ATTACHMENT F: QUESTIONNNAIRE RESPONSES AND BACKGROUND INFORMATION

Meridian Institute sent each invitee a questionnaire that prompted invitees to provide information on the nanotechnology R&D programs and relevant laws and regulations in their country/region, as well as their personal views on key issues that should be addressed and international actions that could be taken to ensure the responsible R&D of nanotechnology. Participants from the following countries provided relevant information:

- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- China: Taipei
- Czech Republic
- European Union
- France
- Germany
- India
- Ireland
- Israel
- Italy
- Japan
- Korea
- Mexico
- The Netherlands
- New Zealand
- Romania
- Russia
- South Africa
- Switzerland
- United Kingdom
- United States

Meeting participant submissions are provided in alphabetical order by country on the following pages.

Nanotechnology (NT) in Argentina

Prepared by Jorge TEZON Ph.D.-Consejo Nacional de Investigaciones Científicas y Técnicas, CONICET

This report was based on consultations with local experts and available data from CONICET

Government programs and agencies in the country related to nanotechnology research and development as well as regulation of 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 NT as a main component. CONICET, the National Research Council is member at the organizational level.

Just 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, general legislation could be applied with regard to property rights or environmental risks.

General summary and estimate of public and private sectors investment in NT R&D in the country

An approximate figure for CONICET investment would be around 350.000 US dollars per year. Nationwide, public investment in this field is estimated at less than 500.000 US dollars.

Innovation projects are promoted in several ways. NT could easily find resources but there is a lack of demand for these funds in the private business sector, particularly in the Hi Tech area such as NT.

Key aspects for responsible development of Nanotechnology (NT)

Release or introduction of nanoparticles or nanodevices into open fields affecting humans, animals or food.

Guarantee for control of the nanoparticle/devices activity, their natural degradation or inactivation mechanisms

 i.e. Nanoparticles used in food packaging or processing Nanodevices or nanoparticles with mechanical properties used alone or in combination with "normal materials" in structures that could affect human safety or the environment.
 Nanodevices or nanoparticles with catalytic properties in medicinal or industrial processes for products of human use or effect on the environment Same as remedies for environmental pollution 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. Also 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. In some cases the use of "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

Some countries do not count with the "state of the art" infrastructure to assess risks and apply proper control over their research. Some big 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. Many countries have established national committees to evaluate these practices for the introduction and handling of Genetic Modified Organisms, among others.

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The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" in Alexandria, Virginia, USA.

Response from Australia

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

Investment in Australian nanotechnology from all sources probably is about US\$90Mpa. 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

The major single source of support for nanotechnology comes from the Australian Commonwealth Government **"Backing Australia's Ability Program"** <u>http://backingaus.innovation.gov.au/default2004.htm</u> under the following activities:

- ARC Discovery Grant Programs A\$53M (~US\$37M) total project expenditure committed for projects commenced in 2002-03ARC Networks of Excellence
- Federation Fellowship Program
- **Major National Research Facilities** (MNRF) Program has funded (A\$11.5M) a *Nanostructural Analysis Network Organisation* (NANO) <u>http://www.dest.gov.au/MNRF/</u> consists of 5 universities who have formed a network organisation for resource sharing with a national grid of new and existing instrumentation in microscopy and microanalysis at a nanoscale level. It delivers capabilities to the Australian research community and private sector in atomic and molecular level imaging, analysis and manipulation.
- **R&D Tax offsets for small companies** <u>http://www.ausindustry.gov.au/</u> R&D Tax Concession is a broad-based, market driven tax concession which allows companies to deduct up to 125% of qualifying expenditure incurred on R&D activities when lodging their corporate tax return. A 175% Premium (Incremental) Tax Concession and R&D Tax Offset are also available in certain circumstances.
- **R&D Start Program & Commercial Ready Program** R&D Start is a competitive, merit based grants and loans program that supports businesses to undertake research and development and its commercialisation. The Australian Government is providing more than \$1 billion to 30 June 2011 for the new Commercial Ready program.

CSIRO's Nanotechnology R&D Program <u>http://www.nano.csiro.au/</u> has nanotechnology as one of its Emerging Science Initiatives. CSIRO has the largest nanotechnology activity within Australia with projects in

• Advanced Materials and Nanocomposites

- Nanomaterials for Energy & Environmental Applications
- Nano-biotechnology and Biomaterials
- Nanotechnology for Electronics,

ranging from long term fundamental and strategic research investment to mature nanotechnology products. With 20 Divisions researching in diverse sciences across Australia, the CSIRO about 100 scientists involved in nanotechnology research from 12 of those Divisions. The CSIRO has also developed strong research links with Universities and Industry across the globe. CSIRO expenditure in nanotechnology, covering both strategic and contract R&D, will exceed A\$25Mpa in 2004-05.

Nanotechnology Victoria <u>http://www.nanovic.com.au/</u> 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. It is a company limited by guarantee involving several Victorian Universities and the CSIRO. Total funding of A\$26M comes partly from the members and includes A\$12M 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 from the "Smart State Research Facilities Fund" towards establishing a A\$60M Institute for Bioengineering and Nanotechnology involving the University of Queensland and CSIRO. The AIBN has been established as a national Centre of Excellence for Nanotechnology creating a critical mass in research and development and helping Queensland at the forefront of nanotechnology and bioengineering. Its current focus is in nano-medical devices, drug delivery systems, diagnostic devices, tissue engineering and biomaterials

NanoHouse Initiative <u>http://www.nano.uts.edu.au/nanohouse.html</u> 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 the best of Australia's scientists, engineers, architects, designers and builders working together to design and later build a new type of ultra-energy efficient house and exploiting the new materials being developed by nanotechnology. Both the Commonwealth Government and a range of national and multinational companies are funding the initiative as an entry point into nanotechnology.

2. Please provide an overview of your country's laws and regulations that apply 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 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.

• Worker Safety - In the Commonwealth Government of Australia there is one Act (*Occupational Health and Safety (Commonwealth Employments) Act 1991*) that legislates occupational health and safety and two sets of Regulations. The Act sets out the general

duties of employers, employees, manufactures, suppliers, etc in regards to taking reasonably practicable steps to ensure that the workplace is safe. The two sets of Regulations relate (a) to requirements dealing with the administration of the health and safety system eg Health and Safety Reps, PINs and reporting incidents, etc and (b) to requirements regarding the management of specific hazards eg risk assessment, noise, plant, manual handling, dangerous goods, confined spaces, etc.

At present there are also about 30 Codes of Practice that provide practical advice and solutions about the management of specific health and safety issues (Codes are not mandatory, but they can be used as evidence in determining practicability). 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. Requirements regarding the composition of Material Safety Data Sheets (MSDS) are a case in point, however the various Sate Authorities are working towards a consistent model.

These laws 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. The test for practicability is based on a combination of (a) cost – is the cost prohibitive to justify proof of safety? (b) state of knowledge – do we or should we know whether it is safe?, (c) what is the level of risk? and (d) what is the consequence of an incident? The onus is on the employer/ product manufacturer/ designer to demonstrate practicability under similar circumstances then we must also do so. Demonstration that we have taken all reasonable steps to minimise risks can happen through adherence to formal Standards, Regulation or Codes of Practice (none of these currently exist for nanotechnology) or through a formal documented risk assessment. In addition, courts usually look at the prior level of consultation between the employer/ manufacturer and employees or end users in assessing culpability.

- Environmental Impact 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). Thus, in NSW we have the *Dangerous Goods Act (1975)*, *Environmentally Hazardous Chemicals Act (1985)* and Dangerous Goods (General) Regulation (1999) and in Victoria there is the *Control of Hazardous Materials Vic Environment Protection Act 1970* and *Dangerous Goods (Storage and Handling) Regulations 2000*. Each State has a different set of categories, but in most cases nanotechnology-based products would potentially fall within the hazardous materials, or discharges to air or water categories.
- For industrial chemicals (including cosmetics), regulation is by the Commonwealth Government under the *Industrial Chemicals (Notification and Assessment) Act 1989.* The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) provides (a) a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effect of industrial chemicals and (b) assesses all chemicals new to Australia and assesses those chemicals already used (existing chemicals)

on a priority basis, in response to concerns about their safety on health and environmental grounds. Their <u>approach</u> to the scientific assessment of chemicals covers the areas of toxicity, exposure and use to assess the environmental, public health and occupational health and safety risk. 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, OH&S and public health considerations.

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

(For the purpose of the meeting, our reference to "responsible" nanotechnology R&D includes the need to address environmental and human health and safety concerns, as well as efforts to ensure the substantial expected benefits of nanotechnology will not adversely affect human integrity and dignity and other ethical issues.)

OHS:

- 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 (eg 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?)
- 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 (eg via pervasive and low-cost RFID technology enabled through nanotechnology) and loss of personal freedoms from security measures (eg via pervasive biometrics enabled through nanotechnology)
- Ethical criteria around hybrid biological-inorganic systems (ie "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")

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

National - Australia:

- Public education programs involving "credible" advocates openly addressing public fears and outlining key issues. The most important outcome is to create informed community dialogue. The CSIRO SEI-Nanotechnology joint workshop recently held in Bendigo, Victoria was significant in that it sought to present for the first time in Australia (possibly globally), various scenarios (showing both the positive and negative sides of nanotechnology) AND it also sought community permission to continue R&D towards a particular social/economic outcome. The NanoHouse Initiative also has public education/outreach as one of its key objectives. It has attracted considerable public and overseas enquiries (including that from several US Museums as a means of public education about how nanotechnology will affect our lives).
- 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). The development and subsidized supply of low cost teaching aids (eg an AFM kit for <\$1000) is also important
- 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 OHS&E and social/ethical matters. In each of these bodies, a group with a composition akin to a medical ethics committee should be set up. One activity should be the development (and funding) of a coordinated media program for nanotechnology.

- Establish an Australian national program on nanotechnology and the environment use of NT in improving water, food, agricultural practices, transport, energy generation storage and use.
- Funding specifically for toxicology research be made available via Commonwealth Govt.
- 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:

- Establish a Global Network for coordination of toxicology R&D and dissemination of toxicology information related to nanotechnology.
- Establish a Global Network for coordination of environmental R&D and dissemination of information related to nanotechnology.

QUESTIONNAIRE International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA. To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at rraimond@merid.org or by fax at +1 970 513 8348.

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

Name

Austrian NANO Initiative

Organizations involved

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 (aws).

