative bodies, their powers of persuasion are necessarily (and rightly, in my opinion) limited, to the extent that they can act to enforce international norms of conduct only in the most extreme cases. Alternative mechanisms that can and should be pursued include bilateral and multilateral discussions among national governments, both informal and formal, to establish and then try to persuade all countries to pursue reasonable standards of conduct. Certainly, the United States historically has used its influence with other countries many times to try to influence their behaviour in favourable ways, through diplomatic channels.
  - l. While governments can play these roles and attempt to constrain behaviour of rogue nations or individuals, in many cases government roles only follow the actions of individuals and informal groups to “stir up” public concern about ethical issues. A good case in point is the global campaign beginning in the 1960s to ban commercial whaling, which was followed much later by formal diplomatic negotiations leading to an international treaty. Another example would be the refusal of European consumers to accept genetically modified foods developed by the United States. Groups in the United States seeking to influence the behaviour of corporations have succeeded in doing so through boycotting of products such as grapes and chocolate products. So the power of individuals and small, informal and formal, non-governmental organizations should not be discounted.
15. *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.*

Several suggestions are:

- a. The predicted creation of new technical capabilities would seem capable of expanding the current limits of sustainable development. A concentrated international R&D effort would

increase the chance of achieving that goal. Joint R&D projects and long-term views would accelerate getting the results.

- b. The challenges here are no doubt more political and social than narrowly technical. It is important that nanotechnology promoters do not treat nanotechnology as a straightforward “technical fix” to problems that will also require political solutions. Nanotechnology is a technical opportunity. The needs of less-developed countries are unlikely to be addressed without a concerted effort that is more about building societal commitments than about creating new technologies. The limits of for-profit corporations, with their requirements to yield high returns on investment, for addressing the needs of the poor should be explicitly discussed. In the context of development, focus on the promises of technological marvels without addressing the underlying societal commitments to attacking poverty and addressing sustainability can ultimately be a distraction from these most serious issues.

A fundamental issue here is political accountability. As I indicated above, the primary impetus for R&D spending in nanotechnology and other arenas of new and emerging technologies is investment for economic growth. Hence, R&D priorities tend not to be aligned with sustainability goals or with goals such as alleviating poverty and establishing human security in developing countries.

At the same time, while development agencies often offer opportunities to invest in R&D toward development goals, many who have participated on the ground in development projects say that technologies developed in such contexts are often inappropriate and go unused, thus failing to contribute to long-term development.

- c. Education
- d. Societies or governments should structure accountability for R&D programs so that they are held accountable to those whose lives are intended to be impacted by the investments made by the program. This would be a tough political sell for most R&D programs, which tend to derive their primary accountability to their sources of funding.
- e. A simple answer is putting money into the key areas of human benefit. The balanced distribution issue is much more complex. Moreover, the global track record is rather poor. A critical question here is the granting of IPR for nanotechnology products and processes. In other areas, e.g., biotechnology, there has been a tendency to go too far in granting patents, apparently tying up the entire field in what Eisenberg has called the anti-commons. One hopes that this could be avoided in nanotechnology. One possibility that could be contemplated along these lines is a coordinated, global R&D effort aimed at meeting a few basic needs of both less and more heavily developed countries – for example, inexpensive and reliable alternatives to fossil-fuel energy, low-cost water purification, etc. Nanotechnology could provide some fruitful avenues of research for addressing those needs, but as discussed above, the political and economic issues associated with such a proposal are probably even more daunting than the technical ones. However, it is the growing global collaboration, both informal and formal, among researchers that has moved nanotechnology (and science and technology in general) forward so rapidly in recent years; a similar collaboration among politicians and business leaders worldwide could help bring the fruits of this explosion of technical innovation to bear on many of the world’s most severe problems.

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(Additional information may be found on [www.nano.gov](http://www.nano.gov) and [www.nsf.gov/nano](http://www.nsf.gov/nano))

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## **ANNEX F – SUMMARIES ON NANOTECHNOLOGY ACTIVITIES FROM OTHER COUNTRIES (BASED ON ANSWERS TO THE MERIDIAN STUDY, NSF SPONSORED, 2004)**

### **NANOTECHNOLOGY IN ARGENTINA**

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*There are several R&D programmes related to nanotechnology.* Argentina is part of Inter-American Materials Collaboration (CIAM) together with the US (NSF), Canada, Mexico, Colombia, Costa Rica, Chile and Brazil. This program funds Research in Materials that includes nanotechnology as a main component. CONICET, the National Research Council is member at the organizational level. Only at CONICET, 60 full time researchers, 40 doctoral and postdoctoral fellows are devoted to nanosciences and nanotechnology and 7 research Centers have NT among their mainstream activities. Twelve research projects on nanosciences (including CIAM initiative) were financed as national projects for a three-year period (with budget restrictions). Some projects on NT were financed within the VI Framework Program of International Cooperation with the European Union. NT was included as a priority also for collaboration at national level between the NSF and the Secretariat for Science, Technology and Innovation (SECYT)

Many national Universities have their own independent initiatives on NT particularly the Universities of Buenos Aires, Mar del Plata and La Plata. The Atomic Energy Commission also has a program on NT.

There is no regulation of this activity other than that related to the evaluation of research proposals. However, once use and risks are established, the general legislation could be applied with regard to property rights or environmental risks.

An approximate figure for CONICET investment would be around 350.000 US dollars per year (2004). Nationwide, public investment in this field is estimated at less than 500.000 US dollars.

#### *Key aspects for responsible development of Nanotechnology (NT)*

Concerns include: (a) Release or introduction of nanoparticles or nanodevices into open fields affecting humans, animals or food; (b) Guarantee for control of the nanoparticle/devices activity, their natural degradation or inactivation mechanisms, i.e. Nanoparticles used in food packaging or processing; (c) Nanodevices with self-replication properties

Interdisciplinary approach: NT implies the joint contribution of several disciplines (chemistry, physics, biology, engineering and design, etc.) Most disciplines have established values and rules and have poor experience in cooperation among them, particularly in the academic field. New interdisciplinary teams, even in the academic world, need specific support and recognition. Safety for some groups may not have the same meaning for others.

Application of knowledge: most research groups aim their work towards devices, arrangements or particles with potential and specific use in the market. The lack of high tech. firms in developing countries may cause the dispersion of efforts or even their appropriation by limited companies outside these countries. Also, in all economies the pressure of the market on research, either in the academic or business sector, may cause potential risks to be overlooked. The cost of international patenting processes may be a restraint on proper appropriation of the research results benefits.

Priority setting: There is poor experience in developing countries in the exercise of priority setting oriented to market or social needs. Moreover, as in many other sciences, the editorial policy of publications, influences the research trends emphasizing the novelty of findings rather the importance of result application. State of the art. instruments, not always available worldwide, is a factor for evaluation of quality. As a positive aspect, the expert peer review practice, common in

the academic world favours the setting of quality standards even before any regulatory initiative is taken.

#### *Some actions to be considered*

Large instruments are only available at National Core Facilities in few countries. While national capabilities are being developed, international cooperation becomes a key issue. (related to internet access and cooperation agreements among parts).

We deem necessary to:

- Promote an active policy towards the protection of intellectual property rights (IP) for many of the key issues. IP agreements between Funding Agencies must contemplate the claims of other institutions (i.e.: universities or firms where research is carried out)
- Promote international establishment of standards for products derived from NT. Many physical or chemical properties may already be measured for regular materials or components but NT contribution may increase significantly some limit values for new materials (viscosity, chemical stability, among many others)
- Promote the remote use of instruments to break the gap between research laboratories and even to allow the access of the manufacturing sector to NT.
- Establish local committees to study potential risks in practices. Investigate risks and hazards and write rules or exchange best practices to overcome them (as done previously with genetic constructions or dangerous chemicals). Would general regulations and standards like those of FDA or EPA be applicable?
- Include safety and ethical issues as a separate chapter in research meetings.

Once risks are clearly identified, the compliance with protocols, safety rules and ethics should be an issue for 1) project proposals at financing agencies and academic and business laboratories 2) release of products to the market 3) appropriate disposal mechanisms.