Description of the program's focus

It focuses a series of research-related structural and accompanying measures. 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**

Strategic objectives

- a) Using the nanoscale sciences and nanotechnologies for business and society by exploiting RTD results;
- b) Strengthening competitiveness by cooperation and networking between science and enterprises by creating and expanding critical masses;
- c) Positioning Austrian interests through increased integration and cross-disciplinary networking in European and international cooperation in research and technology development, in particular in the EU programmes;

- d) Contributing to the expansion and maintenance of research competence through education and training measures for the qualification of specialists in research and technology development;
- e) Contributing to the building and expansion of the corresponding infrastructure as well as building centres in basic research and application-oriented special fields.

Programme action lines

1. Research and Technology Development Project Clusters:

Building and strengthening research, technology and cooperation competence by funding strategically decisive RTD project clusters. These may range from basic research to technology development and should achieve substantial progress in technology and knowhow for science and enterprises;

- 2. *Building and Management of Networks:* Expanding and managing the networking of the Austrian players (universities, research institutes, enterprises, societies) nationally and internationally and with other networks;
- Training and Education Measures: Building up the human resources required for qualitative and quantitative growth by developing, funding and implementing suitable education and training measures for students, researchers and staff members of enterprises;
- 4. Accompanying Measures: Developing, preparing and buying specialist studies, market and feasibility studies, strategic concepts, Technology Foresight Studies and analyses as well as building up a national strategic accompanying research programme (e.g. risk research).

Scope and types of research

R&D project clusters (with both fundamental and applied R&D projects). No topical focus for the time being.

Funding amount

13 M€ (2004)

Any other information

a) Austrian Initiative for Microtechnology coordinated by the Austrian Industrial Research Promotion Fund (FFF) (including stand alone R&D projects in applied and industrial nanotechology). Information under: <u>http://www.fff.co.at/view.php?docid=1586</u>

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: <u>http://www.fwf.ac.at/en/index.asp</u>

2. Please provide an overview of your country's laws and regulations that apply 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 currently no special law or regulations – beyond related fields like chemistry, physics, medicine, biology, safety, environment, energy - applying to nanotechnology developments

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

Public information, safety (in research activities, in production lines, in products) and ethical aspects

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

<u>Regional</u>: networking with technology parks/centres, information to public sector <u>National</u>: cooperation between funding agencies and provinces, communication platform, public information, legislative aspects, market studies, feasibility studies <u>Global</u>: safety issues, ethical aspects, benchmarking for best available programme management methods, market studies

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Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name: Mertens Robert Title: Senior Vice- President MCP Organization: IMEC Country: Belgium Date: June 13, 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

At the moment 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 governement 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 healt and life sciences. The total governement funding in Belgium then is estimated to be 75 Meuro/a.

2. Please provide an overview of your country's laws and regulations that apply 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.

Belgium is following the European laws and regulations in the field of nanotechnology and no other specific regulation is present.

Please answer the following questions:

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

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.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

- 1) For point 3.1: 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.
- 2) For point 3.2: Public awareness should be increased before RFID implanting becomes compulsory.
- 3) For point 3.3: Awareness and open discussion should be increased.

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Please provide the following information about yourself:

Name: José Roberto Leite Title: Director (PhD) Organization: National Council of Scientific and Technological Development – Ministry of Science and Technology Country: Brazil Date: April 05, 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants

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 NN 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

2. Please provide an overview of your country's laws and regulations that apply 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 most important law that is now in the congress to be voted is the so called innovation law (IL). IL intends to regulate the relationships between Universities

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

There are very few industries devoted to nanotechnology in Brazil. About 90% of the activities in NN are in the universities and other governmental institutions. The key issue is how to change this situation and the productive sectors (Industries)

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

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Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name: Oscar Loureiro Malta Title: Dr. Full Professor Organization: Federal University of Pernambuco-Dept. Fundamental Chemistry Country: Brazil Date: April 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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. Especial emphasis is being given to the passage from the phase of learning technology(passive and active) to the phase of innovation.

2. Please provide an overview of your country's laws and regulations that apply 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 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. No scientific or technological project that may potentially affect environment and health is allowed to operate without the recommendation of this Committee.

Please answer the following questions:

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

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.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

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.

International Dialogue on Responsible Research and Development of Nanotechnology Canada –Questionnaire Response

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) of the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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; mission oriented research being undertaken by various federal government departments; and research and development being undertaken by for-profit corporations. In 2003 the OECD requested various national governments to provide data on nanotechnology research being undertaken in their countries. This 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 being 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), the Canada Foundation for Innovation (CFI) and the Canadian Institutes for Health Research (CIHR). 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 2003 NSERC appointed a leading nanotechnology researcher whose role is to enhance collaborations within the research community and to sponsor interdisciplinary nanotechnology research (annual budget of \$1 million). Similarly CIHR established an interdisciplinary competition in 2003 in regenerative medicine including the application of nanotechnology. In 2004 estimated research funding from NSERC is projected to be C\$15 million and from CIHR C\$4 million. In 2002, funding for major capital equipment grants totalled C\$27 million with matching grants from provincial governments of \$41 million. Major funding for salaries, buildings, and equipment to universities is provided by provincial governments based on their teaching component. Quebec in 2001 launched a targeted \$10 million four-year program to build interdisciplinary capability specifically in nanotechnology. Alberta has provided substantial funding to build expertise and research infrastructure but like other provincial governments this funding is included within larger programs.

B. National Research Council Canada (NRC)

NRC undertakes, 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 C\$120 million over five years. The institute will focus on leading edge research in ICT, 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 including NINT was estimated at C\$24 million in FY 2002/03.

C. Mission Oriented Research at Other Federal Laboratories

Natural Resources Canada, Environment Canada, and Health Canada have identified that nanotechnology will impact the work they do including supporting regulatory functions and working for the economic and social benefit of 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 C\$2 million in expenditures on nanotechnology research. Specific expenditures by other federal departments have not been identified.

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.

2. Please provide an overview of your country's laws and regulations that apply 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 can be covered under a number of existing statutes and regulations. It has been noted, however, 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 nanotechnology materials in powder form can 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.

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

Workplace Safety:

-Canada Labour Code Part II -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.)

-Hazardous Products Act -Transportation of Dangerous Goods Act

Environmental and Human Safety:

-Canadian Environmental Protection Act, 1999 and the New Substances Notification Regulations (environmental and indirect human health impacts of industrial and environmental applications; also the "safety net" which covers substances not regulated by any other federal Act or Regulation)

-Food and Drugs Act and Regulations, Cosmetics Regulations, Medical Devices Regulations (human health impacts of foods, drugs, cosmetics and medical devices)

-Consumer Chemicals and Containers Regulations

-Pest Control Products Act and Regulations (environmental and health impacts of pest control products)

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

Science fiction versus science fact

Predicting the future is a very inexact science yet the debate on the responsible development of nanotechnology is overshadowed by unrealistic if not fictional perspectives of what nanotechnology has to offer. We have now moved beyond frankenfoods and genetically modified organisms to grey goo, self-assembling nanobots, and protection of each individual's genetic code. Accepting fiction as fact provides a false premise to challenge existing codes and regulations. The lessons from biotechnology are that communicating science is difficult, the messages are not necessarily trusted, and there is often limited interest outside the scientific community.

Public dialogue and stakeholder involvement

In an age of mass communication, society and our political processes are changing. Interest groups are able to present their message broadly and effectively. This often means that existing structures and regulatory frameworks are continuously scrutinized and challenged. Nanotechnology will provide new and novel substances, and their impact will likely be transformative in many areas of society. There are risks and benefits to nanotechnology, and each citizen has the right to participate in society's choices. There is a need for open dialogue

and the public needs to be informed and engaged. An effective federal risk communication strategy is critical to achieve this.

Metrology

The key breakthroughs that launched nanotechnology are recognised to be the invention of the scanning tunnelling microscope and associated single atom imaging and manipulation tools. Twenty years after the discovery of the STM there is still a substantial need to improve existing tools and develop new ones. It is challenging to observe the in-vitro interaction of individual molecules with cell membranes, to measure energies, binding forces, etc. Effective tools to count air-borne nanoparticulates do not exist but a number of authors have raised concerns about the toxicity of such particles. Today it is difficult to image nano-sized objects. It is even more difficult to measure them reliably and repeatedly.

Risk characterization (exposure and hazard)

Much of value of nanotechnology is conceived on the basis of capturing the benefits of unique properties that may exist at the atomic scale that are not evident at the bulk scale. Although nanotechnology holds enormous promise, it has brought some important concerns. Nanoparticulates may show much greater facility to cross cell, tissue or membrane boundaries and could thus be more effective at delivering their toxic punch. The increased use of nanomaterials will result in ubiquitous environmental exposure, but there is limited data on environmental persistence, bioaccumulation and exposure scenarios. There is also limited but increasing information on impacts of nanomaterials on mammalian systems. More research is needed to determine potential environmental impacts and exposure, and impacts to human health in order to provide the basis for appropriate risk management of nanotechnology.

Equitable benefits

The raison d'etre of many countries for investing in nanotechnology is the potential for economic and commercial benefit. As a consequence, discovery oriented scientists in universities are more actively encouraged to undertake research that can be commercially exploited and to protect rather than share their knowledge. To a great extent nanotechnology research is publicly funded yet the benefits may not be shared within nations. We must also expect that the concentration of nanotechnology research in advanced countries whose governments would wish their corporations will commercially exploit may further widen the gap between rich and poor nations.

Intellectual property

Nanotechnology is part discovery and part invention – the discovery of novel properties and the invention of new materials or products. The possibility that novel properties may be patented by their discoverer may provide revenue to sustain some research but could frustrate the broader application of the discovery and increased commercial competition.

The Gap between R&D and other issues (e.g., NE3LS)

Often the fruits of a discovery are clouded with both benefits and risks – nanocoatings could enable more stable pressures for automotive tyres, reducing fuel consumption considerably at the expense of releasing nanoparticles into the air or water table. Many countries have invested substantial funds to create infrastructure and innovation platforms for nanotechnology applications, yet there has been little research directed to other issues which are critical to being a good steward. Increased attention to the E3 (environment, economic and ethics) and LS (legal, social) issues is required in order to responsibly develop, manage and introduce nanotechnology for public good and benefit.

Privacy and National Security

Privacy and confidentiality might be endangered by the miniaturization of electronics, which could lead to the widespread use of nanosurveillance systems. Nano-terrorism is also an issue. Nanotechnology might be misused for the production of mass weapons of destruction, higher performance antipersonnel devices and espionage systems.

Capacity and Capability

Federal regulatory departments and agencies need to acquire and maintain expertise and capacity to deal with nanotechnology products that are sought to be placed on the marketplace. Appropriate priority and funding must be established to effect this.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

National Level

At the national level, individual countries have a choice for the environment under which they administer nanotechnology research, development and manufacturing:

- Moratorium
- Continuation under existing conditions
- Incremental adjustment to regulatory frameworks
- Comprehensive regulatory frameworks

There is an inherent danger for countries imposing a moratorium on research in that the research may be exported to research paradises devoid of any regulation. Similarly, there is insufficient scientific evidence on which to establish comprehensive regulatory frameworks. Canada, in common with other developed countries, is adapting its regulatory system to smart regulations that are more adaptable to changing technologies, are inclusionary and transparent to the public, and supportive of a market-led economy. This should provide the regulatory mechanisms to make incremental adjustments to existing regulatory frameworks or introduce new regulations.

The responsible development of nanotechnology, however, should be broader than a sciencebased decision regulatory regime. To fully realize nanotechnology's potential for public good and environmental benefit, governments should take a comprehensive and coordinated approach. In Canada, a stewardship approach is being advocated for biotechnology – responsible and integrated management of economic, environmental, health and social interests, while maintaining and improving high standards for product safety. A similar approach could allow for good stewardship of nanotechnology.

International Level

At the international level, there is a need for coordinated activities in the following domains:

- Expansion of CAS registry for new nanomaterials
- Formal scientific studies on exposure, persistence, toxicity of nano materials particularly those materials that may be released into the environment
- Development of nanometrology tools and standards
- Incremental development of risk assessment protocols/methodologies as the science develops
- Establishing international standards for trade in nanoengineered products encompassing production, use and disposal

QUESTIONNAIRE International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA.

To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at rraimond@merid.org or by fax at +1 970 513 8348.

Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name:C.K. LeeTitle:AdvisorOrganization:Ministry of EducationCountry:TaiwanDate:June 14, 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

Taiwan's nanotechnology program has achieved the status of being a National Science and Technology Priority Program, which means that this particular program receive the highest priority during the government budgeting process. The organizational structure of the program is depicted in Fig. 1. Taiwan's nanotechnology program strives to maintain a balance of many variables: academic excellence, industrial utilization, education of the public, establishment of core facilities, as well as nanotechnology conscientiousness. A sample of the 2003 academic excellence program administered by the National Program Office with funding offered by Taiwan's National; Science Council (NSC) is listed in Fig. 2. The funding appropriated by each ministry is listed in Fig. 3.

2. Please provide an overview of your country's laws and regulations that apply 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.

Currently, the standard laws and regulations that govern environmental protection, worker safety, medical professional ethics, laboratory operations, product development protocols, etc., apply equally to the nanotechnology program. However, as of last year, Taiwan's Environmental Protection Agency has also joined the National Nanotechnology Program and has since initiated a special program to study both the positive and the potential negative impacts of nanotechnology. In the on-going project, environmental guidelines regarding nanopowder manufacturing is being assessed, ranging from hazards identification, exposure assessment, and risk management. In addition, a total of 32 critical issues in 6 major areas, which include applications for measurement in the environment, sustainable materials and resources, sustainable processes, natural and global processes, health and environmental safety, as well as societal impact, are being reviewed with an attempt to create the Taiwan EPA statement report. The statement report will encompass areas such as (1) limiting impact to the environment, (2) increasing public awareness and education of the applications and implications of nanotechnology, and (3) establishment of operational guidelines for nanotechnology manufacturers.

Please answer the following questions:

- **3.** In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?
 - Ethical conduct
 - Education of citizens: from K-12 to undergraduate to on-the-job training (life long learning)
 - Good manufacturing as well as responsible laboratory manufacturing practices and guidelines.
 - Public awareness
 - Proper monitoring technologies
 - Proper laws and regulations
- **4.** In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

We need to start by creating a conscientious program and understanding the potential negative impacts of nanotechnology. From there, we can then identify the proper operational as well as monitoring technologies so as to prevent major hazardous situations. A database that can identify all potential hazardous conditions and operations should be established to provide all the necessary background should there be a need to establish a new law or regulation. To ensure the responsible development of nanotechnology, close international collaborations regardless of any political boundaries are a must to guarantee the free flow of information on nanotechnology which can have a tremendous potential to impact society and ethics.

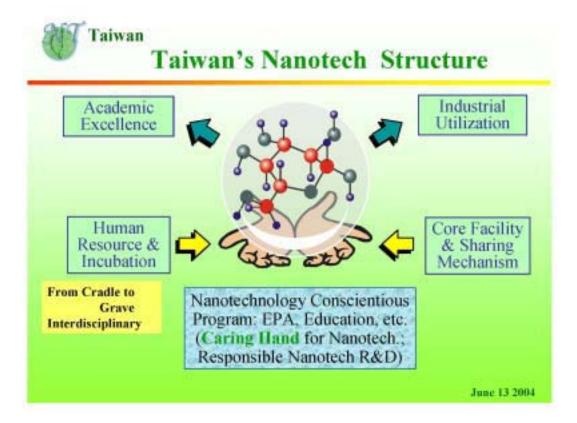


Fig. 1 Organization structure of Taiwan's Nanotechnology Program



Taiwan 2003 Proiects under Academic Excellence Program

Classification	Number	Classification	Number	
1.Basics research on the physical, chemical and biological properties of nanostructures		4. Design and fabrication of interconnects, interfaces and system of functional nanodevices		
Mesoscopic physics and chemistry	9	Nanostructures strengthened optotronic devices	6	
Theoretical calculation, simulation, and prediction of properties of nanostructures	7	Spintronic devices	3	
2.Synthesis, assembly and processing of nanomaterials		Near-field optical storage technologies	1	
Porous and high surface area materials: Mesoporous materials	3	5. Development of MEMS/NEMS technology		
Fuel cell and the related fundamental research	2	Near-field optical nano-lithography	1	
Studies on quantum dot materials and spectrum	5	Microposition and microassembly	0	
Photonic crystal materials	2	Microsensors	2	
Highly transparent organic/inorganic composites	1	Microfluid	3	
Applications of nano-particle materials	5	Soft lithography technology	0	
Fundamental studies in Nanostructured materials	9	6. Nano-biotechnology		
3. Research and development of probes and manipulation techniques		Nanoscale bio-detectors and bio-chips	2	
Nano-patterning technologies	6	Interactions between bio-cells and nanomaterials	3	
	5	Manipulation of bio-molecules	5	
		Manipulation, detection and measurement of bio-cells at nanoscale	2	
		Applications of nano particles for drug delivery and bio-detection	2	

Fig. 2. Sample project list of Taiwan's 2003 Academic Excellence Program

	2003	2004	2005	2006	2007	2008	Tota l	Budge t%
Academic Excellence Program	11.4	12.3	13.6	15.4	15.8	18.0	86.6	13.8
Industrialization Program	46.4	56.6	67.7	75.7	82.0	84.3	412.8	65.5
Core Facilities Program	17.8	20.1	21.9	18.2	18.4	23.0	119.4	19.0
Education Program	0.6	1.5	1.5	1.5	1.5	1.5	8.0	1.3
Program Office (NSC)	0.5	0.5	0.5	0.5	0.5	0.5	3.1	0.5
Total	76.8	91.1	105.3	111.3	118.2	127.2	629.9	100.0
MOEA/Department of Industrial Technology	54.6	64.7	74.3	77.5	83.2	89.1	443. 4	70.4
MOEA/Industrial Development Bureau	0.6	0.7	2.1	2.9	3.5	4.2	14.1	2.2
MOEA/Energy Commission	0.8	1.2	1.2	1.2	1.2	1.2	6.7	1.1
MOEA/Bureau of Standards, Metrology and Inspection	0.9	1.0	1.3	1.5	1.6	1.8	8.0	1.3
National Science Council (NSC)	18.0	19.0	20.9	22.4	22.4	24.1	126.6	20.1
Ministry of Education	0.6	1.5	1.5	1.5	1.5	1.5	8.0	1.3
Atomic Energy Council	0.6	0.9	1.8	1.8	1.8	1.9	8.8	1.4
Environmental Protection Administration	0.2	0.2	0.2	0.2	0.2	0.2	1.4	0.2
Department of Health	0.0	1.3	1.6	1.9	2.3	2.7	9.8	1.6
Program Office (NSC)	0.5	0.5	0.5	0.5	0.5	0.5	3.1	0.5
Total	76.8	91.1	105.3	111.3	118.2	127.2	629.9	100.0

Fig. 3 Taiwan's Nanotechnology Program Budget from Year 2003 to 2008 expressed in Million US Dollars

Questionnaire

Int. Dialogue on Responsible Research and Development of Nanotechnology Organized by NSF and Meridian Institute, 16-17 June 2004, Alexandria, Virginia, USA CZECH REPUBLIC CONTRIBUTION

Name: Title: Organisation:	Vaclav Bouda Professor Department of Mechanics and Materials, Faculty of Electrotechnology, Czech Technical University, Technicka 2, 166 27 Prague 6
Country:	Czech Republic
Date:	2 April 2004
Contact:	phone: +420224352162, e-mail: <u>bouda@fel.cvut.cz</u>

1. Brief description of R&D of nanotechnology in the Czech Republic

- (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. The R&D policy is changing towards a system of grants and public tenders. The ministry for Education, Youth and Sports is the leading ministry with responsibility for research, but also other departments fund research. The research and development council of the government is responsible for shaping the R&D system. There are five national grant agencies, which fund research. Traditionally, the institutes of the Czech Academy of Science carry out a larger part of the research, and the universities are more responsible for higher education.
- (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 subprograms. The sub-program "Manufacturing Processes and Systems" includes the key research direction "Electronic and Photonic Materials and Structures", which focuses on Nano-Electro-Mechanical-Systems (NEMS), molecular also 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 nanosizes. 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. That is why I have been involved with nanotechnology.
 - *Masaryk University in Brno*. Low-dimension semiconducting structures, plasma-chemical deposition for nano-layers, structure and function of biomolecules, proteins, and DNA molecules, fullerens 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 chalkogenides.
 - *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.

2. Overview of laws and regulations that apply to nanotechnology development

- a) Any specific law or regulation that apply to nanotechnology development in the Czech Republic are unknown to me. 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.
- b) 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.

3. Key issues that need to be addressed in order to ensure the responsible development of nanotechnology

- 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.

4. What should be done to ensure the responsible development of nanotechnology in the Czech Republic, at regional level, and at the global level

- a) In the Czech Republic.
 - 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.
 - 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.
 - 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.
 - Nanotechnology development also includes environmental, health, ethical, and legal aspects and the respective regulations should be implemented as soon as possible.
 - Both future government and industry investment in nanotechnology should respect all the mentioned aspects.
- b) 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.
- c) 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.