## **NANOTECHNOLOGY IN AUSTRALIA**

Annual investment in Australian nanotechnology from all sources is about US\$90M in 2004 - 2005. There are numerous programs that support nanotechnology as part of broader educational, R&D or commercial objectives, but none is dedicated solely to nanotechnology R&D. Key R&D programs are:

- The Australian Commonwealth Government "Backing Australia's Ability Program" <http://backingaus.innovation.gov.au/default2004.htm>
- CSIRO's Nanotechnology R&D Program <http://www.nano.csiro.au/> has nanotechnology as one of its Emerging Science Initiatives. CSIRO has the largest nanotechnology activity within Australia. With 20 Divisions researching in diverse sciences across Australia, the CSIRO about 100 scientists involved in nanotechnology research from 12 of those Divisions. CSIRO expenditure in nanotechnology, covering both strategic and contract R&D, will exceed A\$25M (US \$ ?) in 2004-05.
- Nanotechnology Victoria <http://www.nanovic.com.au/> is a vehicle for optimising benefits to State of Victoria from advances in nanotechnology and related sciences by attracting investment, assembling the essential physical and intellectual infrastructure and by leading commercialization initiatives. Total funding of A\$26M (US\$ ?) comes partly from the members and includes A\$12M (US \$ ?) from the Victorian State Government
- Australian Institute of Bioengineering and Nanotechnology (AIBN) <http://www.aibn.uq.edu.au/> The Queensland Government has contributed A\$17.5M (US\$ ?) from the .Smart State Research Facilities Fund. towards establishing a **A\$60M (US\$ ?)** Institute for Bioengineering and Nanotechnology involving the University of Queensland and CSIRO. Its current focus is in nano-medical devices, drug delivery systems, diagnostic devices, tissue engineering and biomaterials
- NanoHouse Initiative <http://www.nano.uts.edu.au/nanohouse.html> The Nanohouse Initiative is a joint initiative between the University of Technology Sydney and the CSIRO and was launched in 2002. It is a collaboration between scientists, engineers, architects, designers

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and builders working together to build a new type of ultra-energy efficient house and exploiting the new materials being developed by nanotechnology.

*Country's laws and regulations that apply to nanotechnology development:* There are no specific laws relating to nanotechnology development. There are specific guidelines related to anything that impacts on worker safety, has an environmental impact or is considered an industrial chemical. Each of the six State Governments also has its own Acts and Regulations and although the principles are consistent, there are some minor differences in individual laws. The existing laws on materials apply to nanotechnology through the obligation of the employer to do everything practicable to ensure the health and safety of both employees and users of the product or process.

Concerning environmental implications, there is no specific Commonwealth Government environmental legislation relevant to the impacts of nanotechnology although there is an *Environmental Protection and Biodiversity Conservation Act 1999*. However, each State and the ACT has its own legislation (<http://www.enviroessentials.com.au/envirolaw/index.php>). Currently, NICNAS does not distinguish materials on the basis of size or allotropy (thus nanoparticle titania and carbon nanotubes are not considered differently from pigment titania or activated carbon). It is under this legislation that the safety and use of nanoparticles in products may need to be assessed in future. Risk assessment by NICNAS involves the following steps: (a) hazard assessment, (b) the establishment of dose-response relationships, (c) exposure assessment and (d) risk management procedures. Such assessment will take into account toxicity, environmental, EHS and public health considerations.

Key issues that need to be addressed in order to ensure the responsible development of nanotechnology:

- Environmental Health and Safety (EHS):
  - Improved toxicology data on nanoparticles and nanostructured materials
  - Establishment of a network to collate and communicate toxicology data and to ensure that duplication of research is minimized
  - Agreement on criteria for what is .acceptable risk. when exploiting nanotechnology
- Environmental:
  - Increased R&D into the accurate measurement of nanoparticles in both air and water and in determination of their origin (natural vs. anthropogenic)
  - Increased resources and R&D effort in issues related to efficient agricultural and aquacultural practices (e.g. controlled release fertilizers/fungicides etc) for improved food production and logistics enabled by nanotechnology
  - Increased resources and R&D effort in issues related to efficient water management and air quality enabled by nanotechnology
  - Increased resources and R&D effort in renewable energy production and managing carbon (and other element) flows through the industrial ecosystem enabled by nanotechnology
- Educational:
  - Much greater emphasis on K-12 education of nanotechnology (curriculum development, low cost demonstrations, teacher training etc). This is already happening in some Asian countries. e.g., Taiwan
  - Appropriate National and regional community education and outreach programs need to be developed
  - Effective whole of community education to avoid distortion and misinformation about the effects (or benefits) of nanotechnology
- Social and Ethical:
  - Agreed ethical criteria to evaluate the introduction of new technology
  - Adequate resources and infrastructure to engage the community in nanotechnology issues (How do we ask permission to introduce new technologies? Whose needs are being served and how do we offer choice?)

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- Adequate resources devoted to ensure that the needs of developing economies are addressed (in particular, for nanotechnology research in water, food production, appropriate manufacturing and health care)
  - Mechanisms to ensure some equity is achieved in the benefits derived from nanotechnology between economies and regions.
  - Minimising intrusions into privacy (e.g. via pervasive and low-cost RFID technology enabled through nanotechnology) and loss of personal freedoms from security measures (e.g. via pervasive biometrics enabled through nanotechnology)
  - Ethical criteria around hybrid biological-inorganic systems (i.e. .synthetic life.)
  - Measures for redeployment and re-education of the workforce to avoid disruption of the existing industrial manufacturing and service base
  - Management of changes in lifestyle and demographics resulting from the above disruption and from improved quality of aged care
  - A range of ethical issues resulting from nanomedicine. eugenics, prolongation of life, cloning, stem cell research etc (nanotechnology will enable some of these .advances.)

Activities that should be done to ensure the responsible development of nanotechnology at various levels:

- National level (Australia): (a) Public education programs involving .credible. advocates openly addressing public fears and outlining key issues. The most important outcome is to create informed community dialogue; (b) School K-12. development of a national nanotechnology education program should be developed and integrated into the school curriculum, rather than taught as a separate subject, and taught with a flexible emphasis (rural vs. urban, indigenous, vocational vs. academic etc); © Establishment of an Australian Nanotechnology Network and an Australian Nanobusiness Alliance to act as forums to engage with the public, the media and governments on EHS and social/ethical matters; (d) Establish an Australian national program on nanotechnology and the environment . use of NT in improving water, food, agricultural practices, transport, and energy; (e) Funding specifically for toxicology research be made available via Commonwealth Government; (f) Increase funding for Australia to form key alliances related to the responsible development of nanotechnology and to participate in international nanotechnology activities.
- Regional: Support for an Asian Nanotech Forum to address specific regional issues in relation to (a) standardization of concepts and measurements, (b) social, environmental, and health issues and (c) Education and Human Resource Development. Support to be sought from Ausaid, WHO, UNESCO, World Bank etc.
- Global: (a) Establish a Global Network for coordination of toxicology R&D and dissemination of toxicology information related to nanotechnology; (b) Establish a Global Network for coordination of environmental R&D and dissemination of information related to nanotechnology.

## **NANOTECHNOLOGY IN AUSTRIA**

The Austrian NANO Initiative is a national programme for funding research and technology development coordinated by the Austrian Space Agency (ASA) under the overall control of the Federal Ministry of Transport, Innovation and Technology (BMVIT), and in cooperation with the Federal Ministry for Economic Affairs and Labour (BMWA) and the Federal Ministry for Education, Science and Culture (BMBWK), the Austrian Council for Research and Technology Development (RFT), the Austrian Science Fund (FWF), the Austrian Industrial Research Promotion Fund (FFF) as well as the Federal provinces, the Federation of Austrian Industries (IV) and the Austria Business Service GmbH. The objective of the NANO Initiative is to promote the qualitative and quantitative growth of the Austrian NANO sector and to bring it more closely to the European community of researchers. [www.asaspace.at/nano](http://www.asaspace.at/nano) . Annual funding is US\$ 13M. (in 2004 - 2005).