European Union

The European Union's submitted "Communication from the Commission: Towards a European strategy for nanotechnology" in lieu of responding directly to the questionnaire; this document may be viewed on line at <u>ftp://ftp.cordis.lu/pub/nanotechnology/docs/nano_com_en.pdf.</u>

NSF international dialogue on nanotechnologies Alexandria, May 17-18th, 2004

Contribution from France :

Françoise Roure, Vice President Legal and economic section, Council general for information technologies, french ministry of economy, finance and industry. Serge Hagège, Ministry of Research & French Embassy in Washington/Office of Science

1. Research and development programs

In France, public fundings of R&D are mainly allocated by

- the Ministry in charge of Research (MR)

- the Ministry of Economy, Finance and Industry (MINEFI)the French agency for innovation (ANVAR)

- the Ministry of Defense

There are three main goals for this public spending:

oTo provide support to R&D in the context of important programs or networks;

oTo support research at the University level and in public research institutes

oTo promote technological spreading in the industry and contribute to sustainable, long term development.

As it is usually the case, it is quite difficult to sum up all the financial efforts made at the national level, in nanotechnology *stricto senso*. Considering the partners listed above the total effort has reached 255 M€/y in 2004, an average of 25% increase per year over the last 4 years.

The following amounts can be identified more precisely:

•Ministry of Research: (http://www.recherche.gouv.fr/recherche/fns/nano.htm)

- « Nanosciences » 63 M€/y

The societal aspects of nanoscience will be included in the 2005 call for proposals. In addition the program ECCO (<u>http://www.insu.cnrs.fr/web/article/dossier.php?dossier=42</u>) has an exotoxicology component.

•Joint action Ministry of Industry - Ministry of Research Research and technological innovation networks *open to international partnership*

- Micro-nano	6 M€/y <u>www</u>	v.rmnt.org
- GenHomme (biotechnologies)	30 M€/y	www.genhomme.org
- Materials and processes	15M€/y	www.reseau-materiaux.com.fr

•Individual actions from Universities and Research Institutes	CEA	52 M€/y
	CNRS	86 M€/y
	INSERM	7 M€/y

- •At the <u>European</u> level (Framework Program), France participates to 3 main programs related to nanotechnologies
 - MEDEA 1500 M€/4years, France 37% : silicon technologies, international roadmap oNew materials (SiC, SiGe...)
 oArchitectures and fab. Technologies (Litho...)
 oMastering Future Technologies (MRAM...)
 - -PIDEA (400 M€/4Y): integrated and miniaturized complex systems oPackaging digital "cores" oAssembly and interconnection with other componants

-EURIMUS (400 M€/4Y), France 20%) : microsystems, sensors...

2. Laws and regulations that apply to nanotechnology development

There are no specific laws and regulations. Common law applies to labour force and environment protection. Cartagena Convention on biodiversity applies if and when relevant to nanotechnology issues.

Ethical issues have recently been raised and there is a recognition of necessity to address them at an early step well in advance of any regulation in order to find out principles. French National Advisory Comity on Ethics (CCNE) recently created a special working party on nanotechnologies.

A common report of the two French parliamentary chambers issued May 6th, 2004 deals with Nanosciences and medical improvement. It recommends that CCNE should send proposals as soon as possible to United Nations when it comes to a *corps de doctrine* on this issue".

Laws and regulations are mainly European driven, beginning with special focus on toxicology and ecotoxicology, but also through other regulations like the one related to human tissue engineering.

European regulation for chemical production and trade (REACH) should apply to nanotechnologies outputs.

3. Key issues to be addressed / responsible development of nanotechnologies

- Full <u>knowledge sharing</u> on nanosciences and technologies is dependent of quality and quantity of relevant data for the international community and requires harmonisation of classifications at a global level : patents, international trade/ customs documentation, production statistics...)

- A new <u>international nano- divide shoud be avoided</u>, as regards the potential benefits of nanotechnologies, and importance of the access to scientific break-through, to development and health.

- Special attention should be given to <u>the right balance between security in privacy</u>, as most of means provided are non accessible to immediate human perception but embedded, disseminated and working on a passive mode even if RF interconnected.
- Ethical issues related to life and dignity, either in the civil or in the military domains, should be adequately addressed.
- Education of general and special interest groups of populations to the nanoworld, the challenges, threats and opportunities need to be done.

4. Conditions for the responsible development of nanotech (national, regional, and global level): some recommendations.

- Promote international knowledge sharing about risk assessment, toxicology and ecotoxicology
- Enter an early dialogue on ethics at the international level
- Involve civil society in an interactive dialogue before adopting communication strategies
- Apply and, if necessary, adapt, international conventions available when they can be easily extended to the nanoworld
- Consider international "good practices" guidelines as an interesting preliminary tool to raise public awareness, giving full respect to diversity of societal models. But it means a capability of implentation and review, **creating common methodology for a shared ongoing normative assessment.**

It means for the future a democratic, transparent and multilateral approach allowing **peer reviews** and providing to each country/participant to the dialogue, an inclusive "level playing field": United Nations and regional involvements should be considered.

- Joint Focus on foresighting *Converging transformational technologies* (CTTs) because of potentially unimaginable effects/ impacts on all aspects of human living and the environment, especially when cognitive sciences and neurotechnologies are at stake.
- Explore the possibilities to reach a multilateral agreement where people commit themselves to a code of conduct and develop a peer to peer reviews methodology to ensure implementation on a voluntary basis.

Answers to the Questionnaire about International Dialogue on Responsible R&D of Nanotechnology

Volker Rieke Federal Ministry of Education and Research Germany

1. Nanotechnology research and development programs in Germany?

Since the late 1980s, the BMBF has been funding nanotechnology research activities in the context 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 p.a. In adition to this steadily increased BMBF collaborative project funding for this research field, starting in 1998 a supporting infrastructure plan was put in place with the establishment of six competence networks, raised to nine actually.

To remain successful in the face of increasing globalisation, Germany must concentrate on its business and science know-how and make better use of these assets. This is exactly where the **"German innovation offensive for nanotechnology"** (started in march, 2004) is taking up the challenge. Germany's strategy to address the nanotechnological value-added chain is based **not** on an outstanding R&D program, but on a framework including all the BMBF programs containing nanotechnological approaches. 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. The main elements of this strategy are:

 \rightarrow To **open up potential markets and boost employment prospects** in the field of nanotechnology

- the green light will initially be given to funding for four leading-edge innovations (NanoMobil / automotive sector; NanoLux / optics industry; Nano for Life / pharmaceuticals, medical technology; and NanoFab / electronics)
- "NanoChance", a new BMBF funding measure for targeted support of R&D-intensive small and medium-sized enterprises, which offers existing companies assistance in the early stage of consolidation, will be established
- the coordination between institutional BMBF funding here especially with regard to synergy effects with the programme-orientated research of the HGF (Helmholtz Association) Centres and funding for nano-sciences through the DFG (Deutsche Forschungsgemeinschaft) — and project support based on structural measures (networking, determining core topics, regular knowledge exchanges) will be optimised.

- → Measures to support innovation will also be implemented to supplement these main elements. For **the funding of young scientists**, the **"Junior Researcher Nanotechnology Competition"** will be continued. The aim of this competition, which was founded in May 2002, is to recognize new innovative approaches at an early stage and to attract top young scientists who have emigrated abroad back to Germany. In addition, activities in the areas of standardization, patents, and training and further education will be launched.
- → The dialogue on innovation and technology assessment will be actively pursued in order to give objectivity and thus direction to the partially critical public **discussion about the opportunities and risks associated with nanotechnology**. 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. The BMBF has commissioned several studies that are designed to deliver in-depth information to provide the major players in the nanotechnology field with the numbers and arguments that will support the further assessment of nanotechnology:
 - One study on the economic potential of nanotechnology will identify current and possible future products created through nanotechnology, and evaluate their market potential. These findings could serve as a decision-making basis for political arguments related to the support of nanotechnology and for investors.
 - Nanotechnology's potential contribution to sustainable development is widely considered to be high. As a "key technology of the 21st century", it could play an important role in helping to boost the economy and improve the environment. To date, scientific literature has discussed nanotechnology's environmental impact only in rudimentary terms while science fiction sometimes describes it in terms of a threat scenario. Quantitative assessments have not yet been made. A study commissioned by the BMBF is designed to provide concrete empirical and quantitative data that will allow experts to scientifically evaluate the environmental opportunities and risks associated with nanotechnology for the first time. The aims are, firstly, to pinpoint nanotechnology's potential effects in terms of sustainability/environment as broadly as possible and, secondly, to quantify these effects as far as possible by citing selected, relevant examples of nanotechnological uses or products.
 - A separate study is focusing on **nanotechnology's uses in medicine and health care**. Nanotechnology is opening up new avenues in the development of innovative therapies and diagnoses. The health-care and socio-economic section of the study will highlight nanotechnology's future social and economic potential in these areas. Potential applications include implants with nanostructured surfaces, specific drug-delivery systems or nanoparticles for medical imaging processes or particle-based hyperthermal procedures.

Based on the findings of these studies, the the TAB-study and on work initiated by the European Commission as part of the sixth EU Framework Program, other research activities will be undertaken as integral part of research projects and separate studies as well in order to provide political leaders with concrete recommendations for action and to develop optional courses of action for the socially acceptable use of nanotechnology.

2. Laws and regulations applying to nanotechnology development?

There is no special regulatory procedure to apply especially for nanotechnological purposes beside the alredy existing general laws and regulations concerning food safety, immission at working places, usage of chemicals and environmental pollution. At the moment, no one sees any need to introduce regulations or additional laws covering nanotechnology. But, within the framework of the socially relevant studies it has commissioned, the BMBF is taking a close look at current conditions regarding the use of nanotechnological products and processes. After all, it is the responsibility of national research policy to ensure a high-level of protection for people and the environment, and to review relevant laws and regulations governing emission, labour and dust protection as far as they apply to nanotechnological processes. Particularly when nanotechnological applications and processes are applied in humans, it is crucial to examine whether the relevant conditions laid down by biomedical legislation are applicable or to what extent the legislative framework requires further development with respect to issues concerning safety and ethics. If it is indicated, the BMBF and the regulatory ministries will push the investigation of possible influences of e.g. nanopowders or nanobiological systems, to describe the upper limits during production and use of nanoproducts.

The field of standardisation is of considerable importantance, because special standardisation processes play a major role in the diffusion of the results of innovation. Concerning standards and non health related regulations there is work underway to define measurement and usage regulations for nanoanalysis, production of ultrathin films with precise thickness, or the measurement of flat and aspherically curved surface. Involved institutes are the PTB, the BAM, the DIN, and some associations like VDI or VDE.

3. Key issues needed to be addressed to ensure a responsible development?

- The clear distinction between real R&D achievements and science fiction illusions. In the main cases it is necessary to name timelines, targeted applications and the basis for further achievements.
- Examination of toxicological effects of nanoparticles.
- For nanotechnologial applications it is necessary to describe the possible show stoppers, the risks associated with an application and the real work, which has to be done to assure the success along the value-added chain.
- To improve the interdisciplinary understanding a different educational systems has to be set up to allow interested pupils to get the necessary information of physics, biology and chemistry related to nanotechnology. Perhaps a higher mobility of the students is needed, sometimes a quick an flexible international mobility is advised.
- At the beginning of an expensive R&D line a description of the whole value-added chain, the involvement of all needed actors for a successful product development, a discussion about usable international cooperation and the early implementation of the future clients, that is mostly the society, is needed.

4. Actions to be done to ensure a responsible development?

- A transparent public information is needed to communicate both the chances and the risks with the aim to achieve wide public perceptions of nanotechnology.

- If the R&D work is in the precompetitive state an open discussion especially on the international level about the application possibilities and their "chances and risks" is needed.
- If necessary, the implementation of regulatory or administration institutions has to be performed in an early state.
- The necessity and level of international cooperation has to be evaluated in a forecasting manner: describing timelines, show stopper, educational bottlenecks (similar to road mapping) and derive from that the possibility (need) for international teamwork (e.g. if toxicological investigations are necessary) in reflection of the competition situation (degree of market vicinity).

QUESTIONNAIRE International Dialogue on Responsible Research and Development of Nanotechnology

Name:PROF. Dr. KAMAL KANT DWIVEDITitle:COUNSELLOR (SCIENCE & TECHNOLOGY)Organization:Embassy of India,
2536 Massachusetts Ave, NW
Washington DC 20008Country:INDIA
June 7, 2004

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) of organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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:

- 1. Nanolithography and Nano-electronics
 - Tata Institute for Fundamental Research
 - Saha Institute of Nuclear Physics
 - Indian Institute of Science
- 2. Drug/Gene targeting, DNA Chips
 - National Chemical Laboratory
 - Delhi University
- 3. Nanotubes
 - Indian Institute of Science
 - Jawaharlal Nehru Center for Advanced Scientific Research.
- 4. Nanostructured High Strength Materials
 - Indian Association for Cultivation of Science
 - National Physical Laboratory
 - Indian Institute of Technology
- 5. Quantum Structures
 - Tata Institute for Fundamental Research
 - Solid State Physics Laboratory
- 6. Manpower Training (Workshops/symposia)
 - Indian Institute of Science
 - Indian Institute of Technology
 - Saha Institute of Nuclear Physics

- 7. 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 (\$7.3 million)

Some areas of ongoing research:

- Application of SWCNT in fluid flow measurements
- Synthesis and properties of nanotubes and nanorods of transition metal oxides, chalcogenides, III-V semiconductor nanowires
- Template synthesis of nanowires
- Synthesis and applications of nano-composites
- Metallurgical routes to engineer the hardness of bulk nano-composites
- Applications of nano-particles, particularly in targeted drug delivery, pigment paints and engineering materials, novel sensors, etc.
- Biosynthesis of nanomaterials
- Biophysics of gene regulation and nano-biotechnology
- Functional, nanostructured films
- Nanolithography, nano-imprinting and nano-manipulation

Future Activities

1. Interaction with Industry to evolve joint projects in following areas Nanoparticle production Drug delivery Nanoelectronics Surface Coatings

2. 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, gassolid 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.

Some possible guiding principles:

- Areas of national interest and priorities like-energy, drinking water, health care, etc.
- Areas where national S&T strength exists
- Areas with commercial potential

FOUR POSSIBLE APPLICATION AREAS:

- Surface Coatings/Engineering with Nanopowders
- Nano Phosphors

- Drug Delivery
- Sensors, devices, nanoelectronics, etc.
- 2. Please provide an overview of your country's **laws and regulations that apply 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.

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.

- 3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?
 - 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.
- 4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.
 - 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.

QUESTIONNAIRE

International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA.

To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at <u>rraimond@merid.org</u> or by fax at +1 970 513 8348.

Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name: Donald Fitzmaurice

Organization: University College Dublin

Country: Ireland

Date: 30 March 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

For an overview of key issues, capabilities, and strategies for nanotechnology R&D in Ireland, please read the Statement on Nanotechnology of the Irish Council for Science Technology and Innovation

(http://www.forfas.ie/icsti/statements/icsti040714/icsti040714_nanotech_statement.pdf)

2. Please provide an overview of your country's **laws and regulations that apply 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.

Please answer the following questions:

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?¹

The key issues in the short and medium terms are the following:

- The evolution of health and safety and environmental regulation to be able to address the concerns of the worker, the nearby resident and the consumer in respect of the manufacture and disposal of nanomaterials and nanomaterials based products.
- The creation of a culture of transparent engagement, facilitated by the regulators, between scientists and engineers in academia and industry and the wider community. This engagement will allow the short and medium term issues above

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

National

Nanotechnology is an enabling technology and will not, in the short or medium terms, impact directly on our lives. Rather, on these timescales, nanotechnology will impact indirectly on our lives through the products and processes it enables.

Generally, therefore, it will be the responsibility of existing regulatory authorities to regulate these products and processes. Accordingly, the existing regulatory authorities will have the central role.

These authorities must engage with the leading scientists and engineers to understand the nature and timing of nanotechnology enabled innovations that will affect the domain that they regulate. In particular, they will need identify and quantify the associated risks.

They must also engage with reputable representatives of the interests of the wider community to understand the nature and magnitude of the concerns of individuals.

¹ For the purpose of the meeting, our reference to "responsible" nanotechnology R&D includes the need to address environmental and human health and safety concerns, as well as efforts to ensure the substantial expected benefits of nanotechnology will not adversely affect human integrity and dignity and other ethical issues.

The regulatory authorities must then facilitate a dialogue between these stakeholders, which will underpin a transparent process leading to effective regulation that has the support of all the stakeholders.

In the long-term new regulatory agencies may be required as a consequence of truly revolutionary capabilities enabled by nanotechnology and its convergence with biotechnology and information and communication technology.

European

The European Commission clearly has a role to manage the evolution of the European-wide regulatory environment to ensure it can regulate nanotechnology enabled products and processes. In particular, it has a role to ensure that the best-practice at national level is applied across all the member states. In doing so it should focus on those activities for which transnational regulation is clearly an advantage.

Global

Similar comments to those made in a European context can be made here.

• Develop the mutual trust and respect that will be needed to address the more difficult long-term issues below.

The key issue in the long terms is the following:

• The evolution of many of the institutions, which constitute the very fabric of society, to accommodate the changed world-view that will be a consequence of the convergence of the animate and inanimate worlds driven by nanotechnology.

Joseph van Zwaren Director for Exact Sciences Ministry of Science and Technology Jerusalem, ISRAEL Tel: 972-2-5411140 email: jo@most.gov.il

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, 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. The center enjoys advanced equipment for electron microscopy, scanning probe microscopy, X-ray characterization, and advanced chemical analysis of materials. In the near future, a unit for nanofabrication, a 'nano-workshop' for preparation of nanometric structures will be established, where the researchers will be able to prepare electrodes and various devices that will enable the integration of nanometric objects and systems with the macroscopic world. This stage is essential for application of research results in the real world. To mention some works in process, Prof Amir Sa'ar (Physics), Prof Shlomo Yitchaik (Chemistry) and Prof Micha Shpira (Neurobiology) are having a lot of success in developing stable Neuron-Electronic or Neuron-Optronic Interface Devices based on porous silicon. They are driven by the vision of creating bio-electronics devices, which will interface between nerve systems and artificial limbs, so that these will be controlled by thought. Prof Itamar Willner's (Chemistry) work on functional Biomaterial-Nanobjects Hybrids for Sensoric and Nanoelectronic Applications has achieved some of world records in terms of sensitivity, as reported at the ACS. Prof Aharon Lewis (Applied Physics), who pioneered Near Field Scanning Optical Microscopy, is working on fusing multi-microscopic imaging as well as nano-material processing to develop realtime in-vivo imaging of intra-cellular dynamics. Prof Danny Porath (Physics) is exploring self organization in DNA-based Nanoelectronics as a means of developing complex circuitry.

At the **Weizmann Institute** in Rehovot, there are two active centers in Nanotechnology. Prof Reshef Tenne, who pionneered 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. It therefore combines clean room nanofabrication with wet molecular biology labs involving DNA and protein manipulations, all under a single roof. Some ten research groups use the facility. Prof Ron Naaman and Prof David Cahen are involved in GaAs based chemical FETs, where a self assembled monolayer, connected to either bio-receptors or NO molecule, forming very sensitive biosensors used in brain research taking place elsewhere at the Institute. Beautiful cooperation is taking place between Dr Roy Bar Ziv and a biochemist, Dr Dan Tawfik, on biologically induced transcription using micro-fluidics. Prof Tenne is enjoying tremendous success in finding novel applications for the nanomaterials that he pioneered for tribological applications. Recently Volkswagen announced their joint cooperation with NanoMaterials, a start-up company based on the technology developed by Prof Tenne and Prof Lev Rappaport of the Holon Academic Institute of Technology. This team developed novel lubricants and tribological coating for the future maintenance free care.

The second Center at **Weizmann Institute** is the Braun Center for Sub-micron Physics (<u>http://www.weizmann.ac.il/smc/index.html</u>),headed by Prof Mordechai Heiblum. The Braun Center for Submicron Research, at the Weizmann Institute of Science, was founded to study and develop submicron semiconductor structures working in the mesoscopic regime. Such systems, called mesoscopic systems, with dimensions ranging from 10 nm to a few micrometers, exhibit coherent electrical and optical characteristics at sufficiently low temperatures. Studies of electron localization, exciton formation, local compressibility, low dimensional transport, electron interference and its phases, and fractional charges, are being conducted with state-of-the-art results. The heart of this Center is the MBE laboratory geared to develop and produce the purest and the most complex GaAs based semiconductors structures (GaAs, AlGaAs, and InGaAs). Nanostructure fabrication is capable of producing 15 nm wide features using an electron beam writing system.

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). BICAMN is home to a number of independent Centers of Excellence including Minerva Research Centers in "Microscale & Nanoscale Particles & Films as Tailored Biomaterial Interfaces" and in "Magnetism and Superconductivity". It has particularly strong research programs in spintronics, low-dimensional magnetism, magnetotransport, and nanomagnets (Frydman, Klein, Yeshurun), dye sensitized solar cells (Zaban), sensors (Lellouche), rechargable batteries, fuel cells, and supercapaciters (Aurbach), photonics (Rosenbluh, Margel), nanoscale thin films and membranes (Deutsch, Sukenik, Frimer, Ulman, Ehrenberg), and in the theory of mechanical and electrical properties of nanoscale systems (Hoz, Basch). Some of the diverse applications being developed by BICAMN researchers include antibacterial nanoparticles for clothing and wound dressings, new methods for encapsulating drugs and drug targeting, nanoparticles for water purification, active coatings for biocompatible implantable devices, new tools for electro-optics, new approaches to DNA testing, rechargeable energy storage devices based on green technology, new approaches to specific cell labeling and separation, new contrast agents for medical imaging, and new magnetic materials for data recording/storage, magnetic sensors, and superconducting filters.