Other related programmes are:

- a. Austrian Initiative for Microtechnology coordinated by the Austrian Industrial Research Promotion Fund (FFF) (including stand alone R&D projects in applied and industrial nanotechnology). Information under: <http://www.fff.co.at/view.php?docid=1586>
- b. Fundamental research projects are promoted by the Austrian Science Fund (FWF). It is equally committed to all branches of science and in all its activities is guided solely by the standards of the international scientific community. Information under: <http://www.fwf.ac.at/en/index.asp>

There is currently no special law or regulations that apply directly to nanotechnology beyond those related fields like chemistry, physics, medicine, biology, safety, environment, energy - applying to nanotechnology developments

*Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are public information, safety (in research activities, in production lines, in products) and ethical aspects.*

*Activities that should be done to ensure the responsible development of nanotechnology at various levels are:*

- Regional - networking with technology parks/centres, information to public sector
- National - cooperation between funding agencies and provinces, communication platform, public information, legislative aspects, market studies, feasibility studies
- Global - safety issues, ethical aspects, benchmarking for best available programme management methods, market studies

## **NANOTECHNOLOGY IN BELGIUM**

Contact: Mertens Robert, Senior Vice- President MCP, IMEC, Belgium

R&D Programs are:

At the moment (June 2004) there is no national nanotechnology program in Belgium although substantial funds are being allocated in this field. The largest investment in the nanotechnology field in Belgium goes to the funding of IMEC (Interuniversity Microelectronics Center, Leuven, Belgium). The regional government of Flanders invests each year 30 Meuro in IMEC mainly for research in the field of nanoelectronics (sub 45 nm Si CMOS, biosensors, organic semiconductors, novel solar cells, spintronics, ...). An estimated additional 30 Meuro in the Flanders region goes to other research labs in the field of nanobio and to various university research groups. This corresponds to a total annual funding of about 60 Meuro for the Flanders region. In the Wallonia region another 15Meuro/a is spent in the field of nanomaterials and nano for human health and life sciences. The total government funding in Belgium then is estimated to be 75 MEuro/year.

Belgium is following the European laws and regulations in the field of nanotechnology and there are no specific regulations for nanotechnology at present.

Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:

1) Some nanotechnology products not only cause potential safety hazards during fabrication but also at their end of life. Examples: - large area displays with nanoparticles - solar modules with nanoparticles. 2) Implantable radio frequency identification devices (RFID) based on nanoelectronics will be the ultimate tool for security access, patient monitoring and safe commercial transactions but there are privacy and freedom concerns. 3) Unlike the containment of chemical and radiation contamination (which ultimately can be confined) biological agents can reproduce and are therefore extremely difficult to contain. A major issue is that our advancement in the ability to engineer bio structures is faster than our progress in understanding their mechanisms.

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Activities that should be done to ensure the responsible development of nanotechnology at various levels are:

- Systems should be set up to collect hazardous large area nanotechnology products at their end of life in order to allow recycling in safe conditions.
- Public awareness should be increased before RFID implanting becomes compulsory.

## **NANOTECHNOLOGY IN BRAZIL**

Contact: José Roberto Leite, Director (PhD), National Council of Scientific and Technological Development . Ministry of Science and Technology

Brazil has three millennium institutes and four cooperative networks in nanoscience and nanotechnology. There are about 300 scientists (PhDs) working in NN in Brazil. The total budget for nanotechnology in 2004 is about US\$ 7 Millions. For the period 2004-2007 is predicted a budget of about US\$ 25 Millions. The programs include nanobiotechnology, nanostructured materials, nanoelectronics, etc

*Contact: Oscar Loureiro Malta, Dr. Full Professor  
Federal University of Pernambuco-Dept. Fundamental Chemistry*

The Brazilian initiative towards a national program in nanoscience and nanotechnology (N&N) started in 2001, based on the existing high level research groups acting in this area in several academic institutions and national research centers. Four research networks have been created with initial funds provided by the Ministry of Science and Technology (MCT) through the National Council for Scientific and Technological Development (CNPq). Two virtual institutes operating in the area of N&N have also been created through the national program Millennium Institutes for Science and Technology. Around 400 scientists are involved. The foci of these programs are in nanobiotechnology and nanostructured materials.

There are no specific laws and regulations that apply to nanotechnology development. The Brazilian government has created a National Committee for Bioethics. The aim is to regulate the impacts of scientific and technological projects on the environment and on health. Science and technology are nowadays a social activity capable to define the future of human kind. To succeed this activity should be exercised on the basis of an Ethical Modernity, in which not only technical but also humanistic aspects are incorporated.

The only possible way to guarantee the incorporation of an ethical modernity and, therefore, the responsible development of new technologies is through education and the creation of strong institutions on the grounds of moral compromises, either at the regional, national or global level.

## **NANOTECHNOLOGY IN CZECH REPUBLIC**

Contact: Vaclav Bouda, Professor, Department of Mechanics and Materials, Faculty of Electrotechnology, Czech Technical University, Technicka 2, 166 27 Prague 6, Czech Republic, phone: +420224352162, e-mail: [bouda@fel.cvut.cz](mailto:bouda@fel.cvut.cz)

R&D Programs are:

- (a) Since 1990, the Czech Republic (10 million inhabitants) has been busy reforming the organization of its state structure. The Gross expenditure for R&D by state is about 0.6% of its GDP.
- (b) The Czech government in Resolution No. 417, April 2003, approved the National Research Program (NRS) for the period from 2004 to 2009. NRS consists of five thematic programs. The thematic program No.3 .Competitiveness in Sustainable Development. is now a part of

program .Progress. announced by the Ministry of Industry and Trade of Czech Republic. This thematic program has six sub-programs. The sub-program .Manufacturing Processes and Systems. includes the key research direction .Electronic and Photonic Materials and Structures., which also focuses on Nano-Electro-Mechanical-Systems (NEMS), molecular electronics, new carbon and bio-mimetic materials. The sub-program .Emerging Technologies. includes the key research direction .Nanotechnologies and Nanomaterials. which focuses on structures and phenomena taking place in nano-sizes. Further key research directions include a strong trend in instruments and equipment for the creation and examination of micro and nanostructures, nanotechnologies applicable in pharmaceuticals, synthesis of thin organic layers, supramolecular chemistry, cosmetics, waste water treatment, catalysts etc. The funding amount devoted to NEMS, nanotechnologies and nanomaterials in the framework of these programs is about 3 millions dollars per each year.

- (c) The Czech Society of New Materials and Technologies (CSNMT) started in 2002 .Nanoscience and Nanotechnology Section. (NNS, head Dr. T. Prnka) with more than 100 members and the steering committee with several working groups. I am a head of working group .Education., which organize the network of Czech universities with the aim to build the infrastructure for experience exchange in education and research, to establish new courses and curricula in the field of nanotechnology, to encourage the collaboration with the Czech Academy of Science etc. NNS also focuses its activity on organization of annual international nanotechnology conferences, creation the English-Czech nanotechnology reference dictionary, dissemination of nanotechnology information etc.
- (d) Universities and their expertise
- *Czech Technical University in Prague.* Diagnostics of nanomaterials, nanoindentation, epitaxial growth, nanocrystalline diamond like layers, polymeric nanocomposites. I am engaged in the modeling of the function of bio-mimetic artificial muscles and in the analysis of the evolution of carbon nanoparticles self-assembly. It is getting clear that only nanotechnology and self-organisation can change the muscle model to a real, widely used device for medicine and NEMS.
  - *Masaryk University in Brno.* Low-dimension semiconducting structures, plasma-chemical deposition for nano-layers, structure and function of biomolecules, proteins, and DNA molecules, fullerenes and nanotube production, diagnostics of nanomaterials, near-field optical microscopy, AFM, magnetic-force microscopy.
  - *Technical University in Liberec.* Nanofibers.
  - *Technical University in Ostrava.* Periodic nanostructures, magneto-optics, layered nanostructures, nanoparticles and nanocomposites clay-polymer, anticorrosion layers, nanomaterials produced by working
  - *Charles University in Prague.* DNA molecules, magneto-optics, optoelectronics, nanostructured metals, research of atomic processes, thin layers, nanocrystalline powders, nanocomposite materials and effect of plasma, conducting polymers, self-organisation, molecular biology, bio-cybernetics, block-copolymers self-assembly.
  - *Palacky University Olomouc.* Nanocomposite and nanostructures analysis, AFM, nanobiotechnology.
  - *University in Pardubice.* Amorphous chalcogenides.
  - *Technical University in Brno.* Nano-structured thin layers, functional gradient materials, nano-structured ceramics, AFM, near field optical microscopy.
  - *University of Chemical Technology in Prague.* Submicron polymeric films with high permittivity.
  - *J. E. Purkyne University in Usti nad Labem.* Thin layers, AFM.
  - *West Bohemia University in Plzen.* Thin and hard layers, nanoindentation.
- (e) Czech Academy of Science and their Expertise

*Physical Institute in Prague.* AFM, STM, MBE and lithography, epitaxial growth, thin semi-conducting layers, magneto-resistance, magnetic memories, spintronics, quantum dots, nanocomposites and nanocrystals.