At Tel Aviv University, the new NanoScience and Technology Center (<u>http://www.tau.ac.il/research/nano/</u>), headed by Prof Yosi Shacham (Engineering) is involved

in research and education programs encompassing areas covered by four faculties: Engineering, Exact Sciences (Chemistry, Physics and Mathematics), Life Sciences and Medicine. The aim is to establish research programs integrating different aspects of traditional disciplines at the nanoscale under one roof. Of special interest, is the interface between biological and artificial nanosystems. The Center houses shared research facilities offering modern fabrication and characterization equipment (for metallic, magnetic, semiconducting, dielectric and organic nanostructures) as well as labs dedicated to more specialized research programs. A graduate course program in NST is planned. The Center is actively seeking to establish collaborations with other, similar Centers worldwide and will develop close ties with the high tech industry in relevant fields. To mention some of the work going on, Prof Yossi Rosenwaks, Prof Gil Rosenman, Prof Ady Aryeh and Prof Shlomo Ruschin, all from Engineering, have succeed in developing a novel way of direct sub micron poling of ferroelectric crystals and are using the structures for novel applications in photonics and bio sensing. Prof Shlomo Ruschin in collaboration with Prof Shlomit Rishpon (Biology) have developed optical biosensors based on integrated optics. Prof Amihay Freeman (Biology) is involved in the design, fabrication, characterization and application of proteins for the integration of biological elements with microelectronics. Pror Yoram Shapira is active in research of organic and semiconducting nanolayers and interfaces, cooperating with Prof Dittrich (HMI, Berlin) and Prof Robinson (University of Otago, New Zealand).

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. This program deals with adopting biological approaches and biotechnology enabled tools, to develop complex systems of tiny dimensions. The incorporation of biology enables applying well known processes, such as evolution and self-construction, to systems that are not biological. He also heads the Ben & Ester Rosenblum Center of Excellence in Nanoelectronics by Biotechnology. Prof Sivan and Prof Erez Braun succeeded in creating electronic circuits that construct themselves by means of biological molecules and genetic coding. Prof Nir Tessler and Prof Uri Banim (Hebrew U.) combine semi-conducting quantum dots with organic semi-conducting quantum dots and nano–rods to be used as novel optical and electronical devices.

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. Prof Raz Jelinek (Chemistry) is involved in novel colorimetric biosensors for studying membrane processes and biomolecular recognition; structure and function of membrane peptides. Many scientists are working on questions pertaining to the fabrication of molecular devices and integrating them into microelectronic circuitry. Prof Oleg Krichevski (Physics) is involved in fluctuations of polymers in aqueous solution, particularly migration of gene sequences within DNA. Prof Yishai Avishai is recently involved in low dimension electron transport in fullerenes and carbon nanotubes,

exploring their potential for molecular electronics. Prof Ron Folman, Prof Baruch Horowitz and Prof Yigal Meir are exploring the use of microelectronic chips to control cold atomic condensates. In the Institute for Applied Bio-Sciences http://www.bgu.ac.il/IAB/, interesting work is taking place in the development of bio-sensors and bio-chips. In that institute, Dr Robert Marks and Prof Levy Gheber are developing novel NSOM or AFM based protein writing for multi-array biosensor fabrication. They have also developed a series of fiber based biosensors, successfully being used to montor water quality in different parts of Israel.

Questionnaire International Dialogue on Responsible Research and Development of Nanotechnology

Name:	ELVIO MANTOVANI
Title:	General Manager
Organizations:	Nanotec IT – Italian Centre for Nanotechnology
Country:	Italy
Date:	5.4.2004

1. Briefly describe your country's nanotechnology research and development programs. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with other participants.

The 2001-2003 National Research Programme (PNR), approved by the Government on December 2000, has allocated funds for \notin 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 roughly 50% of it has been used to finance projects in the field of nanoscience and nanotechnology at universities and public research organizations

The new 2004-2006 PNR is still in preparation, but nanotechnology will be among the priorities.

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 (INFM), 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, supramolecular and nanodimensional systems, nanostructured surfaces and powders, biophysics, biomedical devices, etc.

Very recently a nanotechnology technological district has been financed by the Veneto region and The Ministry for Education, University and Research with 42 Meuro, for building a nanomanufacturing facility and financing R&D projects.

Two master on nanotechnology has been launched by the Padoa University and the Turin Polytechnic.

2. Please provide an overview of your country's **laws and regulations that apply 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 laws that follow the indications of the European Commission.

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?¹

Point out potential benefits and possible detrimental effects for the environment and people, social and everyday life, working activities;

Deepen effects on health care and health policy;

Ascertain privacy implications deriving from the diffusion of nanotechnology.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

Properly address environmental and human health care implications of nanotechnology by exploring their potential benefits and possible detrimental effects and by indicating proper ways and behaviours to minimise risks to the environment and people;

Tune existing legislation/regulation for environment, safety and health at the working place to nanotechnology peculiarity;

Regulate medical application of nanotechnology with reference to pharmaceuticals manufacture, medical products/devices, validation, safety tests and standards, formation of health care teams and therapy;

Tackle and prevent privacy issues and pursue pre-emptive education to beat prejudice.

Questionnaire International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA.

To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at <u>rraimond@merid.org</u> or by fax at +1 970 513 8348.

Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name:	Dr. Kazuharu SHIMIZU	
Title:	Deputy Director-General	
Organization:	Council for Science and Technology Policy, Cabinet Office	
Country:	JAPAN	
Date:	4 th April 2004	

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

(Japan Answer to Question1)

•	RAD program	orpecaetana	forun, etc.	funding amount
1	"Sanctachuslogy Support Project"	Universities, National Institutes (MENT)	Supporting Big Particles in Use. Nanotechnology Researcher's Network Center of Jayan.	2,500 million Ten (FY2004 Proposel)
	"Leading Projects" (Sprojects)	Universities, Netional Institutes, Private Companies (MENT)	RMO for practical or inductrial use, tempols the goals in 5 years	3,300 million Ten (FY2004 Proposed)
	Wateringtony Virtual Laboratory" (10 research regions)	Universities, National Inlititutes (faciling by JST) (MSXT)	Challenging RhD for practical or industrial use, towards the goals in 10-20 years	ajigirus. 7,000 million Te (P12004 Proposed)
•	Darotechnology RND by National Distillate for Materials Dolesce (JDM)	ntheli didixiti	Development of Osnaric Technologies (Include Materials Science)	16,200 million Two (P12004 Propusal)
	Hanotscheelingy R&D by Institute of Physical & Chemical Research (RIREN)	RIKEN (MERT)	Research on Nervoclence, etc.	1,700 million Twn (F12004 Proposed)
0	Orant-in-Ald for Scientific Research	Universities (Passing by JSPS, MEXT)(MEXT)	Batic Fatoarch	*
	Zaniz Reissorik Program.	Character (Puesking by JUTI(MEXT)	Bault Recearch	* 2
	Field of nanoestellione, Reintenb on Advanced Dedinal Declandings, Mathia and Lebrur Robuston, Reintenb Donaio	MHLW	The accelerate projects for improving the addety of medical technology through promoting PAD of non-medical invasion medical devices, siz by using mentichnology.	1,200 milion Ten PY2003 Appropriated)
	Janotachunlogr Program	METI, MEDO, ANT, and other Enterprises	1. Objectives Molectula inclusioning is a functionerestal inclusion for information processing, the environment, community taking is information processing, the environment, community taking is information processing in the function of a subscription to provide the second statement of the function of the function of the program are to carpe the sole. The objectives of this program are to carpe with basic research and development on narrotation legars to the information of the protection of this program are to carpe with basic research and development on narrotachnology materials technology and the type teaches the obtained research results. The objectives of this program are to carp with basic research and the obtained research results. After developing process technology and measurement technology that easies mentions of extremently theorem is a technologies. For creating toporouling functions for an ultransferror technologies for creating toporouling functions of neuroscience and technologies for creating toporouling functions of neuroscience data and income here related to threather, functions on an ultransferror technologies for creating toporouling functions for an ultransferror technologies of an involvementation of accurated data and income here related to threather, functions and processes, and estimistions of an involvementation is the can be utilized in various flating, will be completed involvementation the can be utilized in various flating, will be completed involvementation the can be utilized in various flating will be completed.	skout 7.403 sullins Yes (F12004 Proposed) elevat 7.117 millen Ten (F12005 Appropriatel)
	Pesearth & Development for Sanotermosic Derices	AINT (MET)	 Objectives The projects area at research and development of materials, proceeding becknown, integration and spream assembly for canonications devices. Orals Whight constraint device, opportronics device and carbon manu- proposed devices are developed using ultra-legh guidity discoved, new correlated destroy materials and carbon manufactures for the proposed devices are also devices area obtained, term correlated destroy materials and carbon manufactures. Molecular scale devices are also devices the becoments bechaviology which integrates molecular into MMMS. A-terminal independent drop subscripts in the double-gate MOSFET, producing as a next generation transmitter, successfully developed in this program. 	aleast 600 million Ten 17/2004 Proposedi aleast 570 million Ten 17/2005 Appropriated)
	The development of environmental research based on executerly along	MOR, HIES etc.	Application of nanotechnology to the environmental failth as follows: (1) ubta-caual cized advanced environmental monitoring device. (2) mobil-dimensional evaluation system for health and environment relat. (3) high efficiency tonic compliant removal membranes etc.	350 million Yen PY2004 Proposed
	MENT: Ministry of Education, Cultury JST : Japan Science and Technology JSF: Japan Science and Technology JSF: Japan Science and Technology MILU: Ministry of Residue, Labour at MIET: Ministry of Residue MIST: National Institute of Advanced MIST: National Institute for Environment MIEE: National Institute for Environment	Agency a of Source d Welfare d Inductry chaology Development Organization Industrial Science and Technology		1

2. Please provide an overview of your country's **laws and regulations that apply 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 regulations that apply to nanotechnology development are not enacted especially in Japan.

Please answer the following questions:

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

Since the development of nanotechnology is expected to cause inevitable change in various fields, the key issues may note be focused on so easily. A diverse influence to human health, environment, securities, etc. has to be taken into consideration.

On the other hand, by applying nanotechnology, a remarkable progress will be achieved in many fields such as information technology, medical science, energy conservation, etc. These progresses may cause a drastic change of social systems, industrial structure and individual life style. In order to be ready for such drastic change, innovation in education system, and effective measures in social scientific field such as economy, legal matter, ethic, and culture also have to be discussed.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

Individual country level:

- 1. Prior investigation for the influence of the development of nanotechnology in various areas.
- 2. Education and training for utilizing nanotechnology safely and effectively.

Regional and global levels:

- 1. Mutual assistance for nanotechnology R&D
- 2. Information exchange and deepening mutual understanding through promoting international conference.

Questionnaire International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA.

To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at <u>rraimond@merid.org</u> or by fax at +1 970 513 8348.

Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name: Byung Sam Kang

Title: Deputy Director

Organization: Ministry of Science and Technology

Country: Korea

Date: 16 – 18 June 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

- Frontier Program
 - Nano device, material, mechatronics: \$10M for each during 10 years.
- Facility
 - o Augmented nano fab: silicon, material: \$0.1B
 - Specialized nano fab: non silicon: \$50M

2. Please provide an overview of your country's **laws and regulations that apply 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 Act

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

Please answer the following questions:

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

- Establishing law
- Monitoring activity

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

- National
 - Establishing law
 - Monitoring activity
- Global
 - o Establishing co-work system

Mexico

Meeting participants from Mexico provided the following PowerPoint slides describing nanotechnology research and development in Mexico.

Slide 1



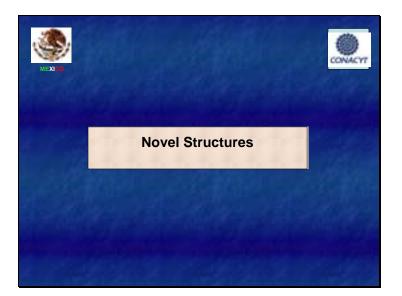




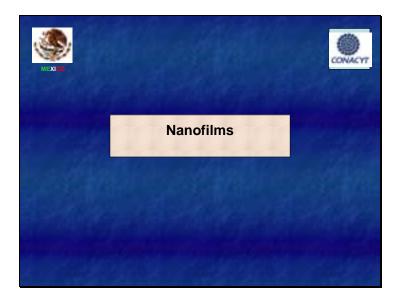




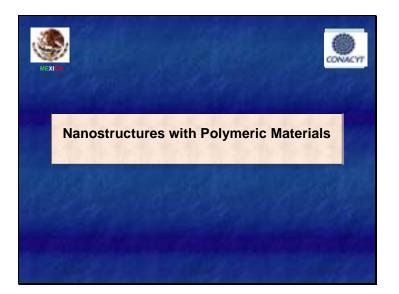
MEXI	Na	noparticles	CONACT	
PARTICLE	METHOD	INSTITUTION	APPLICATIONS	
Ag	Solutions	UNISON, UNAM CINVESTAV- QRO, UASLP	Optics, Medical, Catalysis	
Cu, CuO	Solutions	CINVESTAV-QRO UNISON, UASLP	Hard coatings Electronics	
Ag+Cu Au+Cu (oxides)	Solutions	UNISON, UNAM, CINVESTAV-QRO	Catalysis, Medical Electronics	
Pt	Solutions	CINVESTAV-QRO	Catalysis	
CdS, PbS	Chemical	CINVESTAV-QRO	Optics, Microelectronics	
GaAs	MBE	CINVESTAV-QRO IPN, ICO	Optics, Microelectronics	



O	Novel Nanostructures		CONACT	
ТҮРЕ	METHOD	INSTITUTION	APPLICATIONS	
Fullerens	Various	IPICyT, IPN, CIMAV UNAM	Academic Ultrahard coatings	
Nanotubes	Various	IPICyT, CIMAV, UNAM	Composite Materials Nanoelectronics	
Nanowires	Various	IPICyT, UNAM	Microelectronics	
Molecular Sieves	Various	CIMAV	Catalysis	



xı	Novel N	Vanostructures	CONACYT	
ТҮРЕ	METHOD	INSTITUTION	APPLICATIONS	
Optical	MBE	CINVESTAV, UASLP, BUAP	Electronics	
Magnetic	Sputtering	CIMAV, UNAM, CINVESTAV	Data Storage	
Dialectric	Thermal	UASLP, UNAM	Electronics	
Ferroelectric	MBE	CINVESTAV UNAM	Non Volatile Memories	



MEXI	Nanostr With Polymer	CONACYT	
ТҮРЕ	METHOD	INSTITUTION	APPLICATIONS
Polymer/Nanoclays	Co-extrusion	CIQA, U. Gto., UASLP, UNAM, U de G	High performance materials
Block copolymers	Free Radical Polymerization	CIQA, UNAM	High performance plastics
Biopolymer nanoparticles	SCF CO ₂ Processing	CINVESTAV-Qro, UNAM, IMP, U de G	Controlled-drug release, scaffold, dental
Elecritically-conductive Polymers	Free Radical Polymrerization	CIMAV, CIQA UNAM	Microelectronics





The Netherlands

Government Agencies and Related Funding for 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 latter two collaborate closely, with Senter bearing responsibility for administration and the Academy for scientific quality through peer review of research proposals.

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.

Responsible Nanotechnology: a personal view

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-theart 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.

Questionnaire on Nanotechnology – Response from New Zealand

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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 nanomaterials, 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.

2. Please provide an overview of your country's **laws and regulations that apply 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.

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.

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

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 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.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

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].

Nanotechnologies in Romania Dan C. Dascalu National Institute for Research and Development in Microtechnologies (IMT-Bucharest)

Romanian "nano" initiative. "Romanian initiative on nanoscience and nanotechnologies" was launched in Bucharest on 14th of May, 2004 with the participation of Mr. Ezio Andreta, Director, European Commission. On this occasion he was giving the talk "The future of manufacturing in Europe and the role of nanotechnologies" (Venue: headquarters of the Chamber of Commerce and Industry of Romania and Bucharest, 14 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). "Romanian initiative in nanoscience and nanotechnology" was elaborated by consulting Mr. Renzo Tomellini, Head of Unit, Directorate of Industrial Technologies, European Commission and was presented by Prof. Dan Dascalu, General Manager IMT-Bucharest. The full text was published in the "Micro and NanoTechnologies Bulletin", March 2004 issue, which is also available on web at: www.imt.ro/mnt).

The aim: concentrating resources and correlating efforts. Difficulties: the lack of resources; the absence of priorities; brain drain. The chance of international cooperation, opportunities generated by a "wave of changes" (e.g. European integration of Romania, anticipated by January 2004).

Research programmes: "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).

New Materials, Micro and Nanotechnologies: MATNANTECH -

International cooperation first:

- correlated with European programmes, especially for micro and nanotechnologies (priorities 2 and 3, Framework Programme 6);
- using European models for infrastructures (networks and virtual centres); encouraging European and international cooperation;
- impact at the national scale

Desired:

- impact on research related to health, food, environment, biotechnologies etc;
- higher output for innovative SMEs, spin-off companies etc;
- emphasis on multidisciplinary education and training.

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).

Estimated results: Development of scientific knowledge in the field of science and engineering of new materials, micro and nanotechnologies; New national and international projects, new networks and centers; Scientific publications; mobility and exchanges; Interactive working, new knowledge; Training for researchers; Transfer of results to practical applications, innovative and competitive products and technologies; Development of partnership between research and end-users.

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).

Examples of projects: Nanostructured silicon matrix for biological applications and controlled drug delivery; Nano-icosaedral and nanocrystalline alloys based on aluminium; Electronic noise measurements in nanomaterials: a new method of investigation; Carbonic and metallic nanometric powders for special applications; Intelligent microsystem with enzymatic biosensors for rapid control of the quality of wines; Integrated chemical microsensors for environmental monitoring and food quality control.

Infrastructure projects

4 Thematic Networks:

- Nanobioengineerig (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: Prof. Laura Tugulea, Professor of Biophysics at the Faculty of Physics-University of Bucharest was presenting a proposal for 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".

Conclusion: Steps to follow:

- An inventory of resources. Restructuring?
- Synergy with industry;
- Education and training;
- An overall strategy correlated with the priorities of the country;
- A regional role in the European context;
- Cooperation with U.S., Korea, India etc.

Acknowledgements: To: Corneliu Trisca-Rusu, Executive Director of MATNANTECH, for providing information related to the MATNANTECH programme.

Presentation at the forum "International Dialogue on Responsible Research and Development of Nanotechnology" 17-18 June 2004, Alexandria, VA, US

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 <u>the national level programs</u> 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",

"Bionic sensor micro- and nanosystems", "Nanomaterials and supramolecular system

"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.

<u>At the regional level</u> 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.

At the moment the main direction of Russian research in the area of nanotechnologies are as following:

- biological microchips;
- delivery of new generation of medical agent allowing precise delivery of medicine to the targeted cells;
- biocompatible nanomaterials;
- fullerenes and nanotubes;

- nanomaterials and nanostructures for their application in electronic, energy and machinery industry;
- sensors for gas and fluid environment;
- nanoscale microelectromechanics including LIGA-technologies application based on synchrotron emission.

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.

We pay 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 onto the coordination of activities in the area on nano-related research among other ministries, organizations and scientific institutions.

We prepared a draft of "The Concept paper 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.

Proposals:

- 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 carring 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.

QUESTIONNAIRE International Dialogue on Responsible Research and Development of Nanotechnology

The National Science Foundation (NSF) of the United States and the Meridian Institute are organizing the "International Dialogue on Responsible Research and Development of Nanotechnology" on 16-17 June 2004 in Alexandria, Virginia, USA.

To provide you and the other invitees to the meeting with relevant background information and a common reference, we kindly ask that you provide answers to the following questions. Please return your answers by 2 April 2004 to Rex Raimond at Meridian Institute either by e-mail at rraimond@merid.org or by fax at +1 970 513 8348.

Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name:Pontsho MarupingTitle:Manager: Manufacturing Technology MissionOrganization:Department of Science and TechnologyCountry:South AfricaDate:10 May 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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.

Focus areas	Research areas
Health	Biomaterials, Nano-encapsulation, Nanofibres, Gold Nanoparticles, Platinum
Water	Nano membranes, Electro catalysis and Remediation
Energy	CoInSe 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					

The table below highlights some research acrivities:

	Technical Universities	Wits	UCT	UWC	US	UZ	CSIR	Mintek	NECSA	E6	SASOL
Nano Biomaterials		٥			٥		٥	٥			
Nano Catalysts		٥	٥	٥				٥			٥
Nano Composites	o	٥		٥	٥						
Drug delivery		٥			٥		•	٥			
Electronic materials		٥	٥	٥							
Electro- spinning					٥						
Nano- particles		٥	٥	٥	•	٥	٥	٥	٥		
Nanotubes	Θ	•								o	٥
Nano Polymers	٥				٥		٥				٥
Self- assembly					•			٥			
Surface modification		٥		٥					٥	o	

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 2. Please provide an overview of your country's **laws and regulations that apply 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 specific laws and regulations related nanotechnology development, however the following would generally be applicable:

Occupational Health and Safety Act:

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.