- *Institute of Macromolecular Chemistry.* Biocompatible interfaces, molecular electronics, growth of nanostructures from block-copolymers, polymeric micelles for directed release of medicaments, associated polymers and gelation, development of structure in polymeric systems, EM, NMR, ESRI.
- *J. Heyrovsky Institute of Physical Chemistry.* STS, STM, AFM.
- *Institute of Experimental Technology.* Electron microscopy, NMR, quantum light generators.
- *Institute of Radiotechnologys and Electronics in Prague.* Semiconducting thin layers and surface engineering.
- *Institute of Inorganic Chemistry in Rez near Prague.* Sol-gel preparation of thin magnetic iron layers, nanocomposites with controlled size of nanoparticles, nanostructures for optoelectronics.
- *Institute of Microbiology in Prague.* Nanobiotechnology.
- *Institute of Biophysics in Prague.* Study of DNA and proteins.
- *Institute of Organic Chemistry and Biochemistry in Prague.* Study of proteins.

There are no specific laws and regulations for nanotechnology at present data. However, there are super-ordinate laws Act. No.17/1992 Coll. about the environment in wording of the Act. No.123/1998 Coll. and Act. No. 123/1998 on rights for information about the environment in the wording of the Act. No. 132/2000 Coll.

The Czech Republic will be a member state of EC since May 1, 2004. So, EC laws on nanotechnology are applied in the Czech republic as well.

*Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:*

- a) Governments, universities, industry, professional bodies, and the public have to know that manufacturing at the nanoscale has potential to change both our comprehension of nature and to decrease consumption of energy, water, materials, waste, contaminants etc. They have to know that a main reason for developing nanotechnology is to extend the limits of sustainable development.
- b) The international collaboration is the most important issue to harmonize the national efforts towards a higher purpose than just advancing a few geographical regions.

*Activities that should be done to ensure the responsible development of nanotechnology at various levels are:*

- In the Czech Republic: (a) Nanotechnology may be a key national capability helping industry to become more efficient a competitive. So, the key opportunities and a long-term vision must be developed for nanotechnology research and development in government, universities, and industry. The vision must be based on intellectual drive towards exploiting new phenomena and using the molecular and nanoscale interactions for efficient manufacturing; (b) Education needs an earlier introduction of nanoscience with the understanding of the unity of nature at the nanoscale from the beginning. All universities should introduce courses based on nanoscale science and integrate nanotechnology with physics, chemistry, biology, electronics, medicine, engineering and other fields which enable students to develop hybrid manufacturing, artificial organs, enhancing learning, sensorial capacities etc.; (c) An infrastructure must be established inside and among universities, the Czech Academy of Science, professional groups, and industry with nanotechnology user capabilities. All these institutes must be restructured towards integration with other technologies and continuing

education; (d) Nanotechnology development also includes environmental, health, ethical, and legal aspects and the respective regulations should be implemented as soon as possible; (e) Both future government and industry investment in nanotechnology should respect all the mentioned aspects.

- In the European Community (EC): The Czech Republic will be a member state of EC from May 1, 2004. So, EC programs dedicated to research, development, applications, and environmental aspects of nanotechnology should be implemented soon.
- At the global level: International collaboration is necessary in a field that does not have borders especially where health and environment are of general interest.

## **NANOTECHNOLOGY IN EUROPEAN UNION**

The European Union describes its investment and policies in "Communication from the Commission: Towards a European strategy for nanotechnology".

[ftp://ftp.cordis.lu/pub/nanotechnology/docs/nano\\_com\\_en.pdf](ftp://ftp.cordis.lu/pub/nanotechnology/docs/nano_com_en.pdf).

## **NANOTECHNOLOGY IN INDIA**

Contact: Prof. Dr. Kamal K. Dwivedi, Counsellor Science and Technology, Embassy of India in US, Washington DC 20008, India. (June 7, 2004)

India has a strong R&D base in Physical Sciences, Synthetic Chemistry, Pharmaceuticals, Biotechnology, Biomedical sciences, Information Technology and Materials. Hence, it is feasible to pursue any responsible program in Nanotechnology. More than 30 institutions are involved in research and teaching/training programs in Nanotechnology. Some of the ongoing R&D programs are given below:

- Nanolithography and Nano-electronics: Tata Institute for Fundamental Research, Saha Institute of Nuclear Physics, Indian Institute of Science
- Drug/Gene targeting, DNA Chips: National Chemical Laboratory, Delhi University
- Nanotubes: Indian Institute of Science, Jawaharlal Nehru Center for Advanced Scientific Research.
- Nanostructured High Strength Materials: Indian Association for Cultivation of Science, National Physical Laboratory, Indian Institute of Technology
- Quantum Structures: Tata Institute for Fundamental Research, Solid State Physics Laboratory
- Manpower Training (Workshops/symposia): Indian Institute of Science, Indian Institute of Technology, Saha Institute of Nuclear Physics
- Interaction with Industries: Indian Institute of Science, Confederation of Indian Industries

Budget : Under 10th five year plan (2002-2007), the government has allocated Rs. 1.0 billion. A total of 76 projects have been supported with a grant of Rs. 330 million (US\$ 7.3 million)

### **Future Activities**

- Interaction with Industry to evolve joint projects in nanoparticle production, drug delivery, nanoelectronics and surface Coatings
- Possible collaboration with other countries in areas of mutual interest

#### **(a) Indo-US Collaborations**

DST-NSF projects funded on: CNTs in composites, microwave assisted synthesis, nano-encapsulating materials, nano-composites, multiplexed nano sensor arrays, etc.

#### **Indo-US Conferences:**

5 conferences are held since Nov 2001 on a variety of topics.

DST-NSF Materials Network: To involve larger number of Indian and US institutions on projects of mutual interest in the area of Materials Science including Nanomaterials

**(b) Indo-German Collaborations**

- Indo-German Workshop on Nanomaterials (2001)
- INDO-GERMAN RESEARCH TRAINING GROUP (IGRTG) on Engineered Functional Nano-composites to start (IIT/K,IIT/M,ARCI- Darmstadt, Karlsruhe, Saarbrucken, Ulm)- to focus on magnetic properties, magnetic interactions, gas-solid interactions including catalysis, etc

**(c) Indo-Italian Collaborations**

With focus on industrial relevance and on sharing of experimental facilities and research training.

- Patterned glass and patterned GeAs and SiC
- Metallic and semiconducting nanoparticles in rare earth activated glassy matrix for photonic applications

**(d) Indo-EU Collaborations**

- 2005 Indo-EU Thematic Workshop in Nanoscience & Technology Expected to lead to an Action Plan for India-EU Research Projects
- Lateral entry of Indian researchers in 2003 EC Integrated Projects and Networks of Centres of Excellence in Nanoscience & Technology.

India has not yet framed any specific set of laws which regulate the development of Nano-science and Nanotechnology. However, the Government of India would address this issue at appropriate level to protect national interest and to develop international partnerships for mutual interest.

Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:

- Formulation of credible Nano-Science and Nano-Technology Initiative (NSTI)
- Development of infrastructure for basic and applied research in Universities and other R&D Institutions.
- Availability of adequate financial support from public and private sectors.
- Implementation of a comprehensive Human Resource Development (HRD) programs.
- Establishment of Advance Centers and Institutes of eminence for Nanotechnology.
- Periodical organization of advanced schools, National and International Conferences and training workshops.
- Bilateral and multilateral regional and international collaboration.
- Organization of Exhibitions and Outreach activities.
- Nano S&T shall be treated as high priority area to support R&D.
- Nanotechnology based manpower training in the key areas viz. energy, environment, health care, advanced materials, sensors and devices etc.
- Development of multi-disciplinary nano S&T curriculum for college and university students.
- Enhancement of R&D funding for basic and applied research
- Attractive fellowship packages shall be offered to tap best talents in this field.
- Creation of large number of Chairs to ensure continued involvement of best minds in Nanotechnology.
- Product driven approach shall be adopted to rope-in investment from private sector.