National Health Bill:

The 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.

National Environmental Management Bill:

The 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.

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

For each new research area, it involves:

- Appropriate government policy and regulation

- 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.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

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 focussed 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.

Questionnaire International Dialogue on Responsible Research and Development of Nanotechnology

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Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name: N	Manfred Scriba
---------	----------------

Organization: South African Nanotechnology initiative (SANi)

Country: South Africa

Date: 28 March 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

We have 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 words Gold and Platinum reserves but does minimal processing of these minerals.

The figures of spending in South Africa are not known at present. 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 R&D activities in:

Health
Biomaterials, Nano-encapsulation, Nanofibres, Gold Nanoparticles, Platinum
Water
Nano membranes, Electro catalysis and Remediation
Energy
CoInSe 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

2. Please provide an overview of your country's **laws and regulations that apply 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.

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.

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsi ble development of nanotechnology?

Firstly, 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.

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

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.

Questionnnaire International Dialogue on Responsible Research and Development of Nanotechnology

Name:	Karl Hoehener, Juergen Hoeck
Title:	
Organization:	TEMAS AG
Country:	Switzerland
Date:	June 1, 2004

1. Research and Development Programs

In Switzerland, three Nano initiatives are currently in execution:

1. NCCR, National Center of Competence in Research Nanoscale Science focusing on basic research and ultimate limits, an initiative of the Swiss National Science Foundation (<u>www.nccr-nano.org</u>).

The funding amount is 7 Mio US\$ per year

- Nanotechnologies and Microsystems a bottom up approach of CTI, the funding agency for Technology and Innovation (<u>www.bbt.admin.ch</u>), to support applied R&D-projects. The funding amount is 7 Mio US\$ per year
- 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 (<u>www.ethrat.ch/topnano21</u>). The funding amount is 10 Mio US\$ per year

2. Laws and Regulations that apply to Nanotechnology Development

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.

3. Key issues to be addressed

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.

4. What should be done to ensure responsible development of Nanotechnology

Laws and regulations applying to 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.

Questionnaire International Dialogue on Responsible Research and Development of Nanotechnology

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Please review the invitee list that was attached to your invitation. If there are additional invitees from your country, please coordinate a single submission from your country.

Please provide the following information about yourself:

Name:	Randal Richards
Title:	
Organization:	The Engineering and Physical Sciences Research Council
Country:	United Kingdom
Date:	May 19, 2004

Please provide the following information:

1. Briefly describe your country's nanotechnology **research and development programs**. Please provide the name of the program, the name(s) the organization(s) involved, a brief description of the program's focus, the scope and types of research being conducted, the funding amount, and any other information you would like to share with the other participants.

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.

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

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 that apply 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.

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)

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

3. In your opinion, what are the key issues that need to be addressed in order to ensure the responsible development of nanotechnology?

The Royal Society and Royal Academy of Engineering within the UK are conducting an enquiry into the whether nanotechnology is likely to lead to new issues concerning ethical, health, safety or social issues which are not covered by current legislation. This enquiry has conducted a broad based consultation with the UK stakeholder community and is due to report in June 2004.

Key issues that need to be addressed include:

- Examination of the toxicological effect (if any) of nanoparticulates both *in vivo* and *in vitro*.
- o Examination of the environmental impact (if any) of nanoparticulates
- Toxicology of carbon nanotubes, particularly concerning their interaction with DNA
- Public perceptions of nanotechnology

4. In your opinion, what should be done to ensure the responsible development of nanotechnology? Please address this question by describing what you think might be done at national levels in individual countries, at regional levels, and at the global level.

Very succinctly key actions for the nanotechnology community to ensure the responsible development of nanotechnology are:

- National targeted programmes of public engagement and dialogue specifically exploring the benefits and disadvantages from nanotechnology
- At a national level, facilitating interdisciplinary working engaging physical sciences through to biologists and clinicians to address research challenges.
- Raise the level of international collaboration and interaction on issues of toxicological and environmental impacts of nanotechnology.

Questionnaire International Dialogue on Responsible R&D of Nanotechnology

Reply by: Dr. M.C. Roco Senior Advisor for Nanotechnology at NSF; Chair NSTC/NSET USA June 12, 2004

1. Nanotechnology R&D programs in USA

The National Nanotechnology Initiative (NNI) is a long-term research and development program that currently coordinates 19 federal agencies. The investment is about \$960 million in the fiscal year 2004 (beginning October 1, 2003). The NNI was established in October 2000, and has been coordinated by the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC). The main goals of NNI are: to extend the frontiers of nanoscale science and engineering and to facilitate the development of beneficial applications of nanotechnology; to establish a balanced and flexible infrastructure, including a skilled workforce; and to address the societal implications of nanotechnology. The Federal nanotechnology investment per agency since the beginning of NNI is given in Table 1. The annual implementation plan for fiscal year (FY) 2004 is balanced between fundamental research, nine Grand Challenges, centers of excellence and networks, infrastructure, and societal and educational implications of nanotechnology.

In addition, state, local, and private organizations have regional nanotechnology investments in infrastructure and education, as well as support for business. Their contribution is estimated in fiscal year 2003 to be about half of the federal investment in NNI.

Federal Department or Agency	FY 2001 Actual (\$M)	FY 2002 Actual (\$M)	FY 2003 Actual (\$M)	FY 2004 Current Plan (\$M)	FY 2005 Request (\$M)
National Science Foundation (NSF)	150	204	221	254	305
Department of Defense (DOD)	125	224	322	315	276
Department of Energy (DOE)	88	89	134	203	211
National Institutes of Health (NIH)	40	59	78	80	89
National Institute of Standards and technology (NIST)	33	77	64	63	35
National Aeronautics and Space Administration (NASA)	22	35	36	37	53
Environmental Protection Agency (EPA)	6	6	5	4	5
Homeland Security (TSA)	-	2	1	1	1
Department of Agriculture (USDA)	1.5	0	1	1	5
Department of Justice (DOJ)	1.4	1	1	2	1
TOTAL	465	697	862	960	982

Table 1. Contribution of key Federal agencies to NNI investment in \$ million/year (each Fiscal Year (FY) begins on

 October 1 of the previous year and ends on September 30 of the respective year)

(% of FY 2000 investment of \$270M)	(172%)	(258%)	(319%)	(356%)	(364%)

More than 10% of the NNI budget addresses 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 (National Institute of Occupational Safety and Health), USDA, and DOD. NSF has a focus on nanoscale processes in the environment and on societal implications in its programs since August 2000. NSF will award about \$16 million in 2004 for grants with primary focus on environment and nanotechnology, and additionally about the same amount for multidisciplinary projects including the environmental issues. A list of 100 grants, including abstracts, is available on

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. NSF's Nanoscale Science and Engineering Centers (NSEC) and the National Nanotechnology Infrastructure Network (NNIN) are required to have research and education components addressing the environmental and societal implications. Three federal agencies now have focused efforts to study the potential risks of exposure to nanomaterials: the National Toxicology Program (NTP) - a multiagency effort established in the Department of Health and Human Services, NIOSH, and EPA. The NTP studies will focus 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 fiveyear program to assess the toxicity of ultrafine and nanoparticles. EPA is funding research at universities to examine the toxicity of manufactured nanomaterials such as quantum dots, carbon nanotubes, and titanium dioxide. 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. 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 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.

2. Laws and regulations that apply to nanotechnology development

On December 3, 2003, the President signed into law the 21st Century Nanotechnology Research and Development Act (Public Law 108-153). A section of that Law is dedicated to societal implications.

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 6 agencies in FY 2001 to 10 agencies in FY 2002 and 19 agencies in FY 2004.

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 of Occupational Safety and Health (NIOSH)
- Occupational Safety and Health Administration (OSHA)
- US Department of Agriculture (USDA)
- Consumer Product Safety Commission (CPSC)
- US Patent and Trade Office (USPTO)

Research to establish the knowledge base that is used by regulatory agencies to inform their decision-making process may be performed by federal agencies, such as NSF, NIH, NIST, EPA, FDA, NIOSH, OSHA, USDA, DOE, and DOD, or may be performed by industry or other private sector research institutions.

NSET/NSTC has established the National Nanotechnology Coordinating Office (NNCO) in 2001 as its secretariat with one of its role to monitor potential unexpected consequences of nanotechnology; the NNCO has certain responsibilities pursuant to PL 108-153. The Nanomaterial Environmental and Health Implications (NEHI) working group was established in 2003 to address environment, health and safety (EHS) issues, including risk assessment, identification and prioritization of EHS research needs, and communication of information pertaining the EHS of nanomaterials to researchers and others who handle and use nanomaterials.

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". In some cases, pre-market review and approval is required (e.g. drugs, food packaging, 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:

- In the environments (in air, water, soils):

Toxic Substance Control Act (TSCA), administered by EPA.

Clean Air Act for particulate matter, which could include ultrafine particles in the future, administered by EPA

- Waste disposal acts, administered by EPA
- 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 of 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)

- Nanoparticles for drugs to be metabolized in human body, to be used as diagnostics or therapeutic medical devices (such as quantum dots); Regulated by FDA
- Nanostructured "particles/substances" to be incorporated into food; FDA and USDA share the regulations (such as food additives, food coloring)
- 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, NIOSH, NIST, USDA 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.

3. Key issues that need to be addressed in order to ensure the responsible development of nanotechnology

- 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
- 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
- Avoiding possible adverse EHS (environment/health/safety) aspects of nanotechnology by practicing "green chemistry" (clean processes and processing) and "environmentally benign manufacturing"
- Using nanotechnology to understand, measure, and reduce/control pollution from our current processes
- Ethical aspects related to the distribution of the benefits of nanotechnology
- Best mechanisms for communicating with the public
- Issues related to individual rights, such as privacy, have access to healthcare, and various topics at the confluence of nanotechnology, biotechnology, information technology, and cognitive sciences.

4. Suggested measures to ensure the responsible development of nanotechnology (at national, regional, and global levels)

- Develop better understanding on environment, health and societal implications of nanotechnology through continued support of R&D programs
- 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 2001. Follow-on to the 2000 workshop was held in December 2003, and several NNI grantees and research direction meetings were held in 2003-2004
- 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 natural and process-byproduct 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
- Evaluate various issues in the broader societal context and from an international perspective
- Promote two-way interactions with the public at the local, national, and international levels.