**NANOTECHNOLOGY IN ISRAEL**

Contact: Joseph van Zwaren, Director for Exact Sciences, Ministry of Science and Technology, Jerusalem, ISRAEL, Tel: 972-2-5411140 email: jo@most.gov.il

There is an Israel National Nanotechnology Initiative. With 8 new NST Centers opening in Israel during the last four years and at least one international well attended NST conference every month, it is hard not to feel the excitement that is taking place in the research community about this field. The Nano-Bio-Info Convergence is taking place at an accelerating rate and many research projects typically involve many various disciplines; biotechnology, physics, chemistry,

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material engineering, electrical engineering and even computer science. The feeling is that the discoveries made during the next ten, fifteen years will lay the foundation for the hi-tech industry of the twenty first century, which will replace the current microelectronics industry and create several new ones in the process.

The Hebrew University in Jerusalem has just inaugurated their Center for NanoScience and Nanotechnology, which has currently a strong focus on Nanocharacterisation (see <http://www.nanoscience.huji.ac.il/>). This center serves over twenty tenured scientists, as well as scientists from other universities and industry.

At the Weizmann Institute in Rehovot, there are two active centers in Nanotechnology. Prof Reshef Tenne, who pioneered synthesis of inorganic nanotubes and fullerene materials, heads the newly formed Nanoscale Science Center. The center is focused on converging nanoscale science with molecular biology. The second Center at Weizmann Institute is the Braun Center for Sub-micron Physics (<http://www.weizmann.ac.il/smc/index.html>).

Bar Ilan University's Center for Advanced Materials and Nanotechnology (BICAMN) includes 17 senior faculty and over 150 PhD scientists and graduate students. One of the outstanding strengths of BICAMN is in developing new approaches to creating nanomaterials. It has been designated as the EU Marie Curie Training Site for Novel Fabrication Methods for Nanoscale Materials.

At Tel Aviv University, the new NanoScience and Technology Center (<http://www.tau.ac.il/research/nano/>), headed by Prof Yosi Shacham (Engineering) is involved in NO molecule, forming very sensitive biosensors used in brain research taking place elsewhere at the Institute.

Bar Ilan University's Center for Advanced Materials and Nanotechnology (BICAMN) includes 17 senior faculty and over 150 PhD scientists and graduate students. One of the outstanding strengths of BICAMN is in developing new approaches to creating nanomaterials. It has been designated as the EU Marie Curie Training Site for Novel Fabrication Methods for Nanoscale Materials. BICAMN scientists have published over 400 nanoscience papers in refereed journals in the past 5 years and the Advanced Materials Sub-Group was ranked 13th in Europe in Nanoscience Citations (1996-2000).

In the North, in Haifa, many faculty members at the Technion strongly believe in the great potential of harnessing biology in the service of creating non-biological systems, such as electronic circuits a million times denser than those on the market today. Prof Uri Sivan heads the Technion's cross campus program on Nanotechnology, involving over fifty research groups.

In the South, at Ben Gurion University, the Ilse Katz Center for Nano- and Meso-Science and Technology (<http://www.bgu.ac.il/nanocenter/>) was established for studying materials and processes at the nanometer size range. The head of the center is Prof Yigal Meir (Physics). The center is focused on understanding the physical and chemical properties of "nano-scale" materials, and the design of novel chemical and bio-chemical molecular systems, which would exhibit unique chemical, electronic, or optical properties.

## **NANOTECHNOLOGY IN MEXICO**

Contact: José Lever: Director of Intern. Activities, CONACyT Jesús González: Coordinator of the National Nanotechnology Program

The government support is in academia (13 Centers and Universities) for novel structures, nanofilms, nanoparticles, and polymer Nanostructures with an annual budget in 2003: of 12.5 M (62 Projects 19 Institutions since 1998).

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## **NANOTECHNOLOGY IN THE NETHERLANDS**

A number of government agencies in the Netherlands are responsible for the public funding of nanotechnology research and development in the Netherlands. The most important are The Netherlands Organization for Scientific Research (NOW, i.e. the Dutch research council) and two of its subsidiaries, the Technology Foundation STW and the Foundation for Fundamental Research on Matter (FOM), as well as Senter, an agency that is part of the Ministry of Economic Affairs and the Royal Netherlands Academy of Arts and Sciences.

The combined research councils run a nanoscience theme program with a total of approximately 40 M. of allocated funds over the period running from 1998 to 2014. About 9 programs, running for an average period of 4-5 years have been funded in this way. The main thrust of public funding for nanotechnology is provided by Senter, which has recently funded three programs in the area of nanotechnology, NanoNed, MinacNed, and BioMaDe for a period of 4 to 5 years. The total budgets of these are 200, 60 and 30 M., respectively, half of which will be directly made available by the government, the other half will be financed from European Research funds as well as from the private sector. NanoNed, which should be seen as the national program for nanotechnology in The Netherlands, consists of a consortium of 9 R&D institutes that will conduct research around 12 themes (termed flagship programs) four of which have already started in 2003, whereas the other 8 will start in 2004. MinacNed does not only have a smaller budget, but is also not exclusively focused on nanotechnology, with much of the allocated funds directed towards microtechnology. BioMaDe, a research institute focusing on bionanotechnology already started in 2000, and was funded through Senter in two sequential steps in 2000 and 2004. In both these cases (MinacNed and BioMaDe) 50% of the budget will be made available by the government, as described for NanoNed.

At the moment no detailed studies of private investments in nanotechnology are available, but a rough estimate would be around 50 to 100 M. for the next 4 to 5 years. Most of this money will come from large corporations such as Philips (also a consortium member in NanoNed), ASML, DSM, AKZO Nobel, Unilever etc.

The question of how to ensure a responsible development of nanotechnology first of all requires a definition of what is responsible, and what is not. In my view we need to look at future applications, without branching out into science fiction (e.g. self-replicating nano-assemblers, grey or green goo), i.e. develop scenarios that are realistic on the basis of the current-state-of-the-art technology. Since nanotechnology as it is currently defined is not one technology, but many, these scenarios will have to be defined per application area and their implications assessed individually. To ensure public acceptance all relevant parties, i.e. scientists, industry, NGO.s, citizens, governments should then take part in the discussion to evaluate the legal, societal, ethical and technological implications and define in this way what is acceptable and what is not. In this way a general agenda of directions and goals to be addressed by nanotechnology in each of the application areas can be defined, and depending on the outcome of this a regulation mechanism can be put into place. The latter should only be contemplated if existing regulation is deemed insufficient.

## **NANOTECHNOLOGY IN NEW ZEALAND**

The MacDiarmid Institute for Advanced Materials and Nanotechnology (<http://www.macdiarmid.ac.nz/>) is a primary focus for nanotechnology research in New Zealand. The institute involves researchers based at several New Zealand universities and government research institutes, with nanotechnology research investigating nano-engineered materials and devices. Work programs include nano-lithography, fabrication and characterisation of nano-materials, and developing molecularly patterned surfaces for selective adhesion of cells and proteins.

Some nanotechnology related research involving chemistry and engineering is also being undertaken at several other universities. For example, the Department of Chemical & Materials Engineering, University of Auckland, is undertaking research into nano-structured materials and coatings. The Department of Chemistry, University of Otago is looking at the magnetic behaviour of metallic complexes that may be useful for nano-components (switches and memory devices).

Research funding comes primarily from government. A company called Nano Cluster Devices Ltd has recently been established, and is concentrating on commercialisation of hydrogen sensors and a deposition control system allowing local, sub-monolayer control of particle deposition.

New Zealand does not currently have any laws or regulations specifically relating to nanotechnology. Depending on the nature of the development a range of legislation would apply to nanotechnology developments. Some of the key pieces of legislation, and agencies involved, are:

- The **Hazardous Substances and New Organisms Act** is concerned with protecting the health and safety of people, communities, and the environment from adverse effects associated with the development or use of hazardous substances and new organisms. Some nanotechnology products may meet the requirements of a hazardous substance in this Act.
- The Hazardous Substances and New Organisms Act is administered by the Environmental Risk Management Authority, a quasi-judicial body that examines the risks, costs, and benefits of new hazardous substances or organisms on a case by case basis.
- The **Medicines Act** is concerned with the safe and ethical uses of human medicines, therapeutics, or medical devices. Medicines, therapeutics, or medical devices that are or include products derived from nanotechnology may, therefore, be subject to this Act. Assessments are undertaken by the New Zealand Medicines and Medical Devices Safety Authority, a unit within the Ministry of Health.
- The **Agricultural Compounds and Veterinary Medicines (ACVM) Act** is concerned with preventing or managing risks associated with the use of agricultural compounds and veterinary medicines. Such compounds that are or involve products derived from nanotechnology may require assessment for risks to animal welfare, trade, agricultural security, and food residue safety. The ACVM Group in the New Zealand Food Safety Authority is responsible for the regulatory control of agricultural compounds (veterinary medicines/plant compounds), and their importation, manufacture, sale and use. This involves (i) producing standards for what compounds are exempt from registration, and those that require assessment and registration; (ii) assessing and audit applications for registration to import, manufacture, or use a new agricultural compound or veterinary medicine.
- The **Animal Welfare Act** covers the use of animals in research, testing, and teaching. Consequently, nanotechnology research and development that involves animals would be subject to this Act. The National Animal Welfare Advisory Committee and the National Animal Ethics Advisory Committee develop codes of welfare and codes of ethical conduct, respectively, that guide institutional animal ethics committees.
- The **Health and Safety in Employment Act** promotes the prevention of harm to all persons at work and other persons in, or in the vicinity of, a place of work. This includes imposing various duties on persons who are responsible for work and those who do the work, and setting requirements that relate to taking all practicable steps to ensure health and safety. These requirements will be applicable to those involved in nanotechnology research & development. The Occupational Health and Safety Service, based in the Department of Labour, is responsible for facilitating best practice workplace health and safety.

*Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:*

- As with any new technology, it is essential to ensure that risks to human health and the environment are adequately assessed during the development phase. Part of this will involve determining whether nanotechnology applications pose risks that are not currently addressed through existing legislation or regulation, or safety testing. Researchers themselves should

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- be considering potential health and safety risks of new compounds or materials and initiating research to collect data useful for such assessments.
  - Another critical factor, highlighted in the Public Perceptions of Agricultural Biotechnologies in Europe 2002 study, is to avoid mistaken interpretations of public perceptions of the issues. Such mistakes can lead to policies that fail to adequately respond to public concerns.
  - Trust in regulatory agencies is essential, and not just a nanotechnology issue. Building and maintaining trust will involve transparency in decision-making, including explaining how uncertainty is taken into account by decision makers and demonstrating how views from the communities and other interested groups are taken into account. Some groups will be concerned that innovation is being stifled by regulatory requirements, while other will consider that health and safety issues are not being properly or openly considered. Countries will differ on what factors their regulatory systems consider.
  - There is a need to distinguish what are the different types of nanotechnology applications because there is a danger of talking about nanotechnology as a single cohesive discipline. Different applications will present different issues.

Several suggestions for responsible development of nanotechnology are:

- Nanotechnology is only the latest example of potentially significant technological developments. Many initiatives, therefore, will not be nano-technology specific but applicable to other areas of science and technology.
- Regulatory processes must be transparent, with clarity around what is involved and how decisions are made. Regulations need to provide assurance for the protection of health and safety while also not unnecessarily restricting innovative research. [This is relevant at national level.]
- Funding agencies should encourage research into the health, environmental and social impacts of new technologies as part of the normal R&D process, rather than engaging in such research close to commercialisation or application. Currently there appears to be a lack of good social science research proposals that address such issues, so encouragement needs to be given to bringing social scientists, natural scientists, and engineers together. [This is relevant at national level.]
- It is critical for policy makers (and other interested parties) to avoid simplistic interpretations of sector views, so they need to encourage and be involved in general discussions of key concerns. It is important to acknowledge possible risks and to make it clear what is being done to address them. [This is relevant both nationally and internationally].
- Nanotechnology is not a discrete industry so attempts should be made to distinguish the different types of potential applications. Issues associated with particular applications can then be focused upon. [This is an international issue].

## **NANOTECHNOLOGY IN ROMANIA**

*Romanian "nano" initiative* on nanoscience and nanotechnology was launched in Bucharest on 14th of May, 2004. The idea of such initiatives for Eastern European Countries was launched by the European Commission at the EuroNanoForum 2003 (Trieste, Italy, 9-12 December 2003) ([www.imt.ro/mnt](http://www.imt.ro/mnt)).

*The aim of the initiative is concentrating resources and correlating efforts.* Difficulties: the lack of resources; the absence of priorities; brain drain.

*Research programmes include:* Nano. topics (2000-2004) in the previous national programme, initiated by contacts with NSF: Nanotechnologies in the MATNANTECH programme (2001-2004/2006), coordinated by the Ministry of Education and Research-Department of Research; Engineering and nanosciences. in the 2004 call of the National Council for University Research (CNCSIS).

Thematic areas (examples): *Composite materials; Smart materials* (Smart materials with applications in building, biomedicine and electronics, Chemical and biochemical sensors);

*Biomaterials and biosubstances* (New / advanced materials which are stable, biocompatible and useful for diagnose and therapy); *Advanced materials with electrical, optical, magnetic and thermo mechanic properties* (Functional and multifunctional advanced materials); *Micro and nanoelectronics and optoelectronics*; *Micro and nanotechnologies for interfaces, transducers and Microsystems, Nanostructured materials, micro and nanostructures* (Nanostructured materials for biomedical use; Nanostructured nanoparticles and composite nanostructures with selective properties; Nanostructures and nanostructured materials for applications in electronics, mechanics, metallurgy).

*MATNANTECH: Statistics:* 184 projects plus 9 priority projects; 176 collaborative projects (and 8 projects with a single participant); 187 participating organizations (54 research institutes, 20 universities, 23 large enterprises, 90 SMEs); 1512 researchers (920 full time), 408 young researchers, 18.8 MEuro total budget (2001-2006).

*A list of infrastructure projects is:*

- 4 Thematic Networks:
  - Nanobioengineering (BIONANONET) - 11 organizations;
  - Nanotechnologies (NANOTECHNET) - 13 organizations;
  - Materials and structures for micro and nanoengineering (MINAMAT-NET) - 7 organizations;
  - Tough materials - 6 organizations;
- 2 Virtual Centres: Nanobiotechnology (CENOBITE) - 9 organizations; Nanomaterials and new production processes (NANOMATFAB) - 7 organizations.
- 2 Centers of Excellence: Oxide multifunctional materials (TECHMAT) - 3 organizations; Microstructures, microsystems for microwaves - 1 organization;
- 2 Centers for Training and Consultancy: Microengineering (CESME) - 5 organizations; Nanomaterials, nanostructures, nanotechnologies (3N) - 2 organizations.

NANOMATerials and new FABrication processes (NANOMATFAB) is a .virtual centre. of research, a network of centres working in close cooperation and integrating some activities. It is financed from the MATNANTECH programme. A special feature: NANOMATFAB partners are partners in important EU projects (especially .new instruments. from FP 6) and their list is given below.

*FP 6 PROJECT NAMES AND ACRONYMS:*

- PATENT . Design for Micro & Nano Manufacture (Packaging, Test and Reliability Engineering in Micro & Nanosystems Technologies)
- AMICOM . Advanced MEMS for RF and Millimetre Wave communications
- NANOFUN-POLY . Nanostructured and Functional Polymer-Based Materials and Nanocomposites
- 4M . Multi-Material Micro Manufacture: Technologies and Applications
- NANO2LIFE . A network for bringing NANOtechnologies TO LIFE
- POLYSACCAHRIDES . European Polysaccharide Network
- INSIDE-PORES . In Situ Study and Development of Processes Involving Nanoporous Solids
- SOFTCOMP . Soft Matter Composites . An Approach to Nanoscale Functional Materials
- PINCO . Performance Improvement of Coatings for Fostering European Competitiveness and Promoting Sustainable Development
- STEPS . A Systems Approach to Tissue Engineering Processes and Products
- AMPLE . Advanced Functional Materials Produced by Pulsed Laser Deposition and Related Methods
- ASSEMIC . Advanced Handling and Assembly in Microtechnology
- BIOMAHE . Biodegradable Polymeric Materials for Health and Environment.

*MINATECH-RO:* MINATECH - RO is the acronym of the Romanian scientific and technological park for micro and nanotechnologies approved recently by the Ministry of Education and Research. Part of the new park is located in the Baneasa area (the semiconductor industrial platform, North of Bucharest, close to the airport), with resources made available by IMT-

Bucharest (national R&D institute) and the private company ROMES S.A. Both organisations are offering not only room for companies and access to infrastructure, but also their technological expertise. However, the park extends also to the University "Politehnica" of Bucharest, partner in the consortium which created MINATECH-RO.

The National Institute for Laser Physics is also interested to offer its expertise for the park through a partnership with IMT-Bucharest. The MINATECH-RO should be a scientific park "distributed" also in other important cities in Romania. This distributed character will be promoted by the partnership with the Romanian Chamber of Commerce and Industry through the regional Chambers of Commerce all around the country. The Chamber of Commerce brings new connections, as well as business experience. The partnership with the Chamber of Commerce was proved during the implementation of the Centre for Technological Transfer in Microengineering (CTT-Baneasa, 2003). MINATECH-RO has also direct partnership with other technological transfer centers in the country (ex.: AVANMAT- in the field of advanced materials, CENTI - in the field of environment monitoring and the quality of life).

*The National Master programme:* is part of the "National Joint Master Programme in Nano Science and Nanotechnology". The National Joint Master programme will be jointly developed by cooperation between 4-6 Romanian universities and 6-8 Research & Development institutes from Bucharest, Iasi, Cluj-Napoca and Timisoara. This will allow exploiting the synergy of resources of best equipped didactic and research laboratories and high qualified personnel. The universities and research institutes will cooperate for:

- (a) planning the programme studies;
- (b) curriculum design and development;
- (c) the accomplishment of all activities.

The Master programme will be based on modules: intensive teaching periods (theoretical and laboratory courses, seminars - mainly in universities) and practical stages (of minimum 3 months) in specialized laboratories from universities and research institutes. The length of studies: 2 years. The number of students/year will be around 20. The candidates should be graduates, at least of the first university cycle: in basic science (physics, chemistry, biology, mathematics-informatics), or in engineering sciences. All students will obtain governmental scholarships or grants from the places of practical stage. Private companies will be also invited to participate to the Master programme with: specialists (lectures or tutorial activities) and by hosting laboratories for students' practice.

- *Events, publications and projects representative for Eastern Europe:* "First NanoForum workshop: Sinaia, Romania, October 2003 (the second one will take place in Sofia, Bulgaria, October 2004).
- Workshop EURONET (European networking in micro and nanotechnologies), Sinaia, Romania, September 2003: networks of excellence from Framework Programme presented for the first time, support from the European Commission for both priorities 2 and 3.
- Annual Nanotechnology sessions at an IEEE event: CAS (organised by IMT-Bucharest in Sinaia, Romania, now at the 27th edition) with outstanding participations. In October 2001 Dr. M. C. Roco presented at CAS: "Worldwide trends in nanotechnology";
- National Science Foundation organised a workshop in nanotechnology for Eastern Europe, in 2002 (Brasov, Romania, 30 September- 2 October). Another similar workshop is planned in 2005.
- Series in "Micro and nanoengineering" published by the Romanian Academy (of Sciences): Volumes dedicated to nanotechnology printed in 2001, 2003, 2004;
- Micro and Nanotechnologies Bulletin. (published by IMT-Bucharest quarterly since 2000). Since 2004 it is covering Eastern Europe and not only Romania.
- Specific Support Actions (SSA) financed by the European Commission and coordinated by IMT-Bucharest for networking in micro and nanotechnologies: in Romania, in Eastern Europe;
- SSA and CA (Concerted Actions) financed by the European Commission (with IMT-Bucharest involved) for providing access of Eastern organisations to: projects corresponding

to the .new instruments. (integrated projects and networks of excellence), proposals corresponding to the .new instruments..

## **NANOTECHNOLOGY IN RUSSIA**

Contact: Dr. Mazurenko, Russia

The main background paper for the organization of national research and development in Russia is a document .Fundamentals for science and technology policy in Russia till 2010 and further period. approved by the President of the Russian Federation in spring 2002.

The management of nanotechnology related research and development in Russia is currently implemented at the level of national, institutional and regional programs.

What we can call as the national level programs are: Federal targeted programs .Research and development in priority areas of science and technologies for 2002-2006., .National technological base., .Integration of science and higher education. and .e-Russia..

At the institutional level we can name several programs:

- programs of the Russian Academy of Sciences such as: .Low dimension quantum structures., .Bionic sensor micro- and nanosystems., .Nanomaterials and supramolecular systems., .Biochemical and biological research of pre-molecular systems.:
- programs of the Federal Agency for nuclear energy dealing with ultra-dispersion powder, special materials and technologies.

At the regional level the good example is, for instance, the specialized program of Moscow Government .Nanomaterials and nanotechnologies. and others programs jointly implemented by different organizations in different regions of Russia.

About 360 research teams including more than 80 institutions from the Russian Academy of Sciences, 160 higher schools, 120 industrial and private organizations participate in the implementation of those programs.

To give you an indication regarding the results of those activities I can share with you some figures. Only for 2003 this activities resulted in up to 1230 scientific papers published in leading magazines, 28 Russian patents were granted, including 3 applied by foreign partners.

The highest level of results achieved in those fields as well as quality of knowledge generated by the Russian science, its potential and practical experience in the area of nanotechnologies and nanomaterials is recognized by the world scientific community.

The discovery of principles for tunnel microscopy in 80th made a strong push for the development of research instruments, in particular, scanning probe microscope that allowed performing an assembly of materials and structures at the nano-scale level. Wide implementation of those devices into the practical research has made big impulse to the development of the research in this field for the latest decade worldwide. Some Russian companies have designed and now produce many types of probe microscopes in industrial scale.

Russian research infrastructure includes numerous scientific installation and complexes such as synchrotron emission and neutron sources. Those facilities are in a possession of state research centers such as Center for Nanotechnology and Synchrotron Emission created in Kurchatov Institute, specialized centers of Nuclear Physics Institute, Ioffe Physical and Technical Institute (both of the Russian Academy of Sciences in Saint-Petersburg) and Nuclear Physics Institute of Syberian Branch of RAS.

Therefore in different regions of Russia there are centers that are relatively new or recently reequipped by modern tools and are jointly used by scientific and business community in order to use unique scientific and experimental facilities in the most efficient way.

Russia pays a special attention to the issue of training of highly qualified specialists in the field of nanotechnologies who are also well educated in other areas of science like physics, electronics, optics, material science and biology. 15 Russian universities and higher schools in different

regions have launched new educational programs for special training in the field of nanoelectronics and nanomaterials. The Ministry of Education and Science of the Russian Federation and the Federal Agency for Science and Innovation are responsible and deeply involved into the coordination of activities in the area on nano-related research among other ministries, organizations and scientific institutions.

The draft of .The Concept paper was prepared for the development of nanotechnology-related activities in Russia till 2010. This paper does not yet have an official status and at the moment the national experts are reviewing it. It introduces a guiding principles and general approach of implementing research and development in the field of nanotechnologies and sets a goal to increase efficiency of the relevant national programs.

Several suggestions are::

1. To increase an international responsibility of research in the field of nanotechnologies all interested parties should do its best to promote bilateral and multilateral international cooperation allowing researchers to have an easy access to the results of research and facilitating a direct participation of researchers from different countries in the national nanotechnologies-related programs.
2. Moreover, joint evaluation of progress in this field and coordination of national approaches to the management of relevant activities should be promoted through the regular meeting of scientists carrying out research in this field as well as appropriate responsible national representatives.
3. For a short-term as well as for a long-term perspective it becomes very important to launch joint programs of education, training and exchange of personnel qualified in the field on nanotechnologies.
4. Participation of specialized UN organizations such as UNESCO, UNIDO, WHO and other in the dialogues of carrying out nano-research in responsible manner will be highly valuable.
5. It is essential to hold regular consultations between participating countries on harmonization of national legislature in this field, especially concerning the regulation in the area of IPR.
6. To increase public trust and the responsibility for carrying out nano-related research it is important that the information on state-of-the-art of the research, of important results and their possible dangerous consequences should be regularly made publicly available by leading scientists as well as by responsible governmental representatives.

## **NANOTECHNOLOGY IN SOUTH AFRICA**

Contact: Pontsho Maruping, Manager: Manufacturing Technology Mission, Department of Science and Technology, South Africa (10 May 2004)

South Africa does not currently have top-down structured nanotechnology program. In 2003, a National Nanotechnology Strategy was developed to define areas of relevance and potential to the country. In this financial year, limited financial resources will be allocated for the implementation of this strategy which will include the establishment of university chairs and a nanotechnology network.

There are several institutions undertaking research in nanotechnology in the country and the activities broadly fall under the following areas: water, energy, health, bio-prospecting and chemicals, materials as well as mining and minerals.

Currently there are approximately twelve Universities, four Science Councils and companies that are active in nanotechnology research and development obtaining funding from different sources. The specific funding data is available but in July 2003, the nanotechnology spending was estimated to be:

- Government R&D grants and student support: \$500 000
- Science Council grants: \$1mil
- Private sector funding: \$1.2mil

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There are no specific laws and regulations related nanotechnology development, however the following would generally be applicable:

The Occupational Health and Safety Act has been issued to provide for the health and safety of persons at work and for the health and safety of persons in connection with the use of plant and machinery; the protection of persons other than persons at work against hazards to health and safety arising out of or in connection with the activities of persons at work; to establish an advisory council for occupational health and safety; and to provide for matters connected therewith. This act impacts on worker safety and has provisions that protect workers who refuse to do environmentally hazardous work.

The National Health Bill: aims to provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith. Chapter 8 of the bill deals with control of use of human organs while Chapter 9 deals with health research regulations and ethics.

The National Environmental Management Bill: provides for co-operative governance by establishing principles for decision-making on matters affecting the environment, institutions that will promote co-operative governance and procedures for co-ordinating environmental functions exercised by organs of state. The bill provides for integrated environmental management which requires the integration of the principles of environmental management into the planning and development process and to identify, predict and evaluate the effects which policies, programs, proposals or projects may have on the environment.

Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:

- Appropriate government policy and regulation for new research areas
- Transparency through promoting its public understanding which will allow civil society to debate with scientists on the actual research being conducted and also its impact to society.
- In training of future nanoscientists and nanotechnologists, issues of ethics should also be covered during education, training programmes of future professionals.
- Encourage continuous debates around on the delivery of the science to industry and society at large.

Suggestions for the responsible development of nanotechnology are:

- The level of regulation should depend on the motivation, for example, comprehensive regulations are required where the threat to public harm exists. An example of where this is applied is in the nuclear industry. Since nanotechnology is an emerging science, it is necessary to co-develop the risks assessment as part of the science until a specific risk is eliminated. Both policy makers and the public must evaluate the most appropriate regulatory framework at a national level.
- Regionally and globally, it is necessary to establish self-regulatory frameworks that allow for each country to setup its own safety regulations within given guidelines. To achieve all this, we need to create procedures for technical debates that are open, credible and focused on finding the facts needed to formulate sound policies. These procedures should allow for global easy access to relevant information for making informed choices at national, regional and global level.
- Lessons learned from past experiences with other emerging technologies such as biotechnology should also be applied to ensure that policy does not hamper science and science does not pose undue risks to society

Contact: Manfred Scriba, Organization: South African Nanotechnology initiative (SANi), Country: South Africa (28 March 2004)

There is no official nanotechnology research and development (R&D) programme in South Africa. Funding for nanotechnology R&D currently comes from a number of general funds and mainly two large companies. South Africa now has a Nanotechnology Strategy, which will lead to a national strategic fund of \$5 to 10mil/year from 2005 onwards. The focus in South Africa will be on nanotechnology applications for social development (water, energy and health) and for industrial development (advanced materials, minerals beneficiation and processing) South Africa produces half of the world's Gold and Platinum reserves but does minimal processing of these minerals.

During a workshop held in July 2003 the nanotechnology spending was estimated to be:

- Government R&D grants and student support: \$500 000
- Science Council grants: \$1mil
- Private sector funding: \$1.2mil

South Africa has nanotechnology R&D activities in:

- Health : Biomaterials, Nano-encapsulation, Nanofibres, Gold Nanoparticles, Platinum
- Water : Nano membranes, Electro catalysis and Remediation
- Energy : ColnSe solar cells, Dye solar cell, aSi solar cell, Fuel cells
- Materials : Catalysis using Au and Pt, Composites, Carbon Nanotube Synthesis, Polymers, Nanoparticles, Thin films, Ultra hard Materials, Nano Diamonds, Membranes
- Minerals : Biosynthesis of Nanoparticles, Nanocomposites,
- Atomic modelling

To date we have not done a study to determine which laws apply to nanotechnology. I am not aware of laws specifically mentioning nanotechnology that have been passed to date. The Environmental Health and Safety Act in South Africa is apparently quite good and covers aspects of nanotechnology although not mentioned specifically.

Key issues that need to be addressed in order to ensure the responsible development of nanotechnology are:

- The assessment of possible threats should be done by experts in the field. Secondly, nanotechnology should be subdivided into categories and each will have its own set of issues. For instance a next generation computer chip employing nanotechnology is less of a threat than a spoon full of 4nm Nanoparticles and might again be less of a threat than nanobots (if we ever get them made). So, the key issue is to find the categories and then devise rules and regulations for them.
- Another point to mention is that Nanotechnology should really create benefits for the human race, especially for developing countries. In Africa for instance energy, health and water are major issues that need to be addressed. Nanotechnology should further not lead to yet another divide between the developed and developing nations.

On a global level a panel of experts have to de-mystify nanotechnology by categorising the various areas and applications and suggesting research programmes on safety issues where the information is lacking. The recommendations of this panel will have to lead to some regulations being put into place. In the mean time, all levels of government will have to ensure that nanotechnology development, falls within the current regulations and laws. Governments, especially in the developing countries should carefully consider where nanotechnology can play a role in elevating poverty and suffering. An example is the need for new drugs or drug delivery for AIDS, Malaria and TB. Another example is the use of traditional medicine which has been used in Africa for decades. Nanoencapsulation and Nanoparticles can offer a new way of delivering such drugs.

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## NANOTECHNOLOGY IN SWITZERLAND

Contact: Karl Hoehener, Juergen Hoeck, TEMAS AG, Switzerland (June 1, 2004)

Three Nano initiatives are in execution in Switzerland 2004-2005:

- NCCR, National Center of Competence in Research Nanoscale Science focusing on basic research and ultimate limits, an initiative of the Swiss National Science Foundation ([www.nccr-nano.org](http://www.nccr-nano.org)). The annual funding is US\$ 7M.
- Nanotechnologies and Microsystems - a bottom up approach of CTI, the funding agency for Technology and Innovation ([www.bbt.admin.ch](http://www.bbt.admin.ch)), to support applied R&D-projects. The annual funding US\$ 7M.
- The Technology oriented Program TOP NANO 21 - an initiative of the ETH Board to increase the levels of knowledge about the NANOMETER, intended to lead to new technologies and to support existing technologies through synergies in order to encourage the development of new products and services ([www.ethrat.ch/topnano21](http://www.ethrat.ch/topnano21)). The annual funding amount is US\$10 M.

At the moment there are no laws or regulations that apply especially to nanotechnology development in Switzerland. Common law applies to workers' safety and environmental issues.

In addition to the issues environment, human health, safety concerns and ethical issues we strongly believe that early integration of communication strategies towards public perception of nanotechnology needs to be addressed. Another key issue is to sensitize researchers for risks in handling nanoparticles in air.

Laws and regulations applying to responsible development of nanotechnology should be worked out and implemented on a global level. The implementation of those laws and regulations into nanotechnology research programs should happen on regional and national levels. It should also be the task of the countries or regions to evaluate the implementation and give a feedback to the law making institutions, as well as organizing the communication with the public